MINUTES OF 250th MEETING OF CENTRAL LICENSING BOARD

HELD ON MONDAY 27th OCTOBER, 2016

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250th meeting of the Central Licensing Board (CLB) was held on Thursday 27th October, 2016 in the Committee Room, Drug Regulatory Authority of Pakistan, 4th Floor, T.F. Complex, G-9/4, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, Drug Regulatory Authority of Pakistan.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Dr.Ikram-ul-Haque ,QC/QA Expert.	Member
2.	Dr. Zaka-ur-Rehman, Chief Drug Controller, Primary and Secondary Health Care Department, Govt. of Punjab, Lahore	Member
3.	Mr. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh, Karachi	Member
4.	Mr. Sultan Ahmed, Chief Drug Inspector, Department of Health, Govt. of Baluchistan, Quetta	Member
5.	Mr. Akbar Jan, Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa, Peshawar	Member
6.	Syed Muied Ahmed, Expert in manufacturing of drugs.	Member
7.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
8.	Hafiza Amina Sadia, Deputy Legislative Advisor Ministry of Law, Justice and Human Rights, Islamabad.	Member
9.	Representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad. (Dr. Abdur Rashid, Additional Director attended as representative of QA/LT Division)	Member
10.	Mr. Manzoor Ali Bozdar, Additional Director (Lic.), DRAP, Islamabad.	Secretary
11.	Mr. Abuzar Faizi, Chief Executive, Genome Pharmaceuticals (Pvt) Ltd., and Mr. Arshad Mehmood, Managing Partner, Welwrd Pharmaceuticals as Representative of PPMA	Observer
12.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
13.	Mr. Kamran Anwar, Secretary General PCDA , representative of PCDA	Observer

The Chairman CLB welcomed the honorable members of this Apex Forum & participants of the meeting. The meeting started with the recitation of verses from the Holy Quran.

He further added that all the legal and codal formalities would be taken into account for disposal of cases. Mr. Zeeshan NazirBajar DD (QA), Mr. Adnan Faisal Saim DD(QC) & Dr. Akbar Ali, AD (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 249th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 249th meeting held on 27th October, 2016.

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

The Board considered the following cases of grant of new drug manufacturing license in the light of recommendations of respective panel of experts/inspectors and decided as under:

S#	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s IDCOT Pharmaceuticals, Plot 6/A, Pharmaceutical Zone, M-3, Industrial city, Faisalabad.	**16-06-2016** **Formulation**	The Board approved the grant of DML by way of formulation with following sections: Sections: 1. Absorbent Cotton 2. Cotton Bandage 3. Cotton Crepe Bandage 4. Gauze Section

2.	M/s Maxitech Pharma (Pvt) Ltd., Plot No. E-178, SITE, Phase-II, Super Highway, Karachi	**08-09-2016** **Formulation**	The Board approved the grant of DML by way of formulation with following sections: **Sections (08)** 1. Ointment/Cream/ Lotion (General) Section 2. Ointment/Cream/ Lotion (Steroid) Section. 3. Tablet (General) 4. Capsule (General) 5. Oral Dry Powder Suspension (General) 6. Sachet (General) 7. Liquid Syrup (General) 8. Soft Gelatin Capsule
3.	M/s Magns Pharmaceutical, Plot 7B, Value Addition City, Sahianwala Road, Khurrianwala, Faisalabad.	**25-08-2016** **Formulation**	The Board approved the grant of DML by way of formulation with following sections: Sections: 1. Tablet (General) 2. Capsule (General) 3. Oral Dry Powder Suspension (General)
4.	M/s Biorific Pharma, Plot No. 143, Industrial Triangle, Kahuta Raod, Islamabad	**21-10-2016** **Formulation**	The Board approved the grant of DML by way of formulation with following sections: **Sections:** 1. Dry Powder Section (Vet) 2. Liquid Syrup Section (Vet)
5.	M/s Divine Pharmaceuticals, Plot No. 226-A, Sunder Industrial Estate, Lahore	**04-10-2016** **Formulation**	The Board approved the grant of DML by way of formulation with following sections: **Sections:** 1. Liquid General (Vet) 2. Powder General (Vet)

Item-III:**GRANT OF ADDITIONAL SECTIONS/EXPANSION/AMENDMENTS IN LOPs ETC.**

The Board considered following cases of Grant of Additional Sections & Expansion/Amendments in Layout Plans (LOPs) etc of already licensed units in the light of recommendations by respective panel of experts/inspectors and decided as under: -

S#	Name of the firm / DML No.	Date of Inspection	Decision of CLB
1.	M/s Evergreen Pharmaceuticals, Lahore DML No. **Formulation**	**25-07-2016**	The Board approved the grant of following additional sections /amendment as under:- **Sections:** Dry Powder Suspension (General) Veterinary
2.	M/s Ferozsons Laboratories Ltd., Amangarh, Nowshera, KPK DML No. 000038 **Formulation**	**20-10-2016**	The Board approved the grant of following additional sections /amendment as under:- **Additional /Amendment Sections:** 1. Capsule (General) (Amended) 2. Dry Powder Suspension (Oral) (Amended) 3. Sachet Filling Section. (Amended) 4. Packaging Section (Amended)
3.	M/s Crystolite Pharmaceutical, Plot No. 1 & 2, Road S-2, RCCI Industrial Estate, Rawat	**07-09-2016** **Formulation**	The Board approved the grant of following additional sections /amendment as under:- **Additional Sections:** Sachet Section (General) The Board also took serious note of the remarks of panel and decided to issue letter of displeasure to Federal Inspector of Drugs and copies of the same to panel members as it amounts to directions to the Central Licensing Board. In future panel should make observations and recommendations within its mandate.

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

The Board considered the following cases of Grant of Renewal of Drug Manufacturing Licenses in the light of recommendations by panel of experts/inspectors subject to confirmation of deposition of CRF as admissible under the rules and decided as under: -

S. No	Name of the firm/ Type of License	Date of Inspection	Decision of CLB
1.	M/s Sante (Pvt) Ltd., Plot No. A-97, S.I.T.E, Super Highway, Karachi DML No. 00702 (Formulation)	**22-08-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **25-02-2016 to 24-02-2021**
2.	M/s Helix Pharma (Pvt) Ltd., A-56, S.I.T.E, Manghopir Road, Karachi DML No. 000030 (Formulation)	**22-09-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **24-04-2015 to 23-04-2020**
3.	M/s High-Q Pharmaceuticals, Plot No. 224, Sector 23, Korangi Industrial Area, Karachi DML No. 000597 (Formulation)	**31-08-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **05-07-2016 to 04-07-2021**
4.	M/s Elko Organization (Pvt) Ltd., Plot No. 27 & 28, Sector 12-B, North Karachi Industrial Area, Karachi DML No. 000245 **(Formulation)**	**18-10-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **27-04-2015 to 26-04-2020**

5.	M/s Wilshire Laboratories (Pvt) Ltd., 124/1, Industrial Estate, Kot Lakhpat, Lahore. DML No. 000232 (Formulation)	**18-02-2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **21-07-2015 to 20-07-2020** **For following Sections only** 1. Tablet (General) 2. Capsule (General) 3. Dry Powder for Suspension Section (General) 4. Liquid Injectable (General) 5. Dry Powder for Injection Section (General) 6. Tablet (Narcotic and Psychotropic Sections), 7. Capsule (Narcotic and Psychotropic Sections) 8. Sachet (Narcotic and Psychotropic Sections) 9. Injectable (Narcotic and Psychotropic Sections)
6.	M/s S.J&G Fazul Elahi (Pvt) Ltd., E-46, S.I.T.E, Karachi DML No. 000083 (Formulation)	**17.08.2016**	The Board approved the renewal of Drug Manufacturing Licence for the further period w.e.f **29-09-2015 to 28-09-2020** **For Veterinary Sections only** 1. Oral Liquid (veterinary) 2. Oral Powder (veterinary) 3. Tablet ((veterinary)
7.	M/s UDL Pharmaceuticals (A division of first UDL Modaraba) E-44 & 45, North Western Industrial Zone, Posrt Qasim Authority, Karachi**.** DML No.000693	**20-8-2015** (Formulation)	

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The Board perused the recommendations of panel as under:

Recommendations of the panel:

Based on the strong commitment of the firm's management and comprehensive action plan for further improvements (copy enclosed) the panel unanimously recommends the following.

- Renewal of the drug manufacturing license No. 000693 may kindly be made by the

licensing board for further periods of five years.

- Further improvements for better GMP compliance may be made by the firm in the areas of validation / qualification, revision of existing SOPs, training personnel, addition of technical staff, QA system, sampling procedures, equipment and monitoring of climatic conditions etc.

The Board observed that the panel inspection report is deficient of evaluation proforma and details of sections which panel has inspected. The report does not reveal which dosage forms/sections have been inspected by the panel.

The Board reiterated that panel inspection report and recommendations shall be clear and candid and on prescribed proforma which is in practice and implemented by all FIDs of Pakistan.

The Board further discussed that evaluation report on prescribed proforma provides information in detail with regard to firm and its running sections.

Keeping in view the above situation the Board unanimously decided and deferred the case for comprehensive and complete report along with details of sections on the prescribed evaluation proforma from panel.

Current position

Now FID has submitted report on the evaluation proforma signed by the Federal Inspector of Drugs, Karachi only.

DECISION

The members of the panel who are also members of the Board as well endorsed the evaluation proforma during meeting. Hence, the Board approved renewal of Drug Manufacturing Licence for the further period w.e.f **18-07-2015 to 17-07-2020**

Item No. V **Miscellaneous Cases.**

Case No.1 **SURRENDER OF TABLET (HORMONE/ STEROIDAL) SECTION BY M/S HYGIA PHRMACEUTICALS, PLOT NO. 295, INDUSTRIAL TRIANGLE KAHUTA ROAD, ISLAMABAD UNDER DRUG MANUFACTURING LICENCE (DML) NO. 000523 (FORMULATION)**

M/s Hygia Pharmaceuticals, Islamabad has made a request for surrender of their Tablet (Steroidal/Hormone) Section approved vide letter No. 1-4/2000-Lic (Vol-I) (M-227) Dated 17th June,2011 with registered products.

DECISION:

The Board considered the request of the firm and decided to cancel Tablet (Steroidal/Hormone) Section of M/s Hygia Pharmaceuticals, Islamabad subject to following:

i. **The firm may be asked to take measures for decontamination of Hormonal area especially HVAC ducts and filters etc before production of new products.**
ii. **Area Federal Inspector of Drugs may be directed to ensure that no production activity is being carried out in that area till further orders.**
iii. **Future plan of action may be sought from the firm for utilization of that area.**
iv. **Drug Registration Board may be informed of the decision of the Central Licensing Board for cancellation of Tablet (Steroidal/Hormone) Section for necessary action at their end regarding registered products.**

Case No 2. **DEMOLITION OF PREMISES OF M/S GUYTON PHARMACEUTICALS, 25.5 KM, RAIWAND ROAD, LAHORE.**

M/s Guyton Pharmaceuticals, 25.5 KM, Raiwand Road, Lahore bearing Drug Manufacturing Licence No. 000548 (Formulation) was granted licence on 26 October,2004. Now, Federal Inspector of Drugs, Lahore has forwarded an inspection report whereby he has mentioned that Guyton Pharmaceuticals, 25 .5 KM, Raiwand Road, Lahore has been acquired by the Government of Punjab. Firm is under process of demolishing and machinery is being shifted to ware house under the explained circumstances by firm and physical verification M/s Guyton Pharmaceuticals, 25.5 KM, Raiwand Road, Lahore does not exist as per Drugs Act, 1976 including rules framed thereunder.

2. It is submitted that M/s Guyton Pharmaceuticals, has informed that they have purchased a plot measuring 16 kanal & 13 Marlas for shifting of their already existing registered pharmaceutical company, Gyton Pharmaceutical (DML No. 000548) due to the acquisition of Land by Ring Road Authority Govt of Punjab. They have made an application for verification of site at 4 KM, Raiwand-Manga Road, near adda Khara Khoh, Lahore. Site verification is under process.

DECISION:

The Central Licensing Board deliberated and decided as under:

i. The firm may be issued show cause notice for suspension / cancellation of Drug manufacturing Licence.

ii. Report from Government of Punjab may be obtained regarding inspection of the said firm carried by the task force constituted by the Government of Punjab, as informed by one of the member of Central Licensing Board during the meeting.

iii. Panel including Dr. Ikramul Haq, Member CLB, Additional Director (E&M), Lahore and area Federal Inspector of Drugs to re- verify the current status with reference to previous inspections of the facility with clear and candid recommendations for consideration of Board

Case No.3 RENEWAL OF DRUG MANUFACTURING LICENSE NO. 000732– BY WAY OF FORMULATION OF M/S FIZI PHARMACEUTICAL & CHEMICAL LABORATORIES, 8 KM, RAIWAND ROAD, LAHORE

The Renewal of Drug Manufacturing License No. 000732 of M/s Fizi Pharmaeutical & Chemical Laboratories, 8 KM, Raiwand Road, Lahore was due on 23-06-2016. The firm did not submit renewal of Drug Manufacturing Licence Application till to date. Under Rule 6 of the Drugs (Licensing Registering & Advertising), 1976 a license is valid for a period of five years and may be renewed for further period of five years, if application is made before expiry of validity or within sixty days after period of expiry with payment of additional surcharge of Rupees five thousand for each day.

As renewal application of Drug Manufacturing Licence is not submitted till to date. Hence the said Drug Manufacturing License is not valid under the Drugs Act, 1976 and rules framed there under.

However as per Rule 5 (3) "if the application for Renewal of License is made after the expiry of the validity of the License, it shall be treated as a fresh application."

Licensing Division has already conveyed the status of Drug Manufacturing Licence to area F.I.D on 27th September, 2016 under intimation to the firm that manufacture of drugs in the name of said licence at said premises is prohibited and punishable offence under section 23 read with section 27 of the Drugs Act,1976 and rules framed thereunder.

Concurrence of the Central Licensing Board is solicited for formally issuance of letter for invalid status of the said licence. Moreover, firm may be informed that Drug Manufacturing License is no more valid. However, there is no bar on filing fresh application as per rule 5(3) for grant of Drug Manufacturing Licence.

Decision of CLB:

The Board deliberated on the case and decided as under:

i. **Drug Manufacturing License No.000732(by way of formulation) of M/s Fizi Pharmaceutical & Chemical Laboratories, 8 KM, Raiwand Road, Lahore, is not valid and same shall be conveyed to firm.**

ii. **The firm may make a fresh application, if they desire, for grant of Drug Manufacturing Licence at same premises. Moreover site verification and building lay out approval shall be waived of subject to fulfillment of codal formalities.**

iii. **The decision of the central Licensing Board will be conveyed to Drug Registration Board and QA/LT Division for their necessary actions at their end.**

Case No. 4 - **RENEWAL OF DRUG MANUFACTURING LICENSE NO. OF M/s BECTON DICKENSON PAKISTAN (PVT) LTD,10 KM MURIDKAY SHIEKHUPURA ROAD MURIDKAY,DML# 000673– BY WAY OF FORMULATION:**

The Renewal of Drug Manufacturing License No. 000673 of Becton Dickenson Pakistan (Pvt) Ltd, 10-Km Muridkay-Sheikhupura Road ,Muridkay, was due on 04-11-2014. The firm did not submit renewal of Drug Manufacturing Licence Application till to date. Under Rule 6 of the Drugs (Licensing Registering & Advertising), 1976 a license is valid for a period of five years and may be renewed for further period of five years, if application is made before expiry of validity or within sixty days after period of expiry with payment of additional surcharge of Rupees five thousand for each day.

2. It is informed that DML renewal application is not submitted till to date hence the said Drug Manufacturing License is not valid under the Drugs Act, 1976 and rules framed there under. Manufacture of Drugs in the name of said license and at said premises is prohibited and punishable offence under section 23 and 27 of the Drugs Act, 1976 and rules framed there under.

3. Licensing Division has already conveyed the status of Drug Manufacturing Licence to area F.I.D on 25th Ocotber, 2016 under intimation to the firm that manufacture of drugs in the name of said licence at said premises is prohibited and punishable offence under section 23 read with section 27 of the Drugs Act,1976 and rules framed thereunder.

4. Concurrence of the Central Licensing Board is solicited for formally issuance of letter for invalid status of the said licence. Moreover, firm may be informed that Drug Manufacturing License is no more valid. However, there is no bar on filing fresh application as per rule 5(3) for grant of Drug Manufacturing Licence.

Decision of CLB:

The Board deliberated on the case and decided as under:

i. **Drug Manufacturing License No. 000673 (by way of formulation) of M/s Becton Dickenson Pakistan (Pvt) Ltd, 10-Km Muridkay-Sheikhupura Road ,Muridkay, is not valid and same shall be conveyed to firm.**

ii. **The firm may make a fresh application, if they desire, for grant of Drug Manufacturing Licence at same premises. Moreover site verification and building lay out approval shall be waived of subject to fulfillment of codal formalities.**

iii. **The decision of the central Licensing Board will be conveyed to Drug Registration Board and QA/LT Division for their necessary actions at their end.**

Case No. 5 **SURRENDER OF LICENCE NO. 000679 BY WAY OF SEMI BASIC MANUFACTURE BY M/S VISION PHARMACEUTICALS, PLOT NO. 224, STREET 1, 1-10/3, ISLAMABAD**

A letter received from Vision Pharmaceuticals Plot No. 224, Street No. 1, I-10/3, Islamabad where they have informed that they intend to surrender License No. 000679 by way of Sami Basic Manufacturing.

2. It is submitted that firm have two Drugs Manufacturing Licenses on above mentioned Plot. Licence 000517 by way of Formulation and 000679 by way of Sami Basic Manufacturing. The Drugs Manufacturing License No 000517 by way of formulation was shifted to new premises Plot No. 22-23, Industrial Triangle Kahutta Road, Islamabad with the approval of Central Licensing Board its meeting 234th held on 27th February, 2014. While they had continued their operation of License No. 000679 by way of Sami Basic Manufacturing at Plot No. 224, Street No. 1, I-10/3, Islamabad.

3. Now they have made a request for surrender of License No. 000679 by way of Sami Basic Manufacturing as they have got new Licence for manufacture of drugs at Plot No. 22-23, Industrial Triangle Kahuta Road, Islamabad.

Decision of CLB:

The Board deliberated on the case and acceded to the request of the firm M/s Vision Pharmaceuticals, Plot No. 224, Street No. 1, I-10/3, Islamabad for surrendering the their License No. 000679 for the manufacture of drugs by way of Semi Basic Manufacture. Area Federal Inspector of Drugs may be directed to verify and report that no activity of semi basic manufacture is carried out at the said premises.

Case No.6: CHANGE OF TITLE/ COMPANY NAME AND CHANGE OF MANAGEMENT

1. M/s AGP (Pvt) LTD, B-23, SITE, Karachi, DML No. 000348 , (Formulation) have made an application for change of title and change of management as under and have paid fee of Rs. 100, 000/- for both purposes.

Sr. No	**Existing Title/Name and management of company**	**Interim name/title and management of company after merger of both companies vide orders of Honorable Sindh Highcourt.**	**Proposed Name/ title of company**
01	M/s AGP (Pvt) LTD, B-23, SITE, Karachi, DML No. 000348 , (Formulation). As per Form 29 1.Tariq Moinuddin Khan 2.Syed Zeeshan Mobin 3.Farrukh Ansari 4.Irshad hassan Khan 5.Ayaz Ahmed 6.Khurram Iqbal Khan 7.Massod Karim shaikh	M/s Apollo Pharma Limited. As per Form-29, (Form-A) 1.Tariq Moinuddin Khan 2.Syed Zeeshan Mobin 3.Farrukh Ansari 4.Nusrat Munishi 5.Ayaz Ahmed 6.Khurram Iqbal Khan 7.Massod Karim Sheikh	M/s AGP Ltd. B-23, SITE, Karachi, DML No. 000348 , (Formulation.) As per Article of Association: 1.Tariq Moinuddin Khan 2. Adeela Tariq Khan 3.Syed Zeeshan Mobin

Decision of CLB:

The Board considered and approved the change of name / title of company M/s AGP (Pvt) LTD, B-23, SITE, Karachi to M/s AGP Ltd. B-23, SITE, Karachi. The Board also acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

Sr. No	Existing Title/Name and management of company	Interim name/title and management of company after merger of both companies vide orders of Honorable Sindh Highcourt.	Name/ title of company with new managment
01	M/s AGP (Pvt) LTD, B-23, SITE, Karachi, DML No. 000348 , (Formulation). As per Form 29 1.Tariq Moinuddin Khan 2.Syed Zeeshan Mobin 3.Farrukh Ansari 4.Irshad hassan Khan 5.Ayaz Ahmed 6.Khurram Iqbal Khan 7.Massod Karim shaikh	M/s Apollo Pharma Limited. As per Form-29, (Form-A) 1.Tariq Moinuddin Khan 2.Syed Zeeshan Mobin 3.Farrukh Ansari 4.Nusrat Munishi 5.Ayaz Ahmed 6.Khurram Iqbal Khan 7.Massod Karim Sheikh	M/s AGP Ltd. B-23, SITE, Karachi, DML No. 000348 , (Formulation.) As per Article of Association: 1.Tariq Moinuddin Khan 2. Adeela Tariq Khan 3.Syed Zeeshan Mobin

2. M/s AGP Health care (Pvt) Ltd.D-109,SITE, Karachi. DML No.000044 (Formulation) have made an application for change of title and change of management as under and have paid fee of Rs. 100, 000/- for both purposes.

Sr. No	Existing Title/Name and management of company	Interim name/title and management of company after merger of both companies vide orders of Honorable Sindh Highcourt.	Proposed Name/ title of company with new management
02	M/s AGP Health care (Pvt) Ltd.D-109,SITE, Karachi. DML No.000044 (Formulation) As per Form-29, (Form A) 1. Ayaz Ahmed 2. Farrukh Ansari 3. IrshadHassn Khan 4. Massod Karim Shaikh 5. Syed Zeeshan mobin 6. Tariq Moinuddin Khan	M/s Apollo Pharma Limited. As per Form-29, (Form-A) 1.Tariq Moinuddin Khan 2.Syed Zeeshan Mobin 3.Farrukh Ansari 4.Nusrat Munishi 5.Ayaz Ahmed 6.Khurram Iqbal Khan 7.Massod Karim Sheikh	M/s AGP Ltd. D-109, SITE, Karachi. DML No.000044 (Formulation) As per Article of Association: 1.Tariq Moinuddin Khan 2. Adeela Tariq Khan 3.Syed Zeeshan Mobin

Decision of CLB:

The Board considered and approved the change of name / title of company M/s AGP Health care (Pvt) Ltd.D-109,SITE, Karachi. to M/s AGP Ltd D-109, SITE, Karachi.. The Board also acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

Sr. No	**Existing Title/Name and management of company**	**Interim name/title and management of company after merger of both companies vide orders of Honorable Sindh Highcourt.**	**Name/ title of company with new management**
02	M/s AGP health care (Pvt) Ltd.D-109,SITE, Karachi. DML No.000044 (Formulation) As per Form-29, (Form A) 1. Ayaz Ahmed	M/s Apollo Pharma Limited. As per Form-29, (Form-A) 1.Tariq Moinuddin Khan 2.Syed Zeeshan Mobin 3.Farrukh Ansari 4.Nusrat Munishi	M/s AGP Ltd. D-109, SITE, Karachi. DML No.000044 (Formulation) As per Article of Association: 1.Tariq Moinuddin

	2. Farrukh Ansari 3. IrshadHassn Khan 4. Massod Karim Shaikh 5. Syed Zeeshan mobin 6. Tariq Moinuddin Khan	5.Ayaz Ahmed 6.Khurram Iqbal Khan 7.Massod Karim Sheikh	Khan 2. Adeela Tariq Khan 3.Syed Zeeshan Mobin

3. M/s Sharex Laboratories (Pvt) Ltd, K.L.P Road, Sharex Colony Sadiqabad, District Rahim Yar Khan, has submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee Chalan of 50000/- as under;

Old Management	Retiring Management	New Management (As per Form -29 of S.E.C.P) Page 63/Corr.
1. Mr. Farooq Amin Bajwa CNIC No. 31304-2047851-3. 2. Mr. Muhammad Amin Bajwa CNIC No. 34304-2099881-3. 3. Mr. Abdul Aziz Singhara CNIC No. 31304-8452800-9. 4. Mr. Abrar Hussain Bajwa CNIC No. 31303-2388994-1. 5. Mr. Usman Amin Bajwa CNIC No. 31304-2047852-5. 6. Mrs. Sara Farooq Bajwa CNIC No. 31304-1981928-8. 7. Mr. Affan Hasan Bajwa CNIC No. 31303-3880568-7.	1. Mr. Abdul Aziz Singhara CNIC No. 31304-8452800-9.	1. Mr. Farooq Amin Bajwa CNIC No. 31304-2047851-3. 2. Mr. Muhammad Amin Bajwa CNIC No. 34304-2099881-3. 3. Mr. Abrar Husain Bajwa CNIC No. 31303-2388994-1. 4. Mr. Usman Amin Bajwa CNIC No. 31304-2047852-5. 5. Mrs. Sara Farooq Bajwa CNIC No. 31304-1981928-8. 6. Mr. Affan Hasan Bajwa CNIC No. 31303-3880568-7. 7. Mr. YousafJameelBajwa CNIC No. 31303-5811424-3.

Decision of CLB:

The Board considered and acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

Old Management	Retiring Management	New Management (As per Form -29 of S.E.C.P) Page 63/Corr.
1. Mr. Farooq Amin Bajwa CNIC No. 31304-2047851-3. 2. Mr. Muhammad Amin Bajwa CNIC No. 34304-2099881-3. 3. Mr. Abdul Aziz Singhara CNIC No. 31304-8452800-9. 4. Mr. Abrar Hussain Bajwa CNIC No. 31303-2388994-1.	2. Mr. Abdul Aziz Singhara CNIC No. 31304-8452800-9.	1. Mr. Farooq Amin Bajwa CNIC No. 31304-2047851-3. 2. Mr. Muhammad Amin Bajwa CNIC No. 34304-2099881-3. 3. Mr. Abrar Husain Bajwa CNIC No. 31303-2388994-1. 4. Mr. Usman Amin Bajwa

5. Mr. Usman Amin Bajwa CNIC No. 31304-2047852-5. 6. Mrs. Sara Farooq Bajwa CNIC No. 31304-1981928-8. 7. Mr. Affan Hasan Bajwa CNIC No. 31303-3880568-7.		CNIC No. 31304-2047852-5. 5. Mrs. Sara Farooq Bajwa CNIC No. 31304-1981928-8. 6. Mr. Affan Hasan Bajwa CNIC No. 31303-3880568-7. 7. Mr. YousafJameelBajwa CNIC No. 31303-5811424-3.

4. M/s Venus Pharma, Lahore has submitted request for change in management of the firm as per Form-29 from S.E.C.P along with prescribed Fee Chalan of 50000/- as under;

Existing Management	**Retiring Management**	**Proposed Management as per Page 351-354/Corr**
1. Mr. Shamim Ahmed Siddiqui 2. Mr. Pervaiz Iqbal Siddiqui 3. Mst Ayesha Saleem 4. Mr. Umar Pervaiz Siddiqui 5. Mr. UmairPervaizsiddiqui	1. Mr. Shamim Ahmed Siddiqui	1. Mr. Pervaiz Iqbal Siddiqui 2. Mst Ayesha Saleem 3. Mr. Umar Pervaiz Siddiqui 4. Mr. UmairPervaizsiddiqui

Decision of CLB:

The Board considered and acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

Existing Management	**Retiring Management**	**Proposed Management as per Page 351-354/Corr**
1. Mr. Shamim Ahmed Siddiqui **2. Mr. Pervaiz Iqbal Siddiqui** **3. Mst Ayesha Saleem** **4. Mr. Umar Pervaiz Siddiqui** **5. Mr. Umair Pervaiz siddiqui**	**1. Mr. Shamim Ahmed Siddiqui**	**1. Mr. Pervaiz Iqbal Siddiqui** **2. Mst Ayesha Saleem** **3. Mr. Umar Pervaiz Siddiqui** **4. Mr. Umair Pervaiz siddiqui**

Case No.7: CHANGE OF TITLE OF THE FIRM-RECONSIDEREATION OF THE BOARD

The case was placed before the Board in its 248th meeting held on 29April, 2016 as under: -

M/s Rasco Pharma, 5.5 Km, Near Ali RazaAbad, Holiday Park,Plot #27,Raiwind Road, Lahore has submitted request for change of firms title/Status as per Form-29 from S.E.C.P along with prescribed Fee Chalan of 50000/- as under: -

Present Name/Title /Status of Firm	New Name/Title/Status of Firm
Rasco Pharma, 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore	Rasco Pharma (Pvt.) Ltd., 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore

Decision of 248th meeting of CLB:

The Board considered and acknowledged the change of management from old to new as per Form 29 issued by Security Exchange Commission of Pakistan as under: -

Old Name/Title /Status of Firm	New Name/Title/Status of Firm
Rasco Pharma, 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore	Rasco Pharma (Pvt.) Ltd., 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore

It is submitted that request was for change of title while minutes were recorded as change of management.

Case is placed before the Board for reconsideration of case for change of title of M/s Rasco Pharma, 5.5 Km, Near Ali RazaAbad, Holiday Park,Plot #27,Raiwind Road, Lahore

Decision of CLB:

The Board considered and approved the change of name / title of company Rasco Pharma, 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore to Rasco Pharma (Pvt.) Ltd., 5.5 Km, Near Ali Raza Abad, Holiday Park, Plot #27,Raiwind Road, Lahore

Case No. 8. LEASE DOCUMENT OF PLOT FOR ESTABLISHMENT OF PHARMACEUTICAL FIRM/COMPANY

It is submitted that law is silent regarding type of ownership /allotment / lease /rented premises / land documents of land proposed for establishment of a pharmaceutical units.

2. Now a days applications are being submitted for establishment of pharmaceutical units having documents on land on lease for 5 years, ten years or rented plot. While pre-requisites takes time for establishment of pharmaceutical unit as well as a licence to manufacture drugs is issued for a period of five years and is renewable for further period of five years subject to completion of codal formalities.

3. Plot on lease for specific period and rented plot pose serious problems for Licensing Division as parties prefer to approach courts and litigations continue in the name of ownership of plot and management etc. It becomes also difficult to ascertain name of owners or partners of the company/ firm as required under Section 34 of the Drugs Act, 1976 and rules framed thereunder.

4. Case is placed before the Central Licensing Board for policy decision /guidance for accepting the documents of plot for establishment of pharmaceutical unit.

DECISION:-

The Board considered and deferred the case for the sake of comments of stakeholders including Pharma Industry and reference in this context may be forwarded to Law and Justice Division for legal opinion.

Case 9. **COMPLETION OF RENEWAL APPLICATION UNDER RULE 5 (2A)OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.**

It is submitted that most of times incomplete application for renewal of Drug Manufacturing Licence are received. After preliminary scrutiny of applications shortcomings are conveyed to the firm/ company but they do not bother to compete the application. Resultantly applications are not completed and firm/company continue their operations in the light of Rule 6 of the Drug (Licensing, Registering and Advertising) Rules, 1976. It is also submitted that Central Licensing Board may reject application for renewal of Licence if applicant fail to complete application for renewal of Licence within 30 days under Rule 5 (2A) of the Drug (Licensing, Registering and Advertising) Rules, 1976.

2. Case is placed before the Central Licensing Board for policy consideration that after initial letter of shortcomings under Rule 5 (2A) of the Drug (Licensing, Registering and Advertising) Rules, 1976 firm may be served with two more reminders at senior level before rejecting the application for renewal of Licence under above said rule.

DECISION.

The Central Licensing Board after thorough deliberations and for the fair play decided that first letter to firm under Rule 5 (2A) of the Drug (Licensing, Registering and Advertising) Rules, 1976shall be served with the signature of desk officer giving time period of 30 days to complete the renewal application. If firm/ company fails to complete application in the given time a reminder with the signature of next senior officer to the desk officer shall be issued giving further 15 days time period to complete the application. If firm again fails to comply and compete the renewal application, the case will be brought before the Central Board for rejection of renewal application under Rule 5(2A) of the Drug (Licensing, Registering and Advertising) Rules, 1976.

Case No.10. **PANEL INSPECTIONS UNDER RULE 8 (17) READ WITH RULE 10 (1) AND (2) OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.**

It is submitted that panels of inspectors are constituted under Rule 8(17) read with Rule 10 (1) and (2) of Drug (Licensing, Registering and Advertising) Rules, 1976 for grant of Drug Manufacturing Licence, grant of renewal, grant of additional sections and /or verification of GMP compliance by the Chairman, Central Licensing Board and Board itself. Most of the time inspectors do not coordinate inspections for the reasons best known to them and company/ firm continues to manufacture drugs without panel inspections and even further term of renewal becomes due.

2. It is therefore, proposed that after constitution of panel of inspectors, the panel may be issued two more reminders at one step higher each time than the letter signed by the officer at initial level with time interval of 30 days each time. In case, inspector fail to coordinate the inspection without apparent justification, the case may be referred to Division of Administration for disciplinary proceedings under service rules/ regulations.

DECISION.

The Board deliberated on the issue in detail and considered that though it is the prime responsibility of the Federal Inspector of drugs to coordinate the panel inspection but members of the panel may also play active role for coordination with Federal Inspectors of Drugs for conduction of the panel inspections within stipulated time period and decided to issue reminders to the all panel members to expedite the pending inspection.

Case 11. **DELEGATION OF POWERS FOR ATTESTED COPIES OF DML FOR EXPORT PURPOSE.**

It is submitted that growing export of medicines from Pakistan has lead the firms/ companies to approach Licensing Division for attested copies of Drug manufacturing Licence for export purpose as other countries are asking them to submit attested copy of Drug Manufacturing Licence. Power may be delegated to Secretary, Central Licensing Board for according approval of attestation of DML for export purpose.

DECISION.

The Board deliberated and decided to authorize the Secretary, Central Licensing Board for attestation of copies of Drug manufacturing Licensing as per record.

Case No. 12. M/S MEDI MARKER'S PHARMACEUTICALS (PVT) LTD, PLOT NO.A-104, SITE, HYDERABAD.

The case was placed before the Board as under: -

- A letter No. 17468-2015-DRAP (Lic) dated 04-11-2015 was received from Mr. Abdul Rasheed Sheikh, Federal Inspector of Drugs Lahore along with following orders of Honorable Drug Court Lahore passed on 03-11-2015 and Non-bail able warrants of accused for execution.

On the last date of hearing N.B.W were issued and the same be forwarded to Deputy Inspector General Hyderabad. The reply from the DIG is received, further marked to the Superintendent of Police Hyderabad, but no reply from the S.P Hyderabad is received as yet.

Let us issued N.B.W of arrest of the accused for 20-11-2015 and again forwarded to the DIG Hyderabad with the direction that the previous warrant were not returned back yet. In these circumstances the attitude of the Sindh Police is highly objection. The copy of the order be sent to the DIG and S.P Hyderabad along with warrants with the direction to get execute the warrant and produce the accused before the court, if he failed then a responsible officer not below the rank of Sub Inspector is directed to appear before.

The N.B.W of arrest of the accused forwarded to the Drug Regulatory Authority of Pakistan through Federal Drug Inspector Lahore with the direction to get execute the warrant of the accused and till the arrest of the accused their license may immediately be suspended and the factory premises of the accused shall be scaled under intimation to this Court.
Announced
03-11-2015

- In this regards Drug Regulatory Authority of Pakistan has taken following actions: -

Action Taken by Division of Quality Assurance/Laboratory Testing (QA/LT):

i. Division of (QA/LT) has passed directions to Area Federal Inspector of Drugs Hyderabad, Mr. Hakim Masood to execute the N.B.W against the accused persons in pursuance of orders of Honorable Drug Court Lahore.

Action Taken by Division of Drug Licensing:

i. Division of Drug Licensing requested the Deputy Director General (E&M) Lahore to get complete case record from the relevant provincial Drug Inspector and Honorable Drug Court Lahore so that the case may be processed further.

ii. The orders of Honorable Drug Court Lahore dated 03-11-2015 were placed before the Central Licensing Board (CLB) in its 245th meeting held on 30th December, 2015 for its consideration. The Board considered and decided as under:

Decision of CLB:

Keeping in view the facts of the case, proceeding of the Board and opinion of law expert; the Board considered and decided as under: -

- The Board adopted and endorsed the actions taken by Licensing Division.
- The Board decided to issue a Show Cause notice with personal hearing to the M/s. Medi Marker's Pharmaceuticals (Pvt) Ltd that why their drug manufacturing license may not be suspended in pursuance of the orders of Honorable Drug Court.
- Orders of Honorable Drug Court for sealing of factory premises shall be executed by QA/LT Division through concerned FID.
- The Board directed to send an interim report to the Honorable Drug Court Lahore.

- On 12-01-2016 ,FID appeared before the court and informed that the compliance of Courts Orders dated 03-11-2015 are in progress for the completion of codal formalities and the compliance report will be submitted to the court ,the Honorable Drug Court Lahore has passed further orders dated 12-01-2016 on the above mentioned case in which Drug Regulatory Authority of Pakistan is directed to get execute warrants when they appeared for reply of Show Cause Notice and completed the proceedings and submit report before the court on 28-01-2015.
- On 28-01-2016 again FID appeared before the Honorable Drug Court, Lahore and Submitted the Interim report On behalf of DRAP, and informed Honorable Court regarding progress being made in compliance of the Courts orders. He has further stated that the honorable Drug Court directed to complete the codal formalities and suspend the license of M/s Medi-Markers Hyderabad, till the appearance of accused before the Court under intimation to the court and if they failed, Dr. Muhammad Aslam, Chief Executive Officer, DRAP is directed to appear himself before the court on 17-02-2016. (Copy of order sheet at page 323/Corr).
- Accordingly the Show Cause Notice /Personal Hearing letter was served to the firm; **accordingly, firm was called for personal hearing.**

Proceedings of 247th meeting of CLB

Muhammad Fahim Regulatory Manager of the firm appeared before the Board and presented their point of view in a statement as under:-

"We hereby state that CEO of the company Dr. Abdul Shakoor Usman, Production Manager Mr. Munsif Ali Qureshi and QC Manager RaheelaSaleem has appeared before Drug Court Lahore and an instruction to Drug Regulatory Authority for suspension of license was withdrawn by Drug Court Lahore on February 08, 2016. The same was also delivered by Abdul Rasheed Shaikh FID, Lahore through Drug Court.

For the personal hearing called up by licensing Board on February 22, 2016, we could not personally attend the hearing due to some unavoidable circumstances and feel very sorry for the same and assures the Board for personal presence every time whenever Board will call.

We hereby confirm that we are attending the Drug Court Lahore on each hearing and hopefully our case will be settled very soon from court and orders of the Drug Court Lahore will be provided to Central Licensing Board.

We are very thankful to the Licensing Board giving us a chance for clarification of our position".

Decision of 247th meeting of CLB:

The Board considered and decided to inform the Honorable Drug Court, Lahore regarding the personal hearing and the person appeared before the Board.

Current Proceedings:-

- A letter No. 8174/2016-DRAP (Lic) dated 07-06-2016 was received from Mr. Abdul Rasheed Sheikh, Federal Inspector of Drugs Lahore along with following orders of Honorable Drug Court Lahore passed on 01-06-2016 and Non-bail able warrants of accused for execution.

The State Versus
Medimarker'setc
Present: DDPP for the State
Accused absent
Sheikh Abdul Rasheed Federal Drug Inspector Present

Sheikh Abdul Rasheed Federal Inspector informed that warrants issued by this court were forwarded to Drug Regulatory Authority Islamabad for executions but despite all the efforts were made for execution of warrants, no reply or comply is received yet. From the perusal of record it transpires that this court passed the order for the cancellation of license of M/s Medimarkers Pharmaceutical and after that the accused appeared before the court and moved application through their council for withdrawal of warrants and restoration of license but accused again did not made appearance. Now, it is difficult to procure the attendance of the accused who play hide and seek towards court attended. Drug Regulatory Authority, Islamabad is directed to suspend the manufacturing license of M/s Medimarkar's Pharmaceutical, Situated at A-104 S.I.T.E area Hyderabad Pakistan under intimation to this court by or before 17-6-2016.Abdul Rasheed Sheikh Federal Inspector is directed to intimate the orders of this court to the Drug Regulatory Authority and also informed this court for the proceedings of suspension of license.

Meanwhile repeat the N.B.W of the accused for 17-06-2016 date already fixed and notice to surety also be issued to show cause or to pay the penalty.

Announced
01-06-2016

Actions Taken by Division of Quality Assurance/Laboratory Testing (QA/LT):

1. The N.B.W of arrest of the accessed and sealing of the Firm, were processed by QA/LT division and issued letter No.F.No.2-4/2003/Licensing dated 26-05-2016 and forwarded to concerned F.I.D for execution and copied to Registrar Drug court Lahore for information.

Actions Taken by Division of Drug Licensing:

1. Report has been prepared to intimate the proceedings and decision of CLB to Drug Court Lahore.
2. The orders of suspension of the license of the firm were processed and with the approval of Chairman CLB were placed in agenda of upcoming meeting of CLB for consideration.

Latest Court Orders:

Another letter No.9157/2016-DRAP(L-I) dated 21-06-2016 has been received in Licensing Division on 24-06-2016 along with the orders of Drug Court Lahore, dated 17-06-2016.

On the last date of N.B.W of arrest against the accused issued and forwarded to the Federal Drugs Regulatory Authority, Islamabad, with the direction to suspend the license of M/s Medimarkers Pharmaceuticals. Today Abdul Rasheed Sheikh, Federal Inspector of Drugs present in the court informed that the proceedings of cancellation of license was initiated and still in process and the N.B.W of arrest are forwarded to concerned Federal Inspector, Karachi but no reply received yet.

Abdul Rasheed Sheikh is directed to expedite the process of cancellation of license and complete the proceedings immediately .Meanwhile, Federal Drug Inspector, Karachi is directed to seal the Medimarker's Pharmaceuticals, situated at A-104 S.I.T.E area Hyderabad, Karachi under intimation to this court.

Now to come up for 14-07-2016 further proceedings. Meanwhile, Notice to the surety to appear before the court on the next date of hearing.

ANNOUNCED

17-06-2016

As per the above latest orders of the Drug court following actions are taken:

Actions Taken by Division of Quality Assurance/Laboratory Testing (QA/LT):

- The N.B.W of arrest of the accessed and sealing of the Firm, were processed by QA/LT division and issued letter No. Dy.No.905/2016-QC dated 28th June, 2016 and forwarded to concern F.I.D for execution and copied to Registrar Drug court Lahore for information.

Actions Taken by Division of Drug Licensing:

- The orders of suspension of the license of the firm were processed and with the approval of Chairman CLB were placed in agenda of upcoming meeting of CLB for consideration.

Proceeding of 248th Meeting:

CQC apprised the Board that he has asked from Area FID about compliance of the Court Orders and Area FID has informed that he is in compliance of Court Orders and will seal the factory by today i.e. 13th July, 2016.

Decision of CLB of 248th Meeting:

Keeping in view the proceeding and facts of the case, the Board considered and decided as under: -

i. The Board adopted and endorsed the actions taken by Licensing Division and Quality Assurance/Laboratory Testing QA/LT Division.
ii. The Board decided to issue a Show Cause notice with personal hearing to the M/s. Medimarker's Pharmaceuticals (Pvt) Ltd that why their drug manufacturing license may not be cancelled in pursuance of the orders of Honorable Drug Court.
iii. The Board directed to send an interim report to the Honorable Drug Court Lahore.
iv. The Board advised to communicate the decision of CLB through Area FID, at factory premises and residential address of the owner.

Action taken by Licensing Division:

i. Show cause notice to the firm was issued for suspension/cancellation of Licence on 30th August, 2016 and copy of the same was also forwarded to Chairman, Drug Court, Lahore.

ii. Meanwhile, hearing of the case was held on 31.8.2016 at the Drug Court, Lahore. The order of the court is reproduced as under:

> "***The order dated 1.06.2016 was passed by this Court to procure the attendance of the accused for facing the trial. Now they have surrendered themselves before the Court. In these circumstances, application in hand is thereby accepted and Federal Drug Regulatory is directed to stop the proceedings of the cancellation of licence of Medimarker's under intimation to this Court."***

Now an other order passed by Honourable, Chairman, Lahore Drug Court Lahore dated **19-10-2016** is received through FID, Lahore. Orders of the Court are re-produced as under: -

> *"The case in hand is pending before the court since 16-04-2014 and during that period, accused played hide and seek with the Court even Court passed strict orders for the suspension of drug manufacturing license of the company through Drug Regulatory Authority of Pakistan, Islamabad and premises was sealed, then after adopting all the coercive measures, accused made appearance and moved application for cancellation of the NBW already issued against the accused by this Court. No doubt case of the accused is private complaint and after attending the Court, accused remained absented themselves again and again by playing hide and seek with this Court. Keeping in view*

the attitude of the accused toward Court orders, court is left with no option accept taking serious notice and passing strict order for procuring the attendance of accused persons attracting issuance of NBW of both the accused and forfeiture of their sureties and service be executed through DIG Karachi. Separate notices to their sureties also be issued to show cause or to pay the penalty.

Drug Regulatory Authority of Pakistan, Islamabad is directed to seal the premises of M/s Medimarker's Pharmaceutical A-104 SITE Area Hyderabad Pakistan, through Federal Drug Inspector Karachi and suspend its Drug Manufacturing License by convening special meeting under intimation to this Court till further order*. Ahlmad is directed to convey this order to Sheikh Abdul Rasheed Federal Drug Inspector for onward transmission to quarter concern for immediate compliance.*

Re-list for 27-10-2016*".*

The firm has been called for personal hearing

Proceeding of 250th meeting of Central Licensing Board.

Mr. Rashid Ali, Manager Regulatory Affairs, appeared before the Board on behalf of the company. He contended that he was authorized to appear before the Board. He presented the Medical certificate issued in the name of Dr. Abdul Shakoor S/o Muhammad Usman issued by Dr. Anoop Kumar of M/s Dr. Ziauddin Hospital, Karachi. The contents of Medical certificate are reproduced below:

"*This is to certify that Dr. Abdul Shakoor s/o Muhammad Usman 43 years old was admitted on 18-10-2016 with reference # 00048933/2016 under care of Dr. Imran Bashir and Dr. Saad Niaz Consultant Gastroenterlologist with complaint of epigastric pain for 2 days for which he is investigating for his diagnosis."*

DECISION.

The Board heard the representative of the firm who was called on the orders of the Drug Court, Lahore and decided to suspend the Drug Manufacturing Licence of M/s Medimarker's Pharmaceutical A-104 SITE Area Hyderabad Pakistan till further orders.

Case No. 13 ORDERS OF HONORABLE LAHORE HIGH COURT, LAHORE REGARDING WRIT PETITION NO. 10988/2007 FILED BY M/S MICKO INDUSTRIAL CHEMICALS CO. (PRIVATE) LIMITED, 28-KM FEROZEPUR ROAD, LAHORE.

The case was included in the agenda as under: -

Background of the case: -

The case was placed in 241st meeting of CLB held on 15th May, 2015: -

M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore submitted application for renewal of DML # 000183 (Formulation) for the period 17-11-2005 to 16-11-2010 for which a panel was constituted on 23-09-2005 for inspection of the firm comprising of following experts / inspectors:-

1. Dr. Ijaz Ahmad, Associate Professor, University of Veterinary and Animal Sciences, Lahore.
2. Area Federal Inspector of Drugs, DCA, Lahore
3. Area Assistant Drugs Controller, DCA, Lahore

The above mentioned panel conducted inspection of the firm for renewal of DML and submitted report on 17-08-2006 wherein panel stated that overall condition of the firm was good. The firm had given undertaking that they would remove the shortcomings pointed out within 15 days. Therefore, the panel is of the opinion that firm may be granted renewal of their Drug Manufacturing License by way of formulation and re-packing.

After receipt of inspection report in this office, the then ADC (L & A) issued a letter to Federal Inspector of Drugs, DCA, Lahore, he stated that firm had submitted an under taking to the panel to rectify the shortcomings as pointed out by the panel, but the compliance report concerning the same had not been received so far therefore area FID was requested to verify the same and submit report within 07 days positively.

The area Federal Inspector of Drugs inspected the premises on 31-10-2007, along with Mr. Ghazanfar Ali Khan, ADC, Lahore to check the rectification of shortcomings pointed out during inspection dated 20-07-2006. The area FID submitted inspection report wherein a number of serious GMP non-compliance were reported and she suggested that production of the firm be stopped and renewal of DML may not be considered in light of critical shortcomings and failure of commitment given by the firm to remove the deficiencies pointed out by the panel during previous inspection.

The area FID sealed the factory and on the form of sealing of the factory she stated that *M/s Micko Industrial Chemicals , 28-km Ferozepur Road, Lahore is sealed due to the violation of Section 27(3) of the Drugs Act, 1976 and various other provisions of the Drugs Act, 1976 and rules framed there under . The owner Mr. Khursheed Alam snatched the samples of drugs taken for the purpose of test analysis from driver Ismail with Form 3. FIR was launched in police station, Kahana and the factory is sealed in the presence of Mr. Ghazanfar, ADC, Javed Iqbal, ASI and Tahir Iqbal, Head Constable .*

The firm was then served a Show Cause Notice on 19th November 2007 by the then Secretary CLB and directed to submit reply of the show cause within 15 days.

A letter dated 17-11-2007 was again received from Ms. Aisha Khalil, the then area FID wherein she informed that owner of the firm had challenged the legal process of panel and the accused Mr. Khurshid Alam Sheikh filed a writ petition No. 10988/2007 in Honorable Lahore High Court Lahore through his counsel requesting the Court to declare the sealing order illegal and for award of cost incurred on this petition. Mr. Justice Syed Hamid Ali Shah issued a one sided interin order dated 07-11-2007 hence suspended the sealing order of panel without hearing the panel, till next hearing and ordered for submission of reply and parawise comments in this regard.

In compliance of court order dated 07-11-2007 she along with Mr. Ghazanfar Ali Khan ADC visited the premises on 14-11-2007 to de-seal the factory and found that the seals were broken by the owner and production of drugs was in process. The position was also brought in to the kind notice of Honorable Court vide etter No. 9067/2007-DCA (L-II) dated 14-11-2007.

On 05th December 2007, a letter was issued to the firm from this office by the then Secretary CLB wherein it was stated that refer to the panel inspection report of the firm conducted by area FID Lahore on 14-11-2007 wherein it was reported that production was in-progress while the conditions of renewal of DML have not been fulfilled as reported by the panel during inspection conducted on 30-10-2007. As this is an offence under Rule 13 of the Drugs (Licensing, Registering & Advertising) Rules 1976, therefore, firm was directed to suspend the production with immediate effect till removal of the deficiencies and re-inspection by a panel and approval of Central Licensing & Registration Board.

Recently, On 23-04-2015, a letter was received from Assistant Registrar , wherein he forwarded the order sheet of Honorable Lahore High Court, Lahore for the Writ Petition # 10988/2007 & 11839/2007. The contents of the order sheets are as under:-

> Mr. Bashir Ahmad Tariq, Advocate for the Petitioner.
>
> Ms. Saadia Malik, learned Standing Counsel for Pakistan along with Ayesha Irfan, Federal Inspector Drugs.
>
> Through this single order I intend to dispose of writ petition Nos. 10988 and 11889 of 2007 as both are based on common facts.
>
> 2. In W.P NO. 10988/2007 order dated 30-10-2007 is challenged whereby the factory of the petitioner was sealed for violation of Section 27 (3) and other provisions of the Drugs Act, 1976 and also for the reason that owner of the factory namely Khurshid Alam Sheikh had snatched samples taken from the factory premises by the Federal Drug Inspector.
>
> In other writ petition No. 11889/2007 order for suspension of production is challenged.
>
> 3. Facts, which have surfaced after arguments from both sides, are that he inquiry report was being prepared by the Federal Drug Inspector when samples of some

illegal drugs were allegedly snatched by the owner of the factory. Statedly, due to violation of the statutory provisions and the illegal act by the owner, the factory premises were sealed. As per learned Standing Counsel's assertions, the factory was de-sealed illegally and production was commenced by the petitioner, therefore, another order for suspension of production was passed.

4. Due to multiplicity of litigation, facts of the case are confused. It is asserted by the petitioner that its factory is sealed and production is suspended whereas learned Standing Counsel submits that the production is being carried out illegally at the sealed premises.

5. Be that as it may, it is settled proposition that this Court cannot look into factual controversies in exercise of its constitutional jurisdiction. For resolution of dispute on facts as well as on legal side, this matter is referred to Central Licensing Board, before which report has already been filed by the Federal Drugs Inspector. The Board shall provide opportunity of being heard to the petitioner and shall pass a speaking order within 45 days positively under intimation to the Deputy Registrar (Judicial) of this Court.

Till decision no coercive measures shall be taken

RECORD AND STATUS OF FIRM IN LICENSING DIVISION

The five years tenure of renewal of DML of the firm for the period 17-11-2005 to 16-11-2010 has been expired without any further orders by Central Licensing Board.

Afterwards, firm submitted application for renewal of DML of the firm for the next five years i.e. from 17-11-2010 to 16-11-2015 for which a panel of experts/inspectors was constituted on 10th March 2011 comprising of following members:-

1. Dr. Farzana Chaudhary, (Member DRB) Director IPS University ad Animal Sciences, Lahore
2. Dr. Noor Muhammad Shah, Deputy Director General (L & A), Islamabad.
3. Dr. Sheikh Akhtar Hussain, Deputy Director General (E & M), DCA, Lahore
4. Area Federal Inspector of Drugs, DCA, Lahore.

The report of the above mentioned panel is still awaited.

It is also submitted here that Ms. Aisha Irfan, Area Federal Inspector of Drugs also updated Licensing Division about the recent orders passed by Honorable Court and case background. she stated that all the action taken by her on the directions of the Central Licensing & Registration Board and as per the Drugs Act, 1976 and rules framed there under, hence, no malafide intentions were involved, and the actions were taken in Good Faith by her. She also requested that she may also be provided with an opportunity to present this case in Central Licensing Board personally.

Therefore, the case is placed before the Licensing Board as per orders of the High Court for further directions in the matter.

The firm, M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore and Ms. Aisha Irfan, FID, DRAP, Lahore were called for personal hearing.

Proceedings of the case:

Licensing Division, DRAP apprised the Board that the order sheet of the Honorable Court was received in the Secretariat of the Licensing Division in late hours at Friday on 08th May 2015.

After receipt of the orders of the Honorable Court, Licensing Division processed the case on 11th May 2015 and after approval from competent Authority, letter for personal hearing was issued through Courier to the firm on 13th May 2015.

Area Federal Inspector of Drugs, DRAP, Lahore was contacted telephonically to deliver the copy of the letter of personal hearing to the firm in person but she informed that she couldn't deliver letter because she was at hospital for treatment of illness of his father and her assistant may also not deliver the letter to the firm in person because she is a female. After that, Deputy Director General (E&M), DRAP, Lahore was requested on 14th May 2015 to depute a person from his office who shall deliver letter to the management of the firm by hand. Accordingly, Mr. Shahid Mehmood, LDC, DRAP, Lahore was sent to deliver the letter of personal hearing to the firm, by hand.

When he reached the location of the firm and contacted the person, Mr. Shoib (son of the owner of the firm) opened the gate and viewed the letter and requested him to be seated so that he may contact his father (Owner of the firm) before receiving the letter.

After half an hour, he came and refused to receive letter of personal hearing from him and stated that his father is not in the factory and currently outside the city. Mr. Shahid Mehmood also given in writing the conversation.

The case was presented in 241st meeting of the Board wherein the Board decided as under:-

Decision of the Board:

The Board after thorough discussion and deliberation decided:-

1. *To provide another opportunity of personal hearing to the firm.*
2. *To deliver letter of personal hearing to the firm by registered post/UMS/ through courier.*
3. *To submit an interim report for the appraisal of Honorable Court, regarding current status of the case in the Central Licensing Board.*

Accordingly, above decision of the Board was conveyed to the firm and letter for personal hearing was issued, please.

Proceedings:

The Board was apprised that the letter for personal hearing was sent to the firm via TCS but no any representative of firm is present for personal hearing.

Decision of CLB (M-243):

Keeping in view the facts of the case, the Board unanimously decided for final opportunity of personal hearing. The Board further directed that letter of personal hearing be sent through TCS, Registered

AD, Area FID and also email (if email available). The Honorable Court may again be apprised of the status of the case.

Further Proceedings.

Mr. Khurshid Alam Sheikh, Director Admin for M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore informed the Licensing Division vide letter No. 37/Micko-Lahore dated 01-11-2015 that the orders of single judge in chamber of Lahore High Court dated 23-04-2015 have been challenged before the Division Bench by way of filing inter Court No. 653 & 655, of 2015 and informed that there is hardly any need for personal hearing of the above cases. It is therefore, requested that the matter may be please be protracted till the final disposal of said appeals.

M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore has filed Inter Court Appeal against the judgment passed on W.P. NO. 10/988/2007 in the Honorable Lahore High Court Lahore. The orders of the Honorable Court is as under: -

"For what has been discussed above this Court is of the view that present appeals have not been filed by an authorized person therefore they being incompetently filed are not maintainable and are thus dismissed".

"For the reasons recorded in judgment of even dated passed in ICA No. 653-2015, this Intra Court appeal is dismissed". (Announce Date 26-01-2016)

Proceedings:

The Board was apprised of the background of the case and further apprised that M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore had filed Intra Court Appeal against the judgment passed on W.P. NO. 10/988/2007 in the Honorable Lahore High Court Lahore. The orders of the Honorable Court are as under: -

> "For what has been discussed above this Court is of the view that present appeals have not been filed by an authorized person therefore they being incompetently filed are not maintainable and are thus dismissed".
>
> "For the reasons recorded in judgment of even dated passed in ICA No. 653-2015, this Intra Court appeal is dismissed". (Announce Date 26-01-2016)

The Board was further apprised that after the decision of Intra Court Appeal, M/s Micko Industrial Chemicals Co. (Private) Limited, Lahore has requested for processing the case in the light of previous decision of Honorable Court against writ petition Nos. 10988 and 11889 of 2007.

Decision of CLB:

Keeping in view the facts of the case, the Board unanimously considered and decided for personal hearing of the firm in the light of decision of Honorable Court against writ petition Nos. 10988 and 11889 of 2007.

Accordingly, firm was called for personal hearing.

Proceedings of CLB

Mr. Shehryar Alam S/o Shaikh Khurshid Alam (Son of Director of the firm) and Mr. Bashir Ahmed Tariq, Legal Advisor of the firm appeared before the Board and presented their point of view in a statement as under :-

> "I, sheharyar Alam, representative of Mr. Khurshid Alam Shaikh, stated to the panel that kindly grant us some time to rethink upon the issue of withdrawal of civil suit against Ayesha Khalid (FID). I requested the panel to kindly allow us some time to discuss the issue with the Director Khurshid Alam. I believe that it will bring a positive outcome".

Decision of CLB in 247th meeting :

The Board discussed the case in length, keeping in view the case background history and order of Honorable Court. The Board observed that in the instant case Board has heard one sided point of view of the applicant, so an opportunity of hearing shall be given to concerned FID in the interest of Natural Justice; therefore, Board deferred the case for personal hearing of concerned FID in the upcoming meeting of CLB.

The Board further Directed to send an interim report to the Honorable Lahore High Court, Lahore.

Action taken by the Licensing Division:

In the light of decision of the Central Licensing Board, an interim report was submitted to the Honourable Lahore High Court, Lahore. Moreover, Federal Inspector of Drugs (FID), Lahore has been called.

Proceeding of 250th meeting of Central Licensing Board

Ms. Aisha Irfan, Federal Inspector of Drugs, Lahore appeared before the Board and recorded her statement as under:

> ***"The inspection of M/s. Micko Chemical Industries (Pvt.) Ltd., was conducted on 30-10-2007 alongwith Mr. Ghazanfar Ali Khan, Assistant Drugs Controller, Lahore vide the defunct Ministry of Health, Islamabad letter No. F.1-16/85-Lic (Vol-II), dated 29-07-2007 to check the rectifications of shortcomings pointed-out in previous inspection conducted for the renewal of DML.***
>
> ***It was noticed at the time of inspection that the firm did not rectify the shortcomings and overall condition of the firm was very deplorable, hence clear violations of GMP were observed.***
>
> ***Meanwhile, the samples of the drug Gentian Violet Paint Batch No. G/000404, Wax Aid, Batch No. SG/0142 and Tincture Iodine Batch No. TID/003156, were taken for test / analysis purpose. Mr. Khurshid Alam the owner of the firm behaved in a very harsh manner and snatched the samples alongwith form-3 from the driver of the undersigned. He created***

obstruction in the official duty of the Federal Inspector of Drug, and took away the box of samples and Form-3 with him and left the factory with his wife Mrs. Rubina Khursheed, Chief Pharmacist of the factory. He did not provide the inspection book on demand. The Drugs Controller and Deputy Director General (E&M), Lahore at that time were informed and the Drugs Controller directed, to lodge FIR immediately and seal the factory.

FIR No. 1257/07 dated 30-07-2007 was lodged against Mr. Khurshid Alam, under section 27(3) of Drug Act, 1976 with section 186/506PPC at Police Station, Khana. The factory was sealed in the presence of Assistant Sub Inspector and Head Constable.

The firm had taken interim order from High Court for de-sealing of premises. The undersigned visited the factory on 12-11-2007 as per High Court order in writ petition No. 10988/2007 to de-seal the factory. It was noticed that the seals were already broken and the factory was already opened and illegal production was going on. The order of the court was just to de-seal the factory and the production of the factory was not allowed. The undersigned informed the High Court and the Chairperson, Central Licensing and Registration Board of the above position. The case was referred to Chairperson Central Licensing & Registration Board.

The show cause notice to the firm was issued vide Ministry's letter No. 1-16/85-Lic (Vol-II) dated 19th November, 2007. The production of M/s. Micko Chemical Industries (Pvt.) Ltd. was suspended vide Ministry's letter No. F.1-16/85-Lic (Vol-II) dated 30th November, 2007.

The owner of the firm Mr. Khursheed Alam filed Writ Petition No. 10988/2007 in the High court and three cases of damages against the undersigned in the civil court just to create harassment. The cases are still at different stages in courts as cited below.

S.No.	*Name of Court.*	*Title of Case*	*Nature of case*
01	*In the Court of Qazifi Bin Zair Civil Judge, Lahore.*	*Mrs. Rubina Khurshid Wife of Khurshid Alam, Chief Pharmacit, Micko Indu. Chemical Co., (Pvt.) Ltd., Ferozepur Road, Lahore Vs. Mst. Aisha Khalil, FID, Lahore.*	*For damages Rs. Ten Million.*
02	*In the Court of Mr. Khalid Mehmood, Civil Judge, Lahore.*	*Khurshid Alam, Sh. R/o/ 50-C, F.C.C., Ch Zahoor Elahi Road, Gulberg, Lahore Vs.*	*For damages Rs. 150,40,000/-*

		Mst. Aisha Khalil, FID, Lahore.	
03	***In the Court of Mr. Hymoon Pervaiz, Civil Judge, Lahore.***	***Khurshid Alam, Sh. R/o/ 50-C, F.C.C., Ch Zahoor Elahi Road, Gulberg, Lahore Vs. Mst. Aisha Khalil, FID, Lahore.***	***For damages Rs. 130,40,000/-***

One case of complaint was filed by Mr. Khursheed Alam in Special Judicial Magistrate Lahore, Cantt which the undersigned won and acquitted, the judge gave 08 page judgment in the favor of undersigned stating that the acquittal of the accused is accepted as being on merit and complaint is herby dismissed.

It is pertinent to mention here that the firm is involved in the illegal manufacturing of drugs to date, as the production of the firm was suspended and the firm's Drug Manufacturing License was not renewed as two times the panel inspected the firm for the Renewal of DML in year 2007 and 2011 and in both the inspections serious short comings were pointed out by the panel. Moreover, it is asserted by the petitioner in the High Court that his factory is sealed and production is suspended, where as learned standing counsel submits that the production is being carried out illegally at the premises, as mention in the Lahore High Court order dated 23-04-2015. Moreover, the drugs manufactured by M/s. Micko Industries are freely available in the market.

It is submitted that all the actions were taken on the directions of the Central Licensing & Registration Board as per Drugs Act, 1976 and rules framed there under, hence no malafide intentions were involved, and the actions were taken in Good Faith by the undersigned. The undersigned was not given counsel in the damages cases and in the case of complaint filed by Mr. Khursheed Alam in Special Judicial Magistrate Lahore, Cantt and the lawyers were hired by the undersigned personally and fees paid to them from own pocket. The purpose of Mr. Khursheed Alam owner of M/s. Micko Industries is being fulfilled by creating harassment to the undersigned for the last 09 years, while he is doing illegal business without any fear, hence endangering public life.

It is therefore humbly requested that strict action against Mr. and Mrs. Khurseed Alam owner/Chief Pharmacist of M/s. Micko Industrial Chemical Co., be taken such as the plaintiff be given due punishment under provision of Section 27 (3) and (4) of Drugs Act, 1976 with imprisonment of five years and fine, his DML be cancelled as he is involved in the

illegal manufacturing of drugs. Hence in order to curtail these type of illegal practices in future such as taking law in their own hands by creating harassment and hurdles in the official duties of FIDs stringent action is required. Moreover, it is also requested to give counsel to the undersigned in all the damages cases filed by Mr. Khurseed Alam as the actions were taken in official capacity and in good faith. The damages suits are barred under Section 38 of Drugs Act, 1976 and also liable to be dismissed under Section 07 Rule 11 of the CPC and the compensation of Rs: 200,000/- be given to the undersigned for the fees already paid to lawyers in the last 09 years till to date."

Decision.

The Board deliberated on the basis of statement recorded by Ms. Aisha Irfan, Federal Inspector of Drugs and decided to:

i. **Representative of M/s M/s Micko Industrial Chemicals Co. (Private) Limited located at 28-km Ferozepur Road, Lahore may be called in the next meeting of the Board to record statement regarding facts in the case referred by Honourable High Court, Lahore before conclusive decision on the basis of statement recorded before the Board.**

ii. **Report of the panel dated 06-06-2011 handed over by Ms. Aisha Irfan, Federal Inspector of Drugs during her statement was not found in the record of the Licensing Division. Matter may be investigated to find the gap regarding non availability of report in the record. Thereafter facts may be placed before the Board for its consideration.**

Case No. 14 M/S PHARMEDIC CHEMICALS, 24-KM MULTAN ROAD, LAHORE.

CASE BACKGROUND

i. Central Licensing Board in its 233rd meeting held on 30th &31st December 2013, considered the site verification report of M/s Pharmedic Chemicals, 24-km, Multan Road, Lahore for establishment of a pharmaceutical unit by way of basic manufacture.

The Board after thorough deliberations and keeping in view the rule position rejected the application of Site under Schedule-B (1.2) & (2) of Drugs (Licensing, Registering and Advertising) Rules, 1976.

ii. Firm had filed an appeal before Appellate Board against decision of CLB. Appellate Board in its 142nd meeting held on 24-06-2014 discussed the appeal of the appellant and decided as under:-

"In light of above discussion the Board decided to remand the case to Central Licensing Board for conduction of an inspection by a panel of experts keeping in view the environmental assessment and the rules made under the Drugs Act, 1976 and to decide the case accordingly. "

iii. Accordingly, a panel was constituted by Licensing Division on 17th December 2014 for re-inspection of the site upon the direction of Appellate Board. The composition of panel is as under:-

a. Secretary Punjab Environmental Protection Council or his nominee being the member of the council with qualification & expertise in Environmental Impact Assessment with particular reference to environmental impact of subject case on the safety, efficacy, quality & purity of drugs / medicines planned to be product of the applicant.

b. Chief Drug Controller, Punjab

c. Area Federal Inspector of Drugs, DRAP, Lahore.

iv. Afterwards, a letter was received from Environmental Protection Agency Government of Punjab on 5th March, 2015 regarding site verification for establishment of pharmaceutical unit and submitted following recommendations: -

The undersigned alongwith Director (Monitoring, Laboratories & Implementation), EPA, Punjab, Lahore, visited the site of subject unit on 02-02-2015, Mr. Ajmal Sohail Asif, Area FID, DRAP, Lahore and Dr. Zaka Ur Rehman, Chief Drugs Controller, Punjab, were also present at site. Mr. Ijaz Hussain, General Manager, conducted inspection of the unit. It was informed that the proponent intends to start semi basic manufacturing of Paracetamol from para amino phenol and acetic acid which will be imported.

2. A waste water drain is passing nearby the unit. The production room of the unit is situated at a distance of 331 feet from the drain. Mr. Ijaz provided a copy of report of ambient air quality monitoring within premises of the unit in front of production hall conducted by M/s SGS Lab (a certified lab under certification of environmental labs. Regulations, 2000) (SGS

Ref: ENV-LHR-764/2012). The ambient air quality may fluctuate. Therefore , the authority has approved following conditions for the subject matters

Recommendations: -

i. A properly designed centralized air handling unit with infiltration facility for providing clean air entry into production room should be installed in the unit.

ii. The proponent shall ensure compliance of National Environmental quality Standards (NEQS) and relevant provision of Punjab environmental Protection act, 1997 (Amended 2012).

Now the firm has submitted an undertaking and stated that the honorable authorities of Environmental Protection Agency, Government of Punjab, Lahore has advised the following;

i) A properly designed air handling unit with infiltration facility for providing clean air entry into production room should be installed in the unit.

ii) The proponent shall ensure compliance of national Environmental Quality Standards (NEQS) and relevant provisions of Punjab environmental protection Act, 1997 (amended 2012).

The case was presented in 240th meeting of CLB held on 06-03-2015 for appraisal of the Board because complete inspection report of the panel was not received.

Now complete inspection report of the panel dated 12th March 2015, has been received in the Licensing Division wherein recommendations of the panel are as under:-

"In the light of the physical verification of the site and scrutiny of documents provided by the applicant, and considering the report of Environmental Protection Agency, Punjab the panel recommends that the site may be approved for establishment of a Pharmaceutical unit by way of semi basic manufacturing, as per requirements laid down under paragraph 1 of section 1 of the Schedule B (S.R.O 470(I)/98 dated 15-05-1998) of the Drugs (Licensing, Registering & Advertising) Rules 1976 "

Proceedings:

The Board observed that in the report of Environmental Protection Agency, it is clearly mentioned that ambient air quality may fluctuate and unit is located nearby a waste water drain.

Dr. Zaka- Ur-Rehman, Chief Drug Controller, Punjab / Member CLB (who was also the member of the panel) apprised the Board that since management of the firm has taken preventive measures by building a huge wall between water drain and premises but still obnoxious smell is all around the surroundings of the premises due to the open water drain.

The Board further enlightened the conditions for grant / renewal of a license to manufacture drugs by basic or semi basic manufacture under Rule 15 (a) of the Drugs (Licensing, Registering & Advertising) Rules 1976 wherein it is stated that "the applicant shall provide premises which shall be suitable for intended use, in size and construction and shall be located in an area free from offensive and obnoxious odors and other possible sources of contamination.

The Board showed serious concern with safety of the public health as it will be injustice with the mandate of hygienic conditions required for manufacturing of Active Pharmaceutical ingredient(s) which shall be used in the different formulation for treatment of disease.

The Board is also of the point of view that evaluation of the surroundings of the proposed premises of the applicant shall be made on the scientific and technical basis related to the manufacturing of Active Pharmaceutical Ingredients. Air quality and surroundings of the premises shall be verified according to the requirements of the hygienic condition for APIs intended to be manufactured by the applicant in the future.

Decision of 241 meeting of CLB

In the light of above proceedings, the Board after thorough discussion, deliberation and keeping in view the scientific importance of the matter and public health decided to re-inspect the premises under Rule 15(a) of the Drugs (Licensing, Registering & Advertising) Rules, 1976 by the panel comprising of:-

(i) Dr. Ikram – Ul – Haq, Member CLB
(ii) Prof. Dr. Gul Majeed Khan, Member CLB
(iii)Prof. Dr. Muhammad Saeed, Member CLB
(iv) Syed Mueed Ahmed, Member CLB
(v) Area Federal Inspector of Drugs, DRAP, Lahore

Action by DRAP

Licensing Board conveyed its decision to federal Inspector of Drugs on 03-07-2015 to coordinate the panel inspection with the above said members. The panel conducted inspection on **29-10-2015 and same was forwarded by FID on 07-04-2016** recommendations of which are as under :

i. The firm may be asked to provide a fresh ambient air monitoring preferably through EPA or some other certified Laboratory.

a. the nature and impact on odour on the environment and health of personnel inside the production area if possible.

b. impact of odour on the quality of API intended to be manufactured.

ii. The form may be asked to provide detail of air handling system to be installed in production area and how it will prevent the odour from coming into the production buiding where API is exposed.

iii. The firm may be asked to approach the concerned department if the drain may be covered in front of premises (or what other measures be taken to prevent the odour.)

iv. The report regarding the quality of raw water to be used for production purposes.

Panel recommend that the premises may be re-inspected after the provision of above mentioned / data.

Now FID has forwarded replies of the firm on the report which is placed before the Board.

OBSERVATION	COMPLIANCE
The firm may be asked to provide a fresh ambient air monitoring preferably through EPA or some	The EPA was requested to monitor the ambient air quality which were found within NEQS report

other certified Laboratory. a. the nature and impact on odour on the environment and health of personnel inside the production area if possible. b. impact of odour on the quality of API intended to be manufactured.	no.251-DD(Labs)EPA dated 19/1/16 copy attached. The EPA report shows that the ambient air quality is within NEQS so will not leave any impact on personnel in production. We approached PCSIR (Ministry of Science of Technology) as per their instruction Acetaminophen (paracetamol) vide batch No.P-15-594 of Zenith Chemicals was placed for 7 days and sample drawn by their scientist and tested shows port total compliance with requirement. The report No.ACRC/Pharma/2016/388 dated 04-02-2016 copy attached.
The fIrm may be asked to provide detail of air handling system to be installed in production area and how it will prevent the odour from coming into the production buiding where API is exposed.	The detail introduction of activated carbon base HAVAC system alongwith designed by Fairtech Engineering is attached will be installed before operation after grant of DML.
The firm may be asked to approach the concerned department if the drain may be covered in front of premises (or what other measures be taken to prevent the odour.)	We approached Executive Engineer Lahore drainage division Lahore vide our letter No.PH/LHR/18730 dated 8/2/16. They have informed it is storm water drain can not be covered but some suitable plantation is allowed copy attached.
The report regarding the quality of raw water to be used for production purposes.	The report of raw water vide No.251-DD(Labs)EPA date 19/1/16 copy attached shows the tested parameters are within the permissible limits of NEQS.

DECISION.

The Central Licensing Board deliberated on the case in the light of the facts mentioned above and recommendations of the previous panel of inspectors in its report dated **29-10-2015,** the Board decided that following panel of inspectors/ experts may re-inspect and submit report for decision by the Board on the case.

(i) Dr. Ikram – Ul – Haq, Member CLB
(ii) Syed Mueed Ahmed, Member CLB
(iii) Jawed Yousaf Bukhari, Member CLB
(iv) Area Federal Inspector of Drugs, DRAP, Lahore

Case No.14 **PROVISION OF INFORMATION AND ENDORSEMENT OF MANUFACTURING PROCESS FLOW / PROTOCOL OF MANUFACTURING AND TESTING OF APIs/ BULK DRUGS.**

The case was placed before the Board as under: -

Background of the Case.

The case was presented in 246th meeting of Central Licensing Board held on 22nd February, 2016 and decided as under: -

Decision of CLB:

Keeping in view the above situation, the Board considered, discussed and unanimously decided for panel inspection of the above firms by following panel: -

1. Prof. Dr. Saeed Sb. Member CLB
2. Dr. Ikram-ul-Haq, Member CLB
3. Syed Muid Ahmed, Member CLB
4. Syed JavedYousuf Bukhari, Member CLB
5. Area FID, DRAP, Lahore

The Board further directed the panel: -

- to verify the complete process of manufacturing of every API as per requirement of Rule 10 of the Drugs (Licensing, Registering & Advertising) Rules, 1976.
- to sign / endorse the complete report and their manufacturing process flows of APIs.

The Board further decided that in future above procedure shall be followed for approval any new API.

Following cases have been recommended by the respective panel of experts for provision of information and endorsement of manufacturing process flow / protocol of manufacturing and testing of APIs/ Bulk Drugs.

S#	Name of the firm	Inspection Panel Members	List of Approved APIs	Consolidated list of Approved starting/intermediates for APIs	Remarks
1.	M/s Alpha chemical (Pvt) Ltd, 65-km Lahore-Multan National Highway, Industrial Zone, Chunian, Kasur. DML No. 000373 By way of Basic Manufacture Inspected on **04-06-2016**	1. Dr. IkramulHaq, Member CLB 2. Syed Muied Ahmed, Member CLB. 3. Syed JavedYousaf Bukhari, Member CLB. 4. Mr. Abdul Rashid Shaikh, FID DRAP Lahore.	1. Santonin Powder BP/USP. 2. Ephedrine HCL & Other Salts. 3. Pseudoephedrine HCL & Other Salts. 4. Liquorice Extract. 5. Crude Glycyrrhizic Acid. 6. Monoammonium Glycyrrhizinate. 7. Dipotassium Glycyrrhizinate. 8. 18-Beta Glycyrrhizic Acid. 9. Crude Disogenin 90 ~ 95%. 10. Berberine Hydrochloride. 11. Aescin. 12. Ammonium Chloride. 13. Aluminum Chloride Liquid Gel. 14. Sodium Acid Citrate.	1. Toluene 2. Artemisia Herb 3. Steam 4. Lime Water (Calcium Hydroxide) 5. Hydrochloric Acid (HCL) 6. Ethanol (Ethyl Alcohol) 7. Acetone 8. Molasses 9. Simethicone (Anti Foam) 10. Urea 11. Yeast 12. Deionized Water 13. Benzaldehyde 14. Phosphoric Acid 15. Phenyl Acetyl Carbinol (PAC) 16. Platinum Sponge (Catalyst) 17. Nitrogen Gas 18. Hydrogen Gas 19. Monomethylamine 40% 20. Activated Carbon (DARCO A 51) 21. Celite (Diatomite Filter Aid) 22. N-Butanol 23. (+)-(1S,2S)-2-Methylamino-	The individual process flow chart diagram of each API along with list of starting/raw materials duly endorsed by firm's representatives and panel members is annexed with the report.

			15. Caffeine Citrate. 16. Furazolidone. 17. Sulphamethoxazole. 18. Pyrazinamide.	1-Phenylpropan-1-OL Base 24. Ephedrine Hydrochloride 25. Acetic Anhydride 26. Liquoric Roots 27. Sodium Hydroxide (Solution) 28. Liquorice Extract 29. Sulphuric Acid 30. Crude Glycyrrhizic Acid 31. Ammonium Hydroxide 32. Glacial Acetic Acid 33. Methanol 34. Potassium Hydroxide 35. Dioscorea Roots 36. Hexane 37. Berberis Roots 38. Isopropyl Alcohol (IPA) 39. Dry Aesculus Indica 40. Acetic Acid 41. Ammonia 42. Aluminum Sulphate 43. Dilute Sodium Carbonate 44. Caffeine 45. Monoethanolamine 46. Sodium Nitrite 47. Iron Powder (Iron Oxide) 48. Ice 49. 5-Nitro Furfural Diacetate (5-NFDA) 50. Formaldehyde 51. 4-(N-Acetyl) Amino-N1-(5-	

				Methyl-3-Isoxazolyl) Benzenesulfonamide (Acetyl SMZ) 52. 2-Cyanopyrazine	

2.	M/s Pharmagen Ltd, KotNabiBaksh Wala, Ferozpur Road, Lahore. DML No. 000325 by way of Semi Basic Manufacture Inspected on **30&31-05-2016**	1. Prof. Dr. Muhammad Saeed, Member CLB 2. Dr. IkramulHaq, Member CLB 3. Syed Muied Ahmed, Member CLB. 4. Syed JavedYousaf Bukhari, Member CLB. 5. Mrs. MajidaMujahid, FID DRAP Lahore.	1 Amoxycillin Trihydrate 2 Ampicillin Trihydrate 3 Ampicillin Anhydrous 4 Cloxacillin Sodium 5 Flucloxacillin Sodium 6 Cephradine 7 Cephalexin Hydrate 8 Cefadroxil 9 Cefaclor 10 Cefixime 11 Cefuroxime Axetil 12 Cephradine L-Arginine (Sterile) 13 Ceftriaxone Sodium (Sterile) 14 Cefotaxime Sodium (Sterile)	1 6-Aminopenicillanic Acid (6-APA) 2 7-Amino desacetoxy Cephalosporanic Acid (7-ADCA) 3 7-Amino Chloro Cephalosporanic Acid (7-ACCA) 4 7-Amino Cephalosporanic Acid [7-ACA] 5 7-Amino-3(1H-thiadiazole)-Cephalosporanic Acid (7-TDA) 6 7-Amino 3-vinyl Cephalosporanic Acid (7-AVCA) 7 (7-phenyl-acetamido-3-chloromethyl cephalosporanic acid p-methoxybenzyl ester [GCLE] 8 9,10-Difluoro-2,3-Dihydro-3-Methyl-7-Oxo-(3s)-7h-Pyrido(1,2,3-De)-1,4-Benzoxazine-6-Carboxylic Acid (Levofloxacin Q Acid) 9 Acetyl SMZ 10 Dexamethasone Crude 11 Dexamethasone Base 12 Betamethasone Crude 13 Betamethasone Base	The individual process flow chart diagram of each API along with list of starting/raw materials duly endorsed by firm's representatives and panel members is annexed with the report.

			15 Cephalexin Sodium (Sterile) 16 Cefazolin Sodium (Sterile) 17 Cefoperazone Sodium (Sterile) 18 Ceftazidime Pentahydrate Sterile 19 Cefuroxime Sodium (Sterile) 20 Ciprofloxacin Hydrochloride 21 Moxifloxacin Hydrochloride 22 Pefloxacin Mesylate 23 Levofloxacin 24 Norfloxacin 25 Azithromycin 26 Clarithromycin 27 Sulfamethoxazole 28 Omeprazole 29 Esomeprazole Magnesium Trihydrate 30 Paracetamol 31 Pyrazinamide 32 Naproxen Sodium 33 Ibuprofen	14 Moxifloxacin Q-Acid (1-Cyclopropyl-6,7-Difluoro-1,4-Dihydro-8-Methoxy-4-Oxo-3-Quinoline Carboxylic Acid) 15 2-Chloromethyl-3,5-Dimethyl-4-Methoxypyridine Hydrochloride 16 Omeprazole Sulfide 17 Amlodipine Base Crude 18 7-Chloro-6-Fluoro-1cyclopropyl-1,4-Oxoquinoline-3-Carb-Oxyilic Acid Fluoroquinocolonic Acid (Ciprofloxacin Q-Acid) 19 Ethyl Quinolonic Acid 20 Quinolinyl Propanol 21 Norfloxacin 22 Para Amino Phenol 23 D(-) Alpha Phenylglycine (DAPG) 24 D(-) Alpha Phenylglycine Dane's Salt (DAPG Dane Salt) 25 D(-) P-Hydroxy Phenylglycine (PHPG) 26 D(-) P-Hydroxy Phenylglycine Dane's Salt (PHPG Dane Salt) 27 D(-) Dihydro Phenylglycine Dane's Salt (DHPG Dane Salt) 28 Ceftriaxone Crude 29 Cefotaxime Free Acid 30 Isobutylhydrotope Aldehyde 31 Naproxen Crude	

			34 Simvastatin 35 Atorvastatin Calcium Trihydrate 36 Amlodipine Besylate 37 Montelukast Sodium 38 Mefenamic Acid 39 Sofosbuvir 40 Dexamethasone Sodium Phosphate 41 Betamethasone Sodium Phosphate 42 Betamethasone Valerate 43 Betamethasone dipropionate 44 Dexamethasone Acetate	32 Simvastatin Ammonium Salt 33 Tert-butyl [(4R, 6R)-6-(2-aminoethyl)-2,2-dimethyl-1, 3-dioxan-4-yl] Acetate (Amino Compound) 34 2,8-Diazabicyclo [4,3,0] nonane (Moxifloxacin Side Chain) 35 3-(2-Chlorophenyl)-5-Methyl Isoxazole-4-Carbonyl Chloride (CMIC CHLORIDE) 36 3-(2-Chloro-6-Fluorophenyl)-5-Methyl Isoxazole-4-Carbonyl Chloride (FCMIC Chloride) 37 2-Amino-4-thiazolyl-2-carboxylmethoxy methoxyimino mercaptobenzo thiazol carboxylate (MICA ESTER) 38 Erythromycin, 6-0-Methyl-2, 4-Bis-0-(Trimethylsilyl),9-[0-(1-Ethoxy-1-Methylethyl) Oxime] 39 D,D, Aza Erythromycin 40 Tributyl Ortho Valerate 41 Trimethyl Ortho Valerate 42 2 Mercapto - 5 - Methoxy Benzimidazole 43 Piperazine anhydrous 44 N-Methyl Piperazine 45 2-Cyanopyrazine 46 (S)-Isopropyl 2((S)-2-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl-4-fluoro-3-benzoyl-4-ethyltetrahydrofuran-2-	

				yl)(methoxy)(phenoxy)-phosphorylamino)propanoate 47 2'R)-2'-Deoxy-2'-fluoro-2'-methyluridine 48 N-[(S)-(2,3,4,5,6-Pentafluorophenoxy)phenoxyphosphinyl]-L-alanine 1- Methylethyl ester 49 Ter-Butyl Magnesium Chloride 50 Methyl Tertiary Butyl Ether (MTBE) 51 Pivaloyl Chloride 52 Sodium-2-Ethyl Hexanoate 53 Sodium Acetate Anhydrous 54 Methyl Chloroformate (MCF) 55 Ethyl Chloroformate (ECF) 56 Ethyl Acetoacetate 57 Trimethyl Chlorosilane (TMCS) 58 Hexamethyl disilazane (HMDS) 59 Industrial Methylated Spirit / Denatured Spirit 60 Ortho Phosphoric Acid 61 Sodium Hydroxide Flakes 62 Potassium Hydroxide 63 Megnesium Chloride 64 Cuprous Chloride 65 Sodium Hydro Sulphite 66 Sodium Bisulphite 67 Sodium Sulphate Anhydrous	

				68 Potassium carbonate 69 Sodium Dichromate (anhydrous) 70 Hydrogen Peroxide 71 n-Hexane 72 Cyclohexane 73 Butylated hydroxy Toluene 74 Methylene Chloride (MC) 75 Methane Sulphonic Acid 76 P-Toluene Sulfonic Acid (PTSA) 77 Methane Sulfonyl Chloride 78 Methanol 79 Isopropyl Alcohol (IPA) 80 n-butanol 81 Titanium Isopropoxide 82 Beta Naphthol 83 Di Isopropyl Ethyl Amine 84 Di Isopropyl Ether 85 Cumine Hydrogen peroxide 86 Formaldehyde 87 Methyl Isobutyl Ketone (MiBK) 88 Formic Acid 89 Acetic Acid (Glacial) 90 Calcium Acetate 91 Ethyl Acetate 92 Pivalic Acid 93 2-Chlorobenzoic Acid 94 Benzoyl Chloride 95 D-(-) Diethyl Tartrate	

				96 Diethyl Amine [DEA] 97 Triethylamine (TEA) 98 Disodium Edetate (EDTA-Na) 99 Ethylenediaminetetra-acetic acid Sodium Salt (EDTA-Na) 100 N,N-Dimethyl Aniline 101 Process Water 102 Water for Injection (WFI) 103 N.N Dimethyl Formamide [DMF] 104 N.N Di methyl acetamide [DMAc] 105 2-[2-(4-fluoro-phenyl)-2-Oxo-1-phenyl ethyl] 4-methyl-3-Oxo-perntanoic Acid phenyl Amide (Diketone) 106 L-Arginine Sterile 107 Acetonitrile 108 Dimethyl Sulfoxide (DMSO) 109 Benzene sulphonic acid 110 n-Butyl Lithium 111 Tetra Hydro Furan 112 Imidazole 113 Pyridine 114 N-Methyl Morpholine 115 Activated Carbon 116 Celite / Hyflo / Filter Aid 117 Ammonium Molybdate 118 Sodium Carbonate / Soda Ash 119 Sodium Sulphate	

				120 Sodium Bicarbonate 121 Sodium Hydroxide (Flakes) 122 Ammonium Hydroxide 123 Hydrochloric Acid 124 Sulphuric Acid 125 Phosphorous PentaChloride 126 Sodium Metabisulphite 127 Sodium Chloride 128 Sacchrose 129 Corn starch 130 Glucose 131 Hydroxypropyl Methyl Cellulose 132 Lactose 133 Disodium Hydrogen Phosphate Dihydrate 134 Hydroxypropyl Methyl Phthalate 135 Diethyl Phthalate 136 Sodium Acetate Trihydrate 137 Pyridine Hydro Bromide 138 Sodium Iodide 139 Sodium Hydroxide Lye 140 Diammonium Hydrogen Phosphate 141 Ammonium Dihydrogen Otrtho phosphate 142 Boric Acid 143 Diphenylmethyl (6R,7R)-7-amino-3-Carbonoyloxymethylceph-3-em-4-carboxylate Toluene-p-sulfonic	

				Acid Salt (MDCC) 144 7-[[2-furanyl(sinmethyoxyimino)acetyl]amino]-3-hydroxymethyl ceph-3-em-4-carboxyclic Acid 145 Methoxamine HCl 146 Sin-Methoxyimino Furanyl Acetic Acid Ammonium Salt (SMIA) 147 1-H-tetrazole-1-acetic acid [TAA] 148 2-Methyl-5-Mercepto-1,3,4-thaizole [MMTD] 149 7-amino-3-(1-methyl-1H-tetrazol-5-yl)thiomethyl-3-cephem-4-carboxylic acid (7-TMCA) 150 -{[4-ethyl-2,3-dioxo-1-piperazinyl)Carbonyl]amino}-4-hydroxy-benzene acetic acid [HO-EPCP] 151 N, O-bistrimethyl silylacetamide (N,OBSA) 152 2-Mercaptobenzothiazolyl (Z)-2-(2-Aminothiazole-4-yl)-2-(Tert-Butoxycarbonyl)-Isopropoxyimino] Acetate (TAEM) 153 (Z)-2-(2-Aminothiazole-4-yl)-2-(Tert-Butoxycarbonyl)-Isopropoxyimino Acetic Acid (ATIBAA or ATBA) 154 Diphenylmethyl (6R,7R)-7-	

				amino-3-Carbonoyloxymethylceph-3-em-4-carboxylate Toluene-p-sulfonic Acid Salt (MDCC) 155 Chloro Sulfonyl isocynate (CSI) 156 n- Heptane 157 L-hydroxy propyl cellulose 158 Sodium Lauryl Sulphate 159 Kyron 160 Acetone 161 Toluene 162 Mercaptomethyl Cyclopropane Acetonitrile <u>Packing Materials</u> 1 Anodized aluminium bottle 2 Rubber plug tear off seal 3 Closing lid	

3.	M/s ZafaChemie, Raiwind Manga Bypass, MouzaBahikot, Distt: Lahore. DML No. 000589 by way of Basic Manufacturer Inspected on	1. Prof. Dr. Muhammad Saeed, Member CLB 2. Dr. IkramulHaq, Member CLB 3. Syed Muied Ahmed, Member CLB. 4. Syed JavedYousaf Bukhari, Member	1 Amoxicillin Trihydrate 2 Ampicillin Trihydrate 3 Cloxacillin Sodium 4 Ciprofloxacin HCl 5 Norfloxacin 6 Sulfamethoxazole 7 Paracetamol 8 Pyrazinamide 9 Ibuprofen 10 Amlodipine	1 n-Butanol / n-Butyl Alcohol 2 Piperazine Anhydrous 3 Glacial Acetic Acid 4 Activated Carbon 5 Quinolonic Acid (Q-Acid) / 7-Chloro-1-cyclopropyl-6-fluoro-1,4-oxo-dihydroxo-3-Quinoline Carboxylic Acid 6 Methanol / Methyl Alcohol 7 Ammonia Solution	The individual process flow chart diagram of each API along with list of starting/raw materials duly endorsed by firm's representatives and panel members is annexed with the report.

	04-06-2016	CLB. 5. Mrs. MajidaMujahid, FID DRAP Lahore.	Besylate 11 Alendronate Sodium	(Ammonium Hydroxide) 8 Dimethyl Sulphoxide (DMSO) 9 Ethylene Diamine Tetra Acetic Acid (EDTA) 10 D(-) Alpha Para Hydroxy Phenyl Glycine Dane Salt (PHPG Dane Salt) 11 Isopropyl Alcohol (IPA) 12 Methylene Chloride 13 Pyridine 14 Pivaloyl Chloride 15 6-Amino Penicillanic Acid (6-APA) 16 Triethyl Amine (TEA) 17 2- Ethyl Hexanonic Acid (2-EHA) 18 Dimethyl Acetamide (DMAC) 19 D(-) Alpha Phenyl Glycine Dane Salt (PG Dane salt) 20 4N-Acetyl Sulfamethoxazole / 4-(N- acetyl)Amino-N-(5-methyl-3-isozolyl Benzene Sulfonamide) 21 Sodium Hydroxide 22 Sodium Hydrosulphite (Hydrose) 23 Para Amino Phenol (PAP) / 4-Aminophenol 24 2-Cyanopyrazine (2-CPZ) 25 Sodium Dichromate 26 n-Hexane 27 Isobutyl Phenyl Propanaldehyde /	

				2-(4-Isobutylphenyl)Propionaldehyde 28 CMIC Chloride / 3-(2-chloro phenyl)-5-Methylisoxazole-4-carbonyl Chloride 29 Sodium Chloride 30 Sodium Bicarbonate 31 Ethyl Acetate 32 Sodium Ethyl Hexanoate 33 Benzene or Toluene 34 Nor Acid / 1-Ethyl-6 Fluoro-7-chloro-4-oxo-1,4 Dihydro-3-Quinolinecarboxylic Acid) 35 Benzene Sulphonic Acid 36 Gamma Amino Butyric Acid(GABA) 37 Phosphorous Acid 38 Phosphorus Trichloride 39 Amlodipine Base 40 Industrial Methylated Spirit 41 Acetone 42 Hydrochloric Acid 43 Sulphuric Acid 44 Ethyl Alcohol / Ethanol 45 Purified Water 46 Liquid Nitrogen	

4.	M/s Zenith Chemical Industries (Pvt) Ltd., Lahore.DML No 000733 by way of Semi Basic Manufacture Inspected on **03-06-2016**	1. Prof. Dr. Muhammad Saeed, Member CLB 2. Dr. IkramulHaq, Member CLB 3. Syed Muied Ahmed, Member CLB. 4. Syed JavedYousaf Bukhari, Member CLB. 5. Mr. AjmalSohail Asif, FID DRAP Lahore.	1. Paracetamol 2. Ibuprofen 3. Cetrizine Dihydrochaloride 4. Montelukast Sodium 5. Ciprofloxacin Hydrochloride 6. Ofloxacin 7. Levofloxacin Hemihydrate 8. Moxifloxacin Hydrochloride	1. Para Amino Phenol 2. Glacial Acetic Acid 3. Activated Carbon 4. Sodium Hydrosulphite 5. 2-(4-Isobutylpheny)Propionic acid crude 6. Methanol 7.7-Chloro-1-Cyclopropyl-6-Fluoro-1,4-Dihydro-4-Oxoquinoline-3-Carboxylic Acid (Cipro Q Acid) 8. Piperazine anhydrous 9. N-Butanol 10 Aluminium Chaloride 11. Ethylenediaminetetraceta te 12 Dimethyl Sulfoxide 13. Hydrochloric acid 14. Sodium Hydroxide 15. (S)-(-)-9 floro-2,3 Dihydro-3-Methyl-10-(4-Methyl-1-piperazinyl)-7-oxo-7H-Pyrido(1,2,3-de)-1,4-Benzoxzine-6-carboxylic acid hemihydrates Crude 16. 9,10-Difluoro-2,3-Dihydro-3-Methyl-7-Oxo-7H-Pyrido[1,2,3-de]-1,4-Benzoxazine-6-Carboxylic Acid	The individual process flow chart diagram of each API along with list of starting/raw materials duly endorsed by firm's representatives and panel members is annexed with the report.

				Crude 17. 1-methylpiperazine 18 1- cyclopropyl-6,7-difloro-8-methaxy-4-oxo1,4-dihydro-3-quinoline carboxylic acid(Boric Coordination Complex) 19. (s,s)-2-8-diazabicyclo-(4,3,0)-nonane 20. Acetonitrile 21. Triethylamine 22. Racemic-2-{4(4-chlorophenyl)Phenyl methyl}-1-piperazine Ethanol 23. Potassium Hydroxide 24. N,N-Dimethylformamide 25. Sodium Monochloroacetate 26. 1-[1-[[[(1R)-1-[3-(1E)-2(-7-chloro-2-quinoliyl]phenyl]-3-[2(1-hydroxyl-1-methylethyl)phenyl}propyl]thio methyl}cyclopropane acetic acid(montelukast acid pure) 27 n-Heptane 28. Liquid Nitrogen 29. Purified water	

5.	M/s Citi Pharma (Pvt) Ltd, 3-KM Head Baloki Road, Phool Nagar Kasur. DML No. 000429 by way of Semi Basic Manufacture Inspected on **01-06-2016**	1. Prof. Dr. Muhammad Saeed, Member CLB 2. Dr. IkramulHaq, Member CLB 3. Syed Muied Ahmed, Member CLB. 4. Syed JavedYousaf Bukhari, Member CLB. 5. Mr. Abdul Rashid Shaikh, FID DRAP Lahore.	1. Aspirin 2. Paracetamol 3. Norfloxacin 4. Ciprofloxacin HCl 5. Levofloxacin Hemihydrate 6. Ibuprofen 7. Amoxicillin 8. Ampicillin	1. Para Amino Phenol 2. Glacial Acetic Acid 3. Activated Carbon 4. Sodium Hydrosulphite 5. 7-Chloro-1-Cyclopropyl-6-Fluoro-1,4-Dihydro-4-Oxoquinoline-3-Carboxylic Acid (Cipro Q Acid) 6. N-Butanol 7. Piperazine anhydrous 8. Hydrochloric acid 9. Methanol 10. Disodium Edetate (EDTA) 11. Dimethyl Sulfoxide (DMSO) 12. SODIUM HYDROOXIDE (NaOH) 13. Para Hydroxy Phenyl Glycine (Dane Salt) 14. 6-Aminopenicillanic Acid (6APA) 15 Methylene Chloride 16 Pivaloyl Chloride 17 2-Ethylhexanoic Acid 18 Pyridine	The individual process flow chart diagram of each API along with list of starting/raw materials duly endorsed by firm's representatives and panel members is annexed with the report.

				19 Triethylamine 20 Isopropyl Alcohol 21 Dimethylacetamide 22 Ammonium Hydroxide 25% (Ammonia Liquor) 23 (S)-(-)-9,10-Difluoro-2,3-Dihydro-3-Methyl-7-Oxo-7h-Pyrido[1,2,3-De]-1,4-Benzoxazine-6-Carboxylic Acid (Levo Q Acid) 24 1-Ethyl-6-Fluoro-4-Oxo-1-Yl-1h-Quinoline-3-Carboxylic Acid (Nor-Acid) 25 N-Methyl Piperazine 26 Alpha Phenyle Glycine (Dane Salt) 27 Iso Butyl Phenyl Propionaldehyde 28 Sodium Dichromate (Anhdrous) 29 Sulphuric Acid 30 N-Hexane 31 Salicylic Acid Sublimed 32 Acetic Anhydride 33 Acetone 34 Liquid Nitrogen **Packaging Material.** 35 Corrugated Shippers 36 Corrugated kegs 37 PVC Drum 38 Food Grade	

				Polyethylene bags 39 Printed PVC Tape 40 Cable Ties	

Proceedings of the Board:

The Board appreciated the efforts done by panel. Prof. Dr. Muhammad Saeed further emphasized the efforts rendered by Dr. IkramulHaq member of the panel.

Decision of CLB in its 247th meeting :

The Board appraised the matter and deferred till next meeting for comprehensive presentation of the case.

Proceeding of 250th meeting of Central Licensing Board

Case is brought before the Board for its consideration. The Board appreciated efforts of the members of the panel for their valuable input.

DECISION.

The Central Licensing Board deliberated and decided that :

i. Report of the panel consisting of consolidated list of APIs approved for manufacture by the firm / company , consolidated list of chemicals used for manufacture of APIs, individual APIs alongwith chemicals used for manufacture of particular API and flow charts of manufacture of APIs shall be endorsed as such and forwarded to the Licensing Authority under the Drugs (Import and Export) Rules, 1976.

ii. The Board also decided that following panel of inspectors/ experts shall inspect the facility of pharmaceutical units manufacturing APIs as mentioned above for the purpose of determination of quantity of chemicals/reagents to be used for manufacture of each API and submit its reports with clear and candid recommendations for consideration of the Board.

1. Dr. Ikram-ul-Haq, Member CLB
2. Syed Muid Ahmed, Member CLB
3. Syed JavedYousuf Bukhari, Member CLB
4. Area FID, DRAP, Lahore
5. Dr. Akbar Ali, Assistant Director (Lic), DRAP, Islamabad.

QUALITY ASSURANCE CASES (GMP NON-COMPLIANCE)

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

Case No. i: - M/S PARADISE PHARMA, LAHORE

Background of the case

Mrs. Aisha Irfan, FID Lahore conducted inspection of the firm M/s Paradise Pharma on 13.08.2015. The FID noticed a number of critical observations/ violations in all the production areas. Accordingly an explanation letter was served to the firm on 08.09.2015 with the direction to submit reply within 07 days. The firm failed to submit reply of explanation letter. On 27.06.2016, the FID re-inspected the firm and submitted report in tabulated form identifying previous observation and current status, which are as under:-

Inspection conducted on 13.08.2015	**Inspection conducted on 27.06.2016**
Premises **Entries** Executive / worker's entries provided. However, implementation of changing SOPs was not being done. Workers were seen without uniform/factory shoes.	**Premises** **Entries** Same as before
Storage Area In the de-dusting area empty glycerin bottles were seen, necessary equipments not provided. The rejection area not under lock and key. Empty cartons were stored in the rejection area. No store In-charge was present. Temperature / humidity not being monitored and maintained. In quarantine release material stored. Weighing balance outside dispensing hood.	**Storage Area** Empty bottles were stored in de-dusting are as was observed before. No equipment for de-dusting available. In the Quarantine area, temperature/humidity was not being regulated and monitored. No air conditioner installed. Quarantine labels were not pasted on materials. Flow of air in dispensing hood was not proper. Calibration of weighing balance required.
Finished Goods Store Finished goods store was congested. Temperature / humidity not maintained.	**Finished Goods Store** The Finished goods store was very congested, the cartons were store in front of Air conditioner and it was turned off. The temperature was almost 35^{o}C. The door of finished goods store was wide opened; no air curtain installed and workers were seen shifting the Temperature / humidity not maintained.
Packaging Material Store Separate store has been provided however the condition needs improvements.	**Packaging Material Store** Same as before.
Production Area: **Oral Liquid Section**	**Production Area:** **Oral Liquid Section**

No production was in process, as there was same fault in RO water treatment plant	No separate area for de-cartoning was available. The bottles were de-cartoning in corridor and empty dirty shippers were seen in corridors, contaminating whole area. Bottle blowing area was also used for de-cartoning. The firm was advised to develop cleaning / validation SOPs of water Treatment plant.
Liquid Re-packing Section HVAC system non-functional	**Liquid Re-packing Section** Same as before.
Sachet Section Sachet machine dismantled. No production in process.	**Sachet Section** Same as before.
External Preparation Section Povidone Iodine was in one of the mixing tank. The firm has purchase new automatic filling machine was under installation.	**External Preparation Section** Povidone Iodine was manufactured and was stored in a tank for the last 07 days. No concept of in-process quarantine prevailed. In-process quarantine room was not available.
Quality Control HPLC out of order. FTIR not purchased. QC equipment not calibrated. Digital polarimeter and viscometer required. No improvement seen in QC.	**Quality Control** Quality control was not upgraded as advised before. HPLC was not calibrated. FTIR, Digital Polarimeter, KARL Fisher, Viscometer were not purchased.
Quality Assurance Same as before. The quality assurance department was not established as asked before	**Quality Assurance** The quality assurance department was not developed.
Sanitation/hygiene Needs improvement.	**Sanitation/hygiene** Needs improvement. Safety measures such as fire alarm, smoke detector, proper emergency exit were also required.
The FID further concluded that Overall the same situation prevails as observed in last inspection. No improvements seen. The firm was asked to submit compliance report within one month.	**The FID further concluded that** In view of above findings, it was noticed that the firm has not done improvements as advised, in the last two GMP inspection, same shortcomings in manufacturing areas and quality control were seen. It appears that the firm is habitual and exhibits non-serious behavior towards GMP.

Action Taken by DRAP:- Accordingly, a show cause notice and suspension of production order was served to the firm on 06.09.2016.

Reply of the firm: - The firm vide letter No. Ref: 101/2016-DRAP dated 01.10.2016 submitted detailed reply of showcause notice and informed that all observations noticed by FID have been rectified. The firm requested to give a chance for personnel hearing before the Board.

Proceedings of the 250th Meeting of CLB

Mr. Muhammad Shahzad Khan, Managing Partner of the firm M/s Paradise Pharma, Lahore appeared before the Board for personal hearing. He informed the Board the HVAC is operational, which may be verified any time. He further added that the firm is involved in the manufacturing of re-packing and have only oral liquid section. The observations noted during the inspection of the firm by the FID are given due attention and have been rectified.

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, 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:-

    i. Dr. Ikram ul Haq, Member CLB.
    ii. Mr. Ajmal Sohail Asif, FID, Lahore.
    iii. Mrs. Aisha Irfan, 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.

iii. Production of the firm shall remain suspended till further orders.

Item No. II (Misc. Cases)
Case No. i:- Recommendations for Cancellation / Suspension of Drug Manufacturing Licenses of Pharmaceutical Manufacturing Units.

Background of the case

Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab informed that teams of experts/Drug Inspectors conducted GMP inspections of various pharmaceutical manufacturing units and reported the violations found there by Provincial Quality Control Board, Punjab. He added that the Board after due deliberations recommended cancellation/suspension of Drug Manufacturing Licenses of the firms who were involved in violations of Good Manufacturing Practices (GMP), conditions of license and were involved in manufacturing / selling of substandard drugs. Mr. Abid Saeed Baig further requested to look into the matter and direct the concerned authority to take action in the best interest to curve the menace of spurious and substandard drugs. The case was placed before the CLB in its 249th meeting held on 29.08.2016.

The following firms approach the Lahore High Court, Lahore against decision and got stay order in this regard:-

Sr. No.	Name of the firm	WP No. and Date
1.	Aneeb Pharma	26761-16 dated 27.08.2016
2.	Orta Labs	26762-16 dated 27.08.2016
3.	M/s Sanna Labs, Faisalabad	24578-16 dated 25.07.2016
4.	M/s B.J Pharma, Lahore	26879-16 dated 29.08.2016
5.	M/s Axis Pharma, Faisalabad	26741-16 dated 25.08.2016

However, office of the Director (QA&LT) received stay order on 05.09.2016 from M/s Perfect Pharma, Lahore vide writ petition No. 26506-16 dated 29.08.2016. Keeping in view order of the Honorable Judge, Lahore High Court, Lahore the action could not initiated against the firm.

As per decision of CLB in its 249th meeting following cases were referred to the Secretary, Provincial Quality Control Board, Punjab vide letter dated 03.10.2016, for clarification, as per decision. The reply is still awaited.

i. M/s Lahore Chemical and Pharmaceuticals Works, Lahore
ii. M/s Drug Pharm, Lahore

The Board decided to issue a showcause notice to the firm M/s Redex Pharma, Faisalabad and M/s Mediways Pharma, Lahore on illegal/unauthorized production activities and disobeying the orders of DRAP.

Decision of 250th Meeting of CLB

The Board acceded the decision taken by QA&LT Division with reference to orders of the Lahore High Court, Lahore in respect of the firm M/s Perfect Pharma, Lahore.

Details of the cases are as below:-

Case No. 1: - M/s Redex Pharmaceuticals, Faisalabad

Background of the case

Mr. Ajmal Sohail Asif, FID Lahore conducted inspection of the company on 14.05.2015 to verify GMP compliance and production activities. Following critical observations were noticed by the FID:-

i) The firm has two premises, one having DML and other adjacent (attached) to licensed premises, unlicensed purported for manufacturing of neutraceuticals / herbal products.

Licensed Premises

ii) The licensed premises was found non functional and all manufacturing sections were found closed except oral liquid section (human) where some bottles were placed on filling / packing table and in finish good some products were found.

iii) General cleanliness, sanitation / hygienic conditions, temperature and humidity control were not maintained and unsatisfactory.

iv) The FID directed the firm to stop manufacturing / production immediately as the GMP and licensing requirements were not maintained.

Unlicensed Premises

v) In unlicensed premises various facilities for manufacturing for **herbal** and **registered** products were found including labels, unit cartons, aluminum foils of different pharmaceutical products alongwith various herbal products.

vi) In unlicensed area varied quantity of products such as Felrosol suspension and Broncho MED syrup alongwith herbal products of tablets and syrups were placed.

vii) **Broncho MED syrup was being filled under a tree by workers** (male and female) who were busy in filling, labeling and packing activities under trees and inside the room.

viii) **The FID seized the material** (raw, packing, printed) and finish products along-with syrup filling machine and filled bottles under section 18(1) F of the Drugs Act, 1976 and Schedule V of DRAP Act, 2012. The FID seized and sealed all the material in the presence of Mr. Deedar Ali (Production In-charge)

ix) The FID has reported that **firm is involved in violation of the provisions of Drugs Act, 1976 and rules framed there under** as the firm is involved in the illegal/unauthorized manufacturing of its registered products at an unlicensed premises under extremely unhygienic conditions.

x) The FID emphasized that the firm is not only violating the provisions of the Drugs Act, 1976 but also **put the lives of innocent patients in danger**.

xi) The FID directed the management of the firm to stop all the operations in the licensed/unlicensed premises immediately.

Action Taken by DRAP:- After receiving inspection report, a show cause notice / stop production order in all sections was issued to the firm on 24.06.2015.

Reply of the firm:- In response of the show cause notice, the firm vide letter No. Nil dated 17.11.2015 informed that the FID has made the observation in the neutraceutical site, not in the human site because human site was closed at the time of inspection. The firm further requested for resumption of production.

Proceedings of the 245th Meeting of CLB held on 30.12.2015

The firm was given opportunity of personnel hearing before the Board. But no person appears before the board on behalf of firm. The Board shows displeasure on non serious attitude of the company.

Decision of the 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 decided to provide a last opportunity for personnel hearing and a final notice shall be served to the firm in the next meeting. In case of failure to appear before the Board in the forthcoming meeting, ex-parte decision shall be taken.

Proceedings of the 246th Meeting of CLB held on 22.02.2016

Mr. Ishfaq Ahmad, CEO of the firm M/s Redex Pharmaceuticals, Faisalabad appeared before the Board for personnel hearing. He informed that at the time of visit of FID on 14.05.2015, the factory was closed due to short-circuit of electricity; all the finished goods were shifted in the open area under a tree. On query raised by Director (QA&LT), the CEO of the firm informed that he is metric passed, Mr. Deedar Ali is production manager and Ms. Sadia Ashraf is QCM. He further informed that all the observations identified by FID during his inspection have been rectified and they are ready for inspection for verification of the improvement made by them.

Decision of the 246th Meeting of CLB held on 22.02.2016

After thorough discussion/deliberation, considering all the pros and cons of the case, keeping in view the available record and request from CEO of the firm M/s Redex Pharmaceuticals, Faisalabad, the Board decided to conduct panel cGMP inspection on approved format under Schedule B-II of Drugs (LR&A) Rules, 1976, by the following members:-

i. Prof. Dr. Saeed Member CLB
ii. Dr. Muid Ahmed, Member CLB
iii. Mr. Ajmal Sohail Asif, FID, Lahore

The production will remain stop till recommendation by the panel for resumption of production and accordingly approval from the Board.

The decision was conveyed to the firm on 05.04.2016

Panel inspection report is still awaited
Updated status:-

Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab informed that Mr. Mohsin Asghar, Drug Inspector, Madina Town, Faisalabad with other members inspected the premises on 17.05.2016. The team observed that re-packing of drugs was carrying out in non-approved and unhygienic rooms situated at the roof of the plant / manufacturing unit which were under maintenance and construction work was being done. The Secretary, PQCB, Punjab informed that the firm was found involved in:-

i. Violation of condition of license (DML).
ii. Violation of cGMP.
iii. Manufacturing of drugs in the absence of qualified persons (production In-charge and QC In-charge)

iv. Printing false manufacturing and expiry date on labels of drugs being manufactured.

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 14.05.2015. The firm was issued showcause notice / Suspension of production order on 24.06.2015. The case was discussed in 246th Meeting of CLB, wherein the CLB had constituted following panel of experts to verify the improvements made by the firm:-

a. Prof. Dr. Saeed.
b. Dr. Moid Ahmed.
c. Mr. Ajmal Sohail Asif

Inspection report of the firm is still awaited. The Board also discussed and evaluated the report of provincial drug inspector, Madina Town, Faisalabad, which categorically stated that *"On 17.05.2016, during inspection the committee observed that re-packingof the drugs were carrying out in non approved and un-hygienic rooms situated on the roof of the plant/manufacturing unit which was under maintenance and construction work was being done at the time of the 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, the Board considered the recommendations of the Secretary, PQCB, Punjab and took a serious notice on violation of the orders of the DRAP letter dated 24.06.2015. The Board decided to issue a showcause notice to the firm M/s Redex Pharma, Faisalabad 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

Khwaja Tahir Mahmood, Legal Counsel and Mr. Ashfaq Ahmad, Chief Executive of the firm M/s Redex Pharma, Faisalabad appeared before the Board for personal hearing. Khwaja Tahir Mahmood informed the Board that we own the observations noted by the FID during his inspection conducted on 14.05.2015. There was no production activity in the firm as mentioned by the Provincial Government. He added that the construction work was being carried out at the time of the inspection. Khwaja Tahir Mahmood and Mr. Ashfaq Ahmad gave undertaking before the CLB, which is reproduced as under:-

"The company want to shift its pharmaceutical unit from existing premises to some new place appropriate for production in accordance with cGMP. The shifting from old to new premises will be in phases.

i. Phase-I is purchase of suitable land 03 to 06 months.

ii. Shifting will be done in accordance with DRAP Act, 2012 and rules framed there under as advised by the CLB.

iii. The company will not conduct any production at old existing pharmaceutical unit."

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, undertaking of the Khwaja Tahir Mahmood, Legal Counsel and Mr. Ashfaq Ahmad, Chief Executive of the firm, the Board decided to:-

i. Suspend the production activities of the firm till shifting to the new facility subject to fulfillment of codal formalities.

ii. Resumption of production activities shall be allowed on the new facility, as requested by the firm, after fulfillment of codal formalities including approval of site verification, approval of layout plan, panel inspection and subsequent approval from the Licensing Division.

Case No. 2:- 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 of the 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. Zaka ur Rehman, Member, CLB
iii. Mr. Ajmal Sohail Asif, Area FID.

The decision was conveyed to the firm on 10.02.2016

Panel inspection report is still awaited

Updated Status:-

Mr. Abid Saeed Baig, Secretary, Provincial Quality Control Board, Punjab informed that Deputy Drug Controller Allama Iqbal Town Lahore aongwith 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. 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. Zaka ur 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, thorough verification by the panel of experts regarding improvements made by the firm in the light of cGMP and subsequent approval from the Competent Authority.

DE-SEALING OF PREMISES

Case No. i:- **M/S MEDICURE LABORATORIES, F-109, HUB RIVER ROAD, S.I.T.E., KARACHI**

Background of the case

Mrs. Muneeza Khan, Area FID and Mrs. Umm-e-Laila, ADC, DRAP, Karachi conducted inspection of company on 14.07.2016 to verify the GMP compliance and production activities. The panel noticed number of major and critical observations, which needs urgent attention and rectification. The observations include:-

i) In last GMP inspection the firm had undertaken to overcome most critical observations within next six months and till that their production activities would remain suspended. But instead of overcoming all that observations of last inspection there noticed active production in liquid syrup, tablet and in rests of the manufacturing areas during this inspection under same unsanitary and unhygienic conditions without the active supervision of senior in-charge pharmacist. Not only were this, lot of other critical non-compliances also observed.

ii) During the course of inspection a huge No. of major and minor non-GMP compliances and contraventions to the Drug Act, 1976 were observed in all areas from storage (Raw, Packing and Finished Store)

iii) Severe poor and dirty, unhygienic condition found in all areas.

iv) No HVAC, Air conditioning present in the factory.

v) Expired chemicals being used with no labeling.

vi) No validation, no calibration, no dispensing booth, no area monitoring, no SOPs found.

vii) No documentation present.

viii) 5 workers found in production in street clothes and shoes engaged in coating process.

ix) No qualified staff present in the factory.

x) The FID recommended to lock / seal M/s Medicure Laboratories, Hub River Road, S.I.T.E., Karachi under section 18 (1) (h) till further instructions by the DRAP, Islamabad.

Premises:

xi) All the areas were seen not in accordance with the GMP provisions as flow of materials and workers not identified and even not followed and ultimately creating risks for the final products and workers as well.

xii) The firm was keeping all the raw materials / packaging material in two rooms and in corridors in front of QC lab which is not the designated area as per their stores. No air conditioning was provided in sores to maintain the required temperature. All raw materials were found in open paper bags and containers without proper labeling and status tags. No documentation found in stores. All materials were mixed and no segregation was found. Area was found full of dust and unhygienic poor material

handling observed. No dispensing booth present. GSP guidelines are not followed in spirit.

Production Areas:

xiii) During the inspection in the manufacturing areas some male workers were engaged in the tablet coating process in street clothes and street shoes. There was not concept of clean clothes and clean shoes for production area. No change room with amenities found. All the production was controlled by these workers under the supervision of only technical persons present during the inspection.

xiv) All of the production areas found extremely dirty and under unhygienic poor conditions with unclean dirty rusted broken equipments and machinery. Floors were found wet and very dirty.

xv) Rests of the critical non-compliances are as follows:-

a. There is no HVAC or air conditioning in the whole factory.
b. No validation or calibration performed.
c. No documentation, no SOPs in place or followed.
d. No QC testes or procedures performed.
e. No area monitoring or scientific risk management in place observed.
f. In short the firm has no proper QA system in place and none of technical person for QA was there.

Quality Control:

xvi) Base line equipments were not in place required for testing of their registered products and even calibration records of some equipment kept in lab, was not found.

xvii) No testing process was seen at the time of inspection. No log books, no documentation and record keeping were found.

xviii) All equipments were broken down and found non operation.

xix) Very unhygienic and poor house-keeping observed in QC.

xx) A well established and qualified lab at the premises is not provided.

xxi) A complete QC failure was noticed.

Sanitation and Hygiene:

xxii) Extremely poor sanitary conditions and house-keeping was observed in the whole factory. No proper change rooms, lack of the essential amenities and necessary buffer and air locks do not exist. HVAC facility installed in the whole factory. Workers were not provided any sort of training on GMP issues; cleanliness was not up to the mark. Overall facilities did not have efficiency to control contamination and cross contamination.

Personnel

xxiii) The personnel met during the visit showed very casual behavior to the GMP issues. They were not seemed to have aware of any GMP guidelines. Qualified and experienced staff and more training is requi red on risk based GMP issues so that system can be improved. Organization chart should be re-organized; persons should be given duties in writing. Overall they need professionally qualified and experienced persons for better GMP compliance.

Training

xxiv) Training of staff, records and documentation found insufficient. It was advised to conduct regular training of staff, maintain the training material and manuals available to the staff.

The FID further concluded that

xxv) Based on the areas inspected, the people met and the documents reviewed, and finding of the inspection that is a number of critical and major contraventions of GMP guidelines. Under the explained circumstances M/s Medicure Laboratories, Karachi may not be allowed to manufacture and based on the above critical observations the undersigned has left no option except to lock and seal the whole premises under section 18 (1) (h) of Drugs Act, 1976 because there was chance of manipulation and un-authorize manufacturing.

xxvi) The FID recommended for cancelation of DML of the firm in larger public interest based on the historic evidences.

Action Taken by DRAP:- Accordingly, a show cause notice & suspension of production order was served to the firm for above mentioned violations on 25.07.2016.

Reply of the firm:- The firm vide letter No. Nil dated 30.07.2016 informed that they may be given 03 months time to further upgrade. Moreover he requested to appear before the CLB for personnel hearing.

Proceedings of the 249th Meeting of CLB

Mr. Shah Meer Hussain, Managing Director and Mr. Haider Ali, Managing Partner of the firm M/s Medicure Labs, Karachi appeared before the Board for personal hearing. Mr. Shah Meer Hussain denied the observations noted by the FID. He added that HVAC is installed in the firm. The unit was closed due to the Eid holidays. At the time of the inspection, it was first working day after eid holidays and no production activities were in process. The workers were cleaning the equipments / premises before commencement of production. Mr. Shah Meer Hussain requested to grant him a suitable time for the renovation of the firm.

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, non-serious attitude of the firm, recommendations of the FID to cancel DML of the firm and request of Mr. Shahmeer Hussain to gave them a suitable time for renovation of the firm, the Board decided to suspend the Drug Manufacturing License of the firm M/s Medicure Labs, Karachi for a period of six months, under Section 41 of the Drugs Act, 1976 and Rule 12 (1) of the Drugs (L,R&A) Rules, 1976."

The Decision of the CLB was conveyed to the firm on 03.10.2016.

Present Status

The firm M/s Medicure Laboratories, Hub River Road, S.I.T.E., Karachi vide letter dated 13.10.2016 requested for de-sealing of the premises for the purpose of renovation, up-gradation and proper

installation of HVAC system. As the firm was sealed by the FID under section 18 (1) (h) of the Drugs Act, 1976.

The case was taken up by this section. However, The Additional Director (QA&LT) opined to place the case in the Central Licensing Board.

Proceedings of the 250th Meeting of CLB

The case was placed before the Board on the request of the firm regarding the de-sealing of the premises, in order to carry out the improvements and installation of HVAC, as suggested by the FID. The Board went through the provision of Section 18 (1) (h) of the Drugs Act, 1976 as well as Rule 8 of the Drugs (LR&A) Rules, 1976.

Decision of the 250th Meeting of CLB

After thorough discussion/deliberations, considering all the pros and cons of the case, keeping in view the request of the firm, the Board acceded the request of the firm for the de-sealing of the premises to carry out the improvements and decided to:-

i. Direct the area FID to de-Seal the premises on de-sealing memo, to carry out the improvements

ii. The FID will submit report of upgradation / improvements made by the firm on the monthly basis.

iii. The license shall remain suspended till completion of the suspension of DML till further orders.

Quality Control Cases

Deferred Cases

Subject: - **Manufacturing and Sale of Unregistered Drug Product-PregEase Tablets Batch No.15021 by M/s Zestech Sciences, Karachi for ICI Pakistan, Karachi *F. No. 4-07/2015- (QC)***

The FID-II, Karachi Mrs. Muneeza Khan inspected the premises of M/s ICI Pakistan Limited 5- West Wharf Road Karachi on 19-03-2015 and took the sample of Tab Preg Ease Batch No.15021 manufactured by M/s Zestech Sciences Karachi. The sample was sent to the Federal Government Analyst, CDL Karachi for test/analysis purpose. However, the Federal Government Analyst, CDL, Karachi vide his test report No. KQ.102/2015 dated 13-05-2015 declared the said drug product preg-Ease tablets Batch No.15021 manufactured by M/s Zestech Sciences, Karachi for ICI Pakistan, Karachi as Un-registered drug product under the Drug Act, 1976.

The result of CDL test Report

Remarks:-

"The label of the sample claims "Natural Nutritional Supplement to help calm nausea & vomiting of pregnancy (NVP) vitamin B6 and calcium have been identified as allopathic ingredients. Hence, the sample is declared as un Registered Drug product under the Drug Act 1976"

2 The FID-II served the explanation letter on 26th May 2015 to the firm M/s ICI Pakistan Ltd Karachi and M/s Zestech Sciences Karachi to explain their position. In reply to the FID explanation M/s Zestech Sciences Karachi requested for Appellate testing of drug in question under the provision of Drugs Act 1976 on 30th June 2015. The sample was sent to the Appellate Laboratory NIH Islamabad. The Appellate Laboratory has also declared the sample of said drug product as of substandard quality vide its test report No. 027-

MNHRS/2015 dated 02nd November 2015 along with remarks mentioning the sample unregistered and unlicensed.

The result of Appellate Laboratory:-

Assay:-	**Stated**	**Found**	**Limit**	**Percentage**
Vitamin B6	2mg/tab	1.903mg/tab	90-110%	95.14%
Folic Acid	400mcg/tab	415.68mcg/tab	90-110%	103.92%
Calcium	124.1mg/tab	11.18mg/tab	90-110%	**9.018%**

Does not comply with manufacturer's specification.

The FID-II Karachi furnished the names of responsible accused persons in his report are as under:-

Mr. Ahsan Feroz Proprietor

Mr. Mumtaz Ali Khan Production Incharge

Mr. Ejaz Ahmad Paracha QC Manager

Recommendations of FID:-

"Based on the above submission and Lab reports it can easily be concluded that the drug Preg Ease tablets is un registered un-licensed and Sub-Standard product hence sheer violation of Section 23 &27 of Drugs Act 1976 by the manufacturer M/s Zestech Sciences Plot No. 47/23, Korangi Industrial area Karachi based on the violations committed by the firm it is concluded that the contents of case may be kept on the agenda of upcoming meeting of CLB for permission of prosecution against the firm or the contents may be sent to Director OTC & Herbal for his comments in the light of the SRO 412".

The show cause notices were issued to the above named accused persons offering them opportunity of personal hearing before the Central Licensing Board before its 249th meeting held on 29-08-2016. The Firm had submitted the reply of show cause notice. The case was accordingly placed before the CLB in its 249th meeting held 29th August 2016.

Decision of 249th meeting of CLB

The Board deferred the case due to paucity of time.

The said accused persons were called for personal hearing.

Proceedings:-

Mr. Ahson Feroze appeared before the Central Licensing Board in its 250th meeting held 27th October 2016 and pleaded their case and informed that he is the Managing Director of M/s Zestech Sciences Karachi and M/s Maple Pharmaceuticals Karachi. He was accompanied by Mr. Saeed Khan who informed that he looks the matters of Regulatory affairs of both firms M/s Maple Pharmaceuticals Karachi and M/s Zestech Sciences, Karachi. Mr. Ahson Feroze claimed that their firm (M/s Zestech Sciences Karachi) had not received the copy of test report of Appellate Lab NIH Islamabad and said that the FID had picked three products out of which two were cleared by CDL, Karachi. He informed that their firm has got the enlistment while products were applied to Division of Health & OTC, DRAP, Islamabad.

Decision:-

The Board after detailed discussion, deliberation and keeping in view the facts of the case the Board decided as under:-

1. **To direct the concerned FID Karachi, to re investigate the case by including M/s ICI, Karachi from where the samples were picked for test/analysis as the subject drugs were stocked for sale in the premises of M/s ICI Karachi. The Board directed the FID to submit the complete case after fulfilling codal formalities with provisions of law and along with clear and candid recommendations.**

2. **The Board directed the Quality Control Section to get the status of enlistment of the firm M/s Zestech Science Karachi and product (Tablet Preg Ease) from the Division of Health & OTC, DRAP, Islamabad along with the comments on both laboratories test reports**.

Case No.02

New Cases

(Standard Drug Company Hyderabad)

Case No.A

Manufacture & Sale of Substandard Drug-Netrozol Suspension Batch No.NZ.10A By M/S Standard Drug Company, Hyderabad.

The sample of Netrozol Suspension Batch No. NZ.10-A Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard vide CDL's vide test report No. R.KQ.41/2015 dated 03rd February 2015. The result of CDL on the basis of which sample under reference has been declared sub-standard as the basis of assay are reproduced as under:-

Assay for	Determined amount/5ml	Statedamount/5ml	Percentage
Metronidazole	**133.1469mg**	200.0**mg**	**66.57%**

Limits:- 95.0% to 105.0% **Does Not Comply**.

Remarks:- The sample is of **"Substandard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard vide their test report 010-MNHRS/2015 dated 29th May 2015 are reproduced as under:-.

Assay for	Stated	Found	Limits	Percentage
Metronidazole	**200mg/5ml**	**140mg/5ml**	**95-105%**	**70.0%**

Does not comply with BP-2011

Conclusion:- The sample is of "Substandard" **quality on the basis tests performed.**

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

. As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Netrozol Suspension Batch No.NZ.10A By M/S Standard Drug Company, Hyderabad.

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of **Netrozol Suspension Batch No. NZ 10-A** ***Reg. No. 057829 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as many samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad:***

Case No.b

Manufacture & Sale of Substandard Drug-Netrozol Suspension Batch No.NZ.08A By M/S Standard Drug Company, Hyderabad.

The sample of Netrozol Suspension Batch No. NZ.08-A Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard vide CDL's vide test report No. R.KQ.44/2015 dated 03rd February 2015. The result of CDL on the basis of which sample under reference has been declared sub-standard are reproduced as under:-

Assay for	Determined amount/5ml	Statedamount/5ml	Percentage
Metronidazole	**176.7244mg**	200.0**mg**	**88.38%**

Limits:- 95.0% to 105.0% **Does Not Comply**.

Remarks:- The sample is of **"Sub-Standard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard vide their test report 011-MNHRS/2015 dated 29th May 2015 are reproduce as under.

Assay for	Stated	Found	Limits	Percentage
Metronidazole	**200mg/5ml**	**169.408mg/5ml**	**95-105%**	**84.704%**

Does not comply with BP-2011

Conclusion:- The sample is of "Sub-Standard" **quality on the basis tests performed.**

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Netrozol Suspension Batch No.NZ.08A By M/S Standard Drug Company, Hyderabad.

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of **Netrozol Suspension** ***Batch No. 08-A Reg. No. 057829 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***

Case No.C

Manufacture & Sale of Substandard Drug-Staifaminc Suspension (Mefenamic Acid) Batch No.SF.07-A By M/S Standard Drug Company, Hyderabad

The sample of Staifaminc Suspension Batch No. SF.07-A.Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard on the basis of assay vide CDL's test report No. No. R.KQ.37/2015 dated 06th February 2015 by Federal Government Analyst, CDL, Karachi.

The result of CDL on the basis of which sample under reference has been declared sub-standard are reproduced as under:-

Assay for	Determined amount/5ml	Statedamount/5ml	Percentage
Mefenamic Acid	**21.69mg**	50.0**mg**	**43.38%**

Limits:- 90.0% to 110.0% **Does Not Comply**.

Remarks:- The sample is of **"Substandard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard on the basis of assay vide their test report 08-MNHRS/2015 dated 29th May 2015.

Assay for	Determined PH	Statedamount/5ml	Found	Percentage
Mefenamic Acid	**5.4**	50.0**mg**	18.742mg/5ml	**37.484%**

Limits:- 90.0% to 110.0% **Does Not Comply**.

Remarks:- The sample is of **"Sub-Standard"** quality under the Drug Act 1976.

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

Submitted for the consideration of the Board.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Drug-Staifaminc Suspension (Mefenamic Acid) Batch No.SF.07-A By M/S Standard Drug Company, Hyderabad

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:
"The Board decided to Cancel the registration of Staifaminc* Suspension *Reg. No. 057826 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad

Case No.D

Manufacture & Sale of Sub-Standard Drug- Linobex-C Syrup (Multivitamins) Batch No. LC.09-A By M/S Standard Drug Company, Hyderabad..

The sample of Linobex-C Syrup Batch No. LC.09-A Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st February 2015, was declared Substandard vide CDL's test report No.R.KQ.36 /2015 dated 12th January 2015 by Federal Government Analyst, CDL, Karachi. The result of CDL on the basis of which sample under reference has been declared sub-standard are reproduced as under:-

Assay for	Determined amount/15ml	Statedamount/15ml	Percentage
Riboflavin	**2.60mg**	**3.0mg**	**86.66%**
Limits:-	90.0% to 130.0% **Does Not Comply**.		
Pyridoxine HCL	**0.996mg**	**2.0mg**	**49.8%**

Limits:- 90.0% to 130.0% **Does Not Comply**.

Nicotinamade 21.97mg 23.0mg 95.56%

Limits:- 90.0% to 130.0% Complies

Remarks:- The sample is of **"Substandard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard on the basis of assay vide their test report 013-MNHSR/2015 dated 29th May 2015.

Assay for	**Statedamount/15ml**	**Found**	**Limit**	**Percentage**
Thiamine HCL	**3mg**	**2.79mg/15ml**	**Not less than 90%**	**93.05%**
Does Not Comply.				
Pyridoxine HCL	**2mg**	**1.96mg/15ml**	**Not less than 90%**	**98.0%**
Does Not Comply.				
Nicotinamade	**23mg**	**17.09mg/15ml**	**Not less than 90%**	**74.30%**
Does not Comply				
Riboflavin	3**mg**	2.32mg/15ml	**Not less than 90%**	**77.40%**
Does not comply				

Remarks:- Manufacturer failed to supply his specification for Linobex-C (Vitamin-B complex) Syrup. Therefore, alternative specification (Nabi-Qasim Industries Karachi) was followed for the test and analysis of submitted sample The sample is of **"Substandard"** quality on the basis of assay.

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

. As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

Submitted for the consideration of the Board.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Drug-Linobex-C Syrup (Multivitamins) Batch No. LC.09-A By M/S Standard Drug Company, Hyderabad..

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of Linobex C Syrup* Suspension *Reg. No.004077 decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad

Case No.E

Manufacture & Sale of Sub-Standard Drug-Rheu-K 50mg Tablets Diclofenac Potassium Batch No.RK.01A By M/S Standard Drug Company, Hyderabad.

The sample of Rheu-K 50 mg Tablets Batch No. RK.01A Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard vide CDL's test report No. R.KQ.24/2015 dated 09th February. The result of CDL on the basis of which sample under reference has been declared sub-standard The result of CDL on the basis of which sample under reference has been declared sub-standard are reproduced as under:-

i. **Dissolution Test** **Does Not Comply**

ii.

Assay for	**Determined amount/5ml**	**Statedamount/5ml**	**Percentage**
Diclofenac Potassium	**46.66mg**	50.0**mg**	**93.32%**

Limits:- 90.0% to 110.0% **Complies**.

Remarks:- The sample is of **"Substandard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard on the basis of dissolution test vide their test report 06-MNHSR/2015 dated 29th May 2015.

i. **Dissolution Test** **Does Not Comply**

ii.

Assay for	**Determined**
Diclofenac Potassium	**70.425%**

Limits:- Not less than 75.0% of the labeled amount of Diclofenac potassium dissolved in 60 minutes.

Does not comply with USP-32

Remarks:- 1. ***Reference of Pharmacopoeia BP. Specification is mentioned. However monograph for Diclofenac potassium Tablets is not available in B.P.2013. Therefore USP-32 followed in this regard.***

2. ***Batch No. on the immediate pack is mentioned as OIA whereas on the outer packing it is printed as RK-01A. Moreover batch No. on some strips are not vivid which is misleading and violation of Drug Act 1976***

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

. As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

Submitted for the consideration of the Board.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Drug-Rheu-K 50mg Tablets Diclofenac Potassium Batch No.RK.01A By M/S Standard Drug Company, Hyderabad.

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of Rheu-K Reg. No. 066937 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad

Case No.F

Manufacture & Sale of Substandard Drug- Rheudic-50 Tablets (Diclofenac Sodium) Batch No.RD.04-A By M/S Standard Drug Company, Hyderabad

The sample of Rheudic-50 Tablets Batch No. RD.04-A Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard vide CDL's test report No. R.KQ.23/2015 dated 03rd February. The result of CDL on the basis of which sample under reference has been declared sub-standard The result of CDL on the basis of which sample under reference has been declared sub-standard are reproduced as under:-

i. **Disintegration Time** **Does Not Comply**

ii.

Assay for	**Determined amount/5ml**	**Statedamount/5ml**	**Percentage**
Diclofenac Sodium	39.57**mg**	50.0**mg**	**79.14%**

Limits:- 90.0% to 105.0% **Does not comply**.

Remarks:- The sample is of **"Substandard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard vide their test report 017-MNHRS/2015 dated 29th May 2015.

i. **Disintegration Time:- Determined:-** All the six tablets shows sign of cracks in first 2 hours in 0.1M Hydrochloric Acid

Limits:- No tablets shows sign of disintegration or cracks in first 2 hours in 0.1M Hydrochloric Acid

Dose not comply with BP-2013

Remarks:- The sample is **"Misbranded & Substandard"** quality on the basis of the tests performed.

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

02. As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

Submitted for the consideration of the Board.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Drug-Rheudic-50 Tablets (Diclofenac Sodium) Batch No.RD.04-A By M/S Standard Drug Company, Hyderabad

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of Rheudic-50 Tablets Reg. No.066939 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad

Case No.G

Manufacture & Sale of Sub-Standard Drug-Sodamint Tablets Batch No. SM-09-A By M/S Standard Drug Company, Hyderabad.

The sample of Sodamint Tablets Batch No. SM.09-A Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard vide CDL's test report No.R.KQ.26 /2015 dated 12th March 2015 by Federal Government Analyst, CDL, Karachi. The result of CDL on the basis of which sample under reference has been declared sub-standard are reproduced as under:-

i. **Mass Variation** **Does not Complies**

ii. **Assay for Total Carbonate**:-

Determined 243.6mg calculated as NaHCO3

Limits:- 275.0mg to 325.0mg **Does Not Comply**.

Remarks:- The sample is of **"Substandard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard on the basis of assay vide their test report 018-MNHSR/2015 dated 16th June 2015.

Assay for	Stated amount/tablet	Found	Limit	Percentage
Sodium Bicarbonate 3mg	**300mg**	**230.487mg/tablet**	**90-110%**	76.829%

Does Not Comply.

Remarks:- ***As per label the quantity of sodium bicarbonate is printed as Soda Bicarb.BP 300mg but practically average weight of tablet is 244 mg which is apparently less than the stated amount of Sodium Bicarbonate***.

Conclusion:- The sample is **"Misbranded & Substandard"** quality on the basis of the tests performed.

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

. As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

Submitted for the consideration of the Board.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Drug-Sodamint Tablets Batch No.SM-09-A By M/S Standard Drug Company, Hyderabad.

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of **Sodamint Tablets** ***Reg. No.008879 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***

Case No.H

Manufacture & Sale of Sub-Standard Drug – Staiflic Tablets (Folic Acid) Batch No. SF.03-A By M/S Standard Drug Company, Hyderabad.

The sample of Staiflic Tablets Batch No. SF.03-A Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard vide CDL's vide test report No. R R.KQ.25/2015 dated 23rd February. The result of CDL on the basis of which sample under reference has been declared sub-standard The result of CDL on the basis of which sample under reference has been declared sub-standard are reproduced as under:-

Assay for	Determined amount/tablet	Stated amount/tablet	Percentage
Folic Acid	**83.749 mg**	**5.0mg**	**74.98%**

Limits:- 90.0% to 110.0% **Does not comply**.

Remarks:- The sample is of **"Sub-Standard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard vide their test report 014-MNHRS/2015 dated 29th May 2015.

Assay for	Stated	Found	Limit	Percentage
Folic Acid	5mg/tab	3.586mg/tab	90-110%	77.118%

Does not comply with BP-2011.

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

. As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

Submitted for the consideration of the Board.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Drug – Staiflic Tablets (Folic Acid) Batch No. SF.03-A By M/S Standard Drug Company, Hyderabad.

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of* Staiflic Tablets (Folic Acid) *Reg. No.57828 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad

Case No.I

Manufacture & Sale of Sub-Standard Drug-Montilu 10 mg Tablets (Mountelukast Sodium) Batch No.B01A By M/S Standard Drug Company, Hyderabad.

The sample of Montilu 10mg Tablets Batch No. B01A Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard vide CDL's vide test report No. R.KQ.28/2015 dated 09th February 2015. The result of CDL on the basis of which sample under reference has been declared sub-standard

Assay for	Determined amount/tablet	Stated amount/tablet	Percentage
Mountelukast	**5.908mg**	10.0**mg**	59.08**%**

Limits:- 90.0% to 110.0% **Does not comply**.

Remarks:- The sample is of **"Sub-Standard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard on the basis of assay vide their test report 017-MNHRS/2015 dated 29th May 2015.

Assay for	Stated amount/tablet	Found	Percentage
Mountelukast Sodium	**10mg**	5.3149mg/tab	53.419**%**

Limits:- 90.0% to 110.0% **Does not comply**.

Remarks:- Manufacturer specification was not available for the test and analysis of Montelukast therefore alternate speciation (MERCK Private Limited) The sample is of **"Sub-Standard"** quality on the basis of the tests performed.

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

. As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

Submitted for the consideration of the Board.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Drug-Montilu 10 mg Tablets (Mountelukast Sodium) Batch No.B01A By M/S Standard Drug Company, Hyderabad.

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of* Montilu 10 mg Tablets (Mountelukast Sodium) *Reg. No.067688 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad

Case No.20

Manufacture & Sale of Sub-Standard Drug-Stabru Suspension Ibuprofen Batch No.SB.22A By M/S Standard Drug Company, Hyderabad.

The sample of Stabru Suspension Batch No. SB.22A.Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard vide CDL's test report No. R.KQ.40/2015 dated 06th February 2015 by Federal Government Analyst, CDL, Karachi. The result of CDL on the basis of which sample under reference has been declared sub-standard are reproduced as under:-

Assay for	Determined amount/5ml	Statedamount/5ml	Percentage
Ibuprofen	**34.61mg**	100.0**mg**	**34.61%**

Limits:- 95.0% to 105.0% **Does Not Comply**.

Remarks:- The sample is of **"Substandard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard vide on the basis of assay their test report 09-MNHSR/2015 dated 29th May 2015.

Assay for	Stated amount/5tablet	Found	Percentage
Ibuprofen	**100mg**	**32.43mg/5ml**	**32.43%**

Limits: 95-105%

Conclusion:- The sample is of **"Sub-Standard"** quality on the basis of the tests performed.

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

. As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

Submitted for the consideration of the Board.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Drug-Stabru Suspension Ibuprofen Batch No.SB.22A By M/S Standard Drug Company, Hyderabad.

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of* Stabru Suspension Ibuprofen *Reg. No.057827 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad

Case No.J

Manufacture & Sale of Sub-Standard Drug- Stamelox 15 mg Tablets (Meloxicam) Batch No. SA01-A By M/S Standard Drug Company Hyderabad

The sample of Stamelox 15mg Tablets Batch No. SA01-A Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard CDL's vide test report No. R.KQ.18/2015 dated 12th February 2015. The result of CDL on the basis of which sample under reference has been declared sub-standard are reproduced as under:-

Assay for	Determined amount/tablet	Statedamount/5ml	Percentage
Meloxicam	**12.813mg**	**15.0mg**	**85.42%**

Limits:- 90.0% to 110.0% **Does Not Comply**.

Remarks:- The sample is of **"Sub-Standard"** quality under the Drug Act 1976.

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard on the basis of assay vide their test report 012-MNHRS/2015 dated 29th May 2015.

Dissolution:- **Determined 63.22%**

Limits:- **Not less than 70% of Meloxicam dissolved in 30 minutes.**

Does not comply with BP-32

Conclusion:- The sample is of **"Subsandard"** quality on the basis of the tests performed

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

Submitted for the consideration of the Board.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Drug-Stamelox 15 mg Tablets (Meloxicam) Batch No. SA01-A By M/S Standard Drug Company Hyderabad.

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of **Stamelox 15 mg Tablets (Meloxicam)** ***Reg. No.067648 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***

Case No.K

Manufacture & Sale of Sub-Standard Drug- Standlo 500mg Tablets (Levofloxicine) Batch No.SO-03-A By M/S Standard Drug Company, Hyderabad

The sample of Standlo 500mg Tablets Batch No. SO-03-A Manufactured by M/s Standard Drug Company, Hyderabad .drawn by FID Hyderabad at Karachi from manufacturing premises on 21st January 2015, was declared Substandard vide CDL's test report No. R.KQ.21/2015 dated 26th February 2015 by Federal Government Analyst, CDL, Karachi. The result of CDL on the basis of which sample under reference has been declared sub-standard are reproduced as under:-

Dissolution Test. Does not comply. (Detail is as under)

Tablet No.	%age
01.	22.833
02.	32.735
03.	24.652
04	19.60
05.	24.470
06	21.418

Limits:- Not less than 80.0% **Does not comply with USP 37.**

Remarks:- The sample is of **"Substandard"** quality under the Drug Act 1976

On explanation letter issued by the FID, the firm challenged the CDL report and requested for Appellate Testing under Section 22(5) of Drugs Act, 1976. The Appellate Laboratory has also declared the sample as Substandard vide their test report 015-MNHRS/2015 dated 29th May 2015.

Dissolution:- Determined 27.78%
Limits:- Not less than 80% of the label amount

Remarks:- i. Batch No. printed on the outer carton is SO-03-A whereas on the immediate packing it is mentioned as B3 which is contradictory statement given by the manufacturer.

ii. Manufacture fail to supply the specification for Standlo (Levofloxacin) 500mg tablets Moreover the Levofloxacin Tablets were neither available in BP-2013 nor in USP-32 Therefore alternative specification (Getz Pharma) followed for the test and analysis of provided sample.

Conclusion:- The sample is of **"Substandard"** quality on the basis of the tests performed

The names of the following persons of the firm have been furnished and firm violated the section 23(1)(a)(v) of the Drug Act 1976 by the FID along with its report:-

i. M/s Standard Drug Company, Hyderabad
ii. Mr. Imtiaz Ahmed, (M.D),
iii. Mrs. Qurat-ul-Ain (Production Incharge),
iv. Mr. Haider Zaidi (Quality Control Incharge)

As per procedure show cause notices was issued to the firm and above named accused persons, offering opportunity of personal hearing before the Drug Registration Board. They have been also called for personal hearing.

Submitted for the consideration of the Board.

254th Meeting of DRB

No person cam, however the firm had sent written request for calling in the next meeting as their Managing Director was suffering from high fever and high blood pressure.

Decision

i. The Board decided to give the last opportunity for personal hearing to all persons named in show cause notice otherwise ex-parte decision will be taken by Registration Board.

ii. The Board also decided to get the recalled status and report from the area FID for Drug-Standlo 500mg Tablets (Levofloxicine) Batch No.SO-03-A By M/S Standard Drug Company, Hyderabad

They have been also called for personal hearing.

The 255th meeting of DRB

Proceeding:

Mr Imtiaz Ahmed (Managing Director/Partner) appeared on the behalf of the firm and defended the case

Decision:
The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"The Board decided to Cancel the registration of **Standlo 500mg Tablets (Levofloxicine)** ***Reg. No.066934 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***

The Case placed before the Central Licensing Board on recommendations of Registration Board in its 255th meeting held on17-18th December 2015

The Registration Board decided to cancel the registration following twelve (12) products of M/s Standard Drug Company Hyderabad and recommended to the Central Licensing Board for cancellation of DML of M/s Standard Drug Company Hyderabad as 12 samples drugs product by the firm of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate Lab NIH Islamabad

S.No.	Name of the Product Batch No. & M/s	Remarks	Decision of DRB in its 255th meeting held on 17-18th December 2015
1.	Netrozole Suspension Batch No.NZ10-A M/s Standard Drug Company Hyderabad (***Reg. No. 057829***)	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of*** **Netrozol Suspension Batch No. NZ 10-A** ***Reg. No. 057829 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as many samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
2.	Netrozole Suspension Batch No.NZ.08-A M/s Standard Drug Company Hyderabad (***Reg. No. 057829)***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of*** **Netrozol Suspension** ***Batch No. 08-A Reg. No. 057829 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
3.	Staifaminc Suspension Batch No.SF.07A M/s Standard Drug Company Hyderabad (***Reg. No.***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of Staifaminc*** **Suspension** ***Reg. No. 057826 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e.***

	057826)		***CDL Karachi and Appellate NIH Islamabad***
4.	Linobex-C Syrup Batch No. LC.09-A M/s Standard Drug Company Hyderabad ***Reg. No.004077***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of Linobex C Syrup*** **Suspension** ***Reg. No.004077 decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
5.	Rehu-K 50mg Tablets Batch No. RK.01A M/s Standard Drug Company Hyderabad ***Reg. No. 066937***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of Rheu-K 50mg Reg. No. 066937 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
6.	Rheudic-50 Tablets Batch No.RD.04-A M/s Standard Drug Company Hyderabad ***Reg. No.066939***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of Rheudic-50 Tablets Reg. No.066939 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
7.	Sodamint Tablets Batch No. SM.09-A M/s Standard Drug Company Hyderabad (***Reg. No.008879)***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of*** **Sodamint Tablets** ***Reg. No.008879 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
8.	Staiflic Tablets Batch No.SF.03-A M/s Standard Drug Company Hyderabad ***Reg.***	Substandard (CDL/NIH)	***The Board decided to Cancel the registration of*** **Staiflic Tablets (Folic Acid)** ***Reg. No.57828 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by***

	No.57828		***both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
9.	Montilu 10mg Tablets Batch No.B01A M/s Standard Drug Company Hyderabad ***Reg. No.067688***	Substandard (CDL/NIH)	***The Board decided to Cancel the registration of* Montilu 10 mg Tablets (Mountelukast Sodium) *Reg. No.067688 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
10.	Stabru Suspension Batch No.SB.22A M/s Standard Drug Company Hyderabad ***Reg. No.057827***	Substandard (CDL/NIH)	***The Board decided to Cancel the registration of* Stabru Suspension Ibuprofen *Reg. No.057827 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
11.	Stamelox 15mg Tablets Batch No.SA01-A M/s Standard Drug Company Hyderabad ***Reg. No.067648***	Substandard (CDL/NIH)	***The Board decided to Cancel the registration of* Stamelox 15 mg Tablets (Meloxicam) *Reg. No.067648 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***
12.	Standlo 500mg Tablets Batch No.SO-03-A M/s Standard Drug Company Hyderabad ***Reg. No.066934***	Substandard (CDL/NIH)	***"The Board decided to Cancel the registration of* Standlo 500mg Tablets (Levofloxicine) *Reg. No.066934 and decided to recommended the Central Licensing Board for Cancellation of DML of the Firm as 12 samples of the firm has been declared substandard by both the Labs i.e. CDL Karachi and Appellate NIH Islamabad***

M/s Standard Drug Company Hyderabad has filed Constitutional Petition No.971 of 2016 (MA 6205/2016) through Mr. Imtiaz Ahmed Vs Federation of Pakistan in the High Court of Sindh, Karachi, Circuit Court, Hyderabad against the decision of the Drug Registration Board in its 255th meeting held on 17-18th December 2015for cancellation of registration of twelve registered products of M/s Standard Drug Company Hyderabad. However no directions for Central Licensing Board has been received from Honorable Sindh High Court Karachi, Circuit Court, Hyderabad.

The FID Hyderabad at Karachi vide his letter No.10-02-2016-DRAP(K) dated 01-08-2016 has requested to send the Parawise comments and appointment of Standing Council.

Parawise comments and nomination of standing council are under processed/approval in the Division of legal Affairs, DRAP, Islamabad.

Decision:

The Board after detailed discussion, deliberation, considering the facts and legal provisions decided as under:

"***The Board decided to issue show cause notice for cancellation of DML of the firm M/s Standard Drug Company Hyderabad as recommended by Registration Board in its 255th meeting held on 17-18th December 2015*** ".

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