DIVISION OF DRUG LICENSING
DRUG REGULATORY AUTHORITY OF PAKISTAN
ISLAMABAD
*****

MINUTES OF 238th MEETING OF CENTRAL LICENSING BOARD HELD ON WEDNESDAY, 19th NOVEMBER, 2014.

238th meeting of the Central Licensing Board (CLB) was held on Wednesday, 19th November, 2014 in the Committee Room of Ministry of National Health Services, Regulations & Coordination at Local Government & Rural Development Complex, G-5/2, Islamabad under the Chairmanship of Mr. Faqeer Muhammad Shaikh, Director Drug Licensing, DRAP,/Chairman CLB.

Following members attended the meeting: -

S. No.	Name & Designation	Status
1.	Mr. A.Q Javed Iqbal, Director (QA/LT), as representative of Division of Quality Assurance and Laboratory Testing, DRAP, Islamabad.	Member
2.	Mr. Atta-ur-Rehman, Chief Drug Inspector, Department of Health, Govt. of Balochistan.	Member
3.	Chief Drug Inspector, Department of Health, Govt. of Khyber Pakhtunkhwa (K.P.K). (Mr. Dil Nawaz, Deputy Director, DGHS, Peshawar attended meeting on behalf of Chief Drug Inspector, KPK.)	Member
4.	Chief Drug Controller, Department of Health, Govt. of Punjab (Mr. Talat Farooq Ahmed, Secretary PQCB, Punjab attended on behalf of Chief Drug Controller)	Member
5.	Mr. Qaiser Muhammad, Chief Drug Inspector, Department of Health, Govt. of Sindh.	Member
6.	Dr. Ikram-ul-Haq, QC/QA Expert	Member
7.	Syed Jawed Yousaf Bukhari, QC/QA Expert	Member
8.	Syed Muid Ahmed, Expert in manufacturing of drugs.	
9.	Prof. Dr. Gul Majeed Khan, Professor of Pharmacy	Member
10.	Prof. Dr. Muhammad Saeed, Professor of Pharmacy	Member
11.	Mr. Abdullah, Deputy Director General (Lic.), DRAP, Islamabad.	Secretary
12.	Mr. Tauqeer-ul-Haq & Pervaiz Ahmed, Representative of PPMA	Observer
13.	Mr. Nadeem Alamgir, Representative of Pharma Bureau.	Observer
14.	Mr. Shahzad H. Chaudhary, 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.

The Chairman apprised the members of the Board that proceedings of CLB shall be conducted in an amicable and responsible way to deliver to the public and stake holders in a transparent and efficient manner. Quality shall be given priority and there shall be zero tolerance. He further added that all the legal and codal formalities regarding convening of the meeting have been fulfilled. Mr. Adnan Faisal Saim , DDC (QA) DRAP, Islamabad & Mr. Salateen Waseem Philip ADC/DDC (Lic.) DRAP Islamabad assisted the Secretary CLB in presenting the agenda.

A. LICENSING DIVISION

Item-I **CONFIRMATION OF THE MINUTES OF 237th MEETING**

The Central Licensing Board (CLB) formally confirmed the minutes of its 237th meeting held on Wednesday, 1st October, 2014.

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

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

S No.	Name of the firm	Date of Inspection / Type of License	Decision of CLB
1.	M/s Bajwa Pharmaceuticals Industries, 36-K.M. GT Road, Gujranwala Road, District Sheikhupura.	13-11-2014 (Formulation)	**Approved the grant of DML with following section:** **Section(01)** 1. Liquid Ampoule Injectable (General).
2.	M/s PCP Laboratories, 98-KM, Akhtarabad, District Okara.	24-09-2014 Formulation	**The Board after thorough discussion and deliberation decided and rejected the application for grant of DML according to Rule 10(4-5) of Drugs (Licensing, Registering & Advertising) Rules 1976 due to observations made by the panel during inspection as under:** i. In the Cephalosporin Oral Dry Powder Section, the functioning of HVAC system was not proper as positive pressure was seen instead of negative pressure, manometers were not installed. The firm was asked to provide partition between blistered machine and packing area. ii. In the Cephalosporin Dry Powder Vials Injectable section, in the filling area, the oven structure opens into the Class B area hence the panel advised the firm to provide HEPA filter transfer trolley for transfer of vials into the filling line. HVAC installed,

			however manometers were not installed, in the optical checking room, wooden frames were being used, the firm was asked to replace it. iii. In the Quality Control, FTIR, Karl Fischer, particle counter were not available. In the HPLC, column oven for testing of Cephalosporin were also not available. iv. In the microbiology lab epoxy paint required. v. The firm was required to develop production, Quality Control and Quality Assurance SOPs. The Board directed the firm to rectify the above mentioned shortcomings and no application shall be entertained within three months of the rejection of application as per aforementioned rule.
3.	M/s Vision Pharmaceuticals Plot No. 22, Industrial Triangle, Kahuta Road, Islamabad.	17-11-2014 Semi Basic	**Approved the grant of DML with following sections and APIs.** **<u>Section (02)</u>** i) Pellets/Pelletization ii) Lyophilization

<u>List of APIs</u>

<u>Pellets / Pelletization Section:</u>

Enteric Coated / Delayed Release Pellets (EC/DR) and Delayed Dual Release (DDR)

1. Aspirin
2. Diclofenac Potassium
3. Diclofenac Sodium
4. Duloxetine HCL
5. Dexlansoprazole (DDR)
6. Esomeprazole
7. Exomeprazole Magnesium
8. Lansoprazole
9. Omeprazole
10. Pantoprazole
11. Rabeprazole

Extended Release/ time Release/ Sustained Release and Controlled Release Pellets (XR/SR)

12. Accelofenac
13. Cyclobenzaprine HCL
14. Diclofenac Potassium
15. Diclofenac Sodium
16. Doxcyline Hyclate
17. Ketoprofen
18. Itopride HCL
19. Nitroglycerine
20. Venlafaxine HCL
21. Tizanidine HCL

Immediate Release Coated (IR)

22. Clopidogrel
23. Ferrous Sulphate
24. Folic Acid
25. Fexofenadine HCL

Taste Masked Micro Pellets (for oral suspension) (TM)

26. Ciprofloxacin (base)
27. Ciprofloxacin HCL
28. Levofloxacin
29. Azithromycin
30. Clarithromycin
31. Mebeverine HCL

Lyophilization Section

1. Esomeprazole Sodium
2. Omeprazole Sodium
3. Lansoprazole Sodium
4. Pantorazole Sodium
5. Rabeprazole Sodium
6. Deferoxamine Mesylate
7. Deferoxamine Mesylate
8. Paracoxib Sodium
9. Famotidine

The Board deferred the Thiopentone Sodium, Terlipressin Acetate, Streptokinase, APIs till the firm develops segregated solution preparation room as per recommendations of the panel.

The Board further deferred Tamsulosin HCl, Isosorbide mono nitrate, Isosorbide di nitrate, Itraconazole, Piperaquine and Orlistat APIs due to inappropriate procedure for the manufacturing / cleaning validation of said APIs.

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

The Board considered following cases of Grant of Additional Sections/Expansion/Amendments in Layout Plans (LOP) 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	Type of license	Decision of CLB
1.	M/s Abbott Laboratories (Pakistan) Limited Landhi, Karachi	DML No.000001 (Formulation)	**The Board approved the grant of expansion / amendment in the following existing section:** **Section (01)** Oral Liquid (General)
2.	M/s. Macter International (Pvt) Ltd, F-216, SITE, Karachi.	DML No.000141 (Formulation)	**The Board approved the grant of following existing section after expansion/amended as segregated section:-** **Section (01)** 1.Tablet (Psychotropic)
3.	M/s. Sami Pharmaceuticals (Pvt) Ltd, F-95&145, Off, Hub River Road, SITE, Karachi.	DML No.000072 (Formulation)	**The Board approved the grant of new additional sections as under:-** **Biotech Sections (02)** 1. rDNA Facility. 2. Vaccine Section (Anti-Sera Only)
4.	M/s. Nextar Pharma (Pvt) Ltd, Plot No. E-58, North Western Industrial Zone Port Qasim, Karachi.	DML No.000777 (Formulation)	**The Board approved the grant of new additional section as under:-** **Section (01)** 1. Injectable Ampoules (Biological)
5.	M/s. Jasons Pharmaceuticals, Plot No. 26, St No.SS-2, National Industrial Estate, Rawat, Islamabad.	DML No.000727 (Formulation)	**The Board approved the grant of new additional sections as under:-** **Section (01)** **1.** Liquid Ampoule Injectable Section (General)
6.	M/s. Nabiqasim Industries (Pvt) Ltd, Plot No. 17, Sector 24, Korangi Industrial Area, Karachi.	DML No.000727 (Formulation)	**The Board approved the grant of amendments/expansion according to approved layout plan in the following existing sections:-** 1. Liquid Manufacturing Area (On ground floor). 2. Expansion in Hormones / Glandin manufacturing area (first floor). 3. Additional packaging hall (first floor)

7.	M/s. Hilton Pharma, Plot No.13&14 Sectors 15, Korangi Industrial Area, Karachi.	DML No.000136 (Formulation)	**The Board approved the grant of amendments/expansion according to approved layout plan following existing sections after:** 1. Oral Dry Powder Suspension (General). 2. Sachet (General) 3. Dedicated facilities for blistering & packing. 4. Sachet (Enflor)* *The Board has granted provisional approval of amendments/expansion in already existing Sachet (Enflor) section. The active ingredient of Sachet Enflor is Sacharomyces Boulardii is probiotic which is not a drug after the promulgation of the DRAP Act, 2012. Since the firm has registration of Enflor sachet product, therefore the Board directed to refer the case to Division of Pharmaceutical Evaluation & Research, DRAP, Islamabad to take review of registration of probiotic (Sachet Enflor) product of the firm and to inform CLB for necessary action accordingly.
8	M/s. CCL Pharmaceuticals (Pvt) Ltd 62-Industrial Estate, kot Lakhpat, Lahore.	DML No.000136 (Formulation)	**The Board approved the grant of following new additional section:** 1. Oral Dry Powder Suspension (General) **The Board approved amendments/ expansion in already existing sections:** 1. Tablet (General) amended 2. Capsule (General) amended
9	M/s Univet Pharmaceuticals, 14-km, Adyala Road, Rawalpindi	DML NO. (000424) Formulation (Veterinary)	**The Board approved the grant of following new additional section:-** **<u>Section (01)</u>** 1. Oral Liquid (General) Veterinary
10	M/s Venus Pharma, 23 km Multan Road, Lahore	DML No.000300 (Formulation)	**The Board approved the grant of new Capsule (General) Section & Renewal of Injectable Ampoule (Psychotropic) Section.** The Board also after thorough discussion and deliberation discussed the orders of the Honorable Court of Civil Judge Lahore regarding dispute of suit property. Civil suit No 16/5/2014 filed before Honorable Court of Civil Judge Lahore in respect of M/s. Gallop Pharma, Lahore does not effect on the departmental proceedings as per order of Honorable Civil Judge as under :- *"The respondents are hereby directed not to alienate the suit property illegally & unlawfully till the next date of hearing. However this order will cease to exist if not extended specifically on next date. This order will also have no effect upon any other legal, court or departmental proceedings"*

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 #	Name of the firm	Type of license	Decision of CLB
1.	M/s. Saakh Pharma (Pvt) Ltd, C-7/1, North Western Industrial Zone, Port Qasim, Karachi.	DML No.000588 (Semi Basic)	**Approved the Grant of Renewal of DML for semi basic manufacturing with following APIs:** **Penicillin APIs:-** 1. Ampicillin Anhydrous. 2. Ampicillin Tryhydrate. 3. Amoxicillin Tryhydrate. 4. Cloxacillin Sodium. **Cephalosporin APIs:-** 1. Cefixime. 2. Cephradine. 3. Cefadroxil.
2.	M/s. Jaens Pharmaceuticals Industries, 28-KM, Sheikhupura Road, Lahore.	DML No.000532 (Formulation)	**Approved the Grant of Renewal of DML**
3.	M/s. Biofine Pharmaceuticals (Pvt) Ltd, 74-KM, Industrial Estate, Multan.	DML No.000668 (Formulation)	The Board was apprised that the panel inspection was carried out with delay and even after the expiry of validity of renewal date of the DML of firm. **The Board after thorough discussion and deliberations approved and regularized the Renewal of DML for the period from 10-07-2009 to 09-07-2014.** i). The Board showed its displeasure towards casual behavior of field officers and directed that panel inspections must be conducted regularly according to stipulated time and avoid haphazard inspections after fixation of date of meeting of CLB. ii). The Board advised that in future agenda of CLB's meeting shall be closed before three days of the meeting of Central Licensing Board. iii). Every DDG (E&M) DRAP at provincial Head Quarters & Islamabad should submit regularly, monthly report of pending inspection(s) of the firms in their respective areas mentioning reasons of it.

4.	M/s. McOLSON Research Laboratories (Pvt) Ltd, 26-KM, Lahore Sharkpur Road, District Sheikhupura.	DML No.000664 (Formulation)	**Approved the Grant of Renewal of DML**
5.	M/s. Macter International (Pvt) Ltd, F-216, SITE, Karachi.	DML No.000141 (Formulation)	**Approved the Grant of Renewal of DML for the period 24-11-2014 to 23-11-2019.** The Board also approved and regularized the Renewal of DML for the period 24-11-2009 to 23-11-2014.
6.	M/s. Macter International (Pvt) Ltd, F-216, SITE, Karachi.	DML No.000111 (Basic)	**Approved the Grant of Renewal of DML for the period 24-11-2014 to 23-11-2019.** The Board also approved and regularized the Renewal of DML for the period 24-11-2009 to 23-11-2014.
7.	M/s. Nabiqasim Industries (Pvt) Ltd, Plot No. 17, Sector 24, Korangi Industrial Area, Karachi. (Formulation)	DML No.000727 (Formulation)	**Approved the Grant of Renewal of DML**
8.	M/s. Hilton Pharma, Plot No.13&14 Sector 15, Korangi Industrial Area, Karachi.	DML No.000136 (Formulation)	**Approved the Grant of Renewal of DML**
9.	M/s Risma Laboratories A-2B S.I.T.E Karachi.	DML NO. 000053 (Formulation)	**Approved the grant of renewal of DML of following two sections:** 1. External Liquid (General) 2. External ointment/cream (General) **The Board also allowed resumption of production of above two sections only.** The Board further decided and suspended the manufacturing in Tablet, Capsule, Oral Dry Suspension, Liquid Syrup and Powder sections for three months according to Rule 13 of Drugs (Licensing, Registering & Advertising) Rules 1976 due to following observations made by the panel during inspection. i. The firm informed that the areas for

			manufacturing of Capsule, Tablets, Oral Dry Suspension / Syrups, and Oral Liquids are still under renovation process and HVAC to be installed therefore found closed at the time of inspection. ii. No testing process was seen at the time of inspection. iii. Qualified and experience staff and more training is required 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 the firm needs more professionally qualified and experienced persons for better GMP compliance. iv. The panel also advised the firm to get approval for qualified pharmacist as a production Incharge. v. The firm does not possess approved layout plan by the DRAP Authority. It is advised to get approval for regularized sections by DRAP. The Board directed the firm to rectify the above mentioned shortcomings within a period of three months.
10.	M/s. Alson Pharmaceutical Plot No. 159, 7-B, Industrial Estate Hayatabad, Peshawar.	DML No. 000522 (Formulation)	**Approved the Grant of Renewal of DML**
11.	M/s. Scottman Pharmaceuticals, Plot No. 5-D, I-10/3, Industrial area, Islamabad.	DML No.000498 (Formulation)	**Approved the Grant of Renewal of DML only for following sections verified by the panel as per approved layout plan:-** 1. Capsule (Penicillin) 2. Oral Dry Suspension (Penicillin) 3. Tablet (General) 4. Capsule (General) 5. Injectable Ampoule(General / Analgesic) 6. Injectable Infusion Line (General). i) The Board further decided to re-inspect and verify the Bio-Tech antiviral & Bio-Tech Interferon sections by following panel as per approved layout plan: • Director Biological, DRAP, Islamabad

			• Director NCL, Islamabad. • Area FID, DRAP, Islamabad. ii). The Board directed the firm not to start manufacturing in other sections of the firm unless inspected and allowed by Central Licensing Board. iii). The Board also withdrew following sections as per request of the firm: • Narcotic/Psychotropic Tablets • Prefilled Syringes (Harmones) • Prefilled Syringes (Anti-Coagulants) • Vial Filling (Quinolones) • Inhalers • Lotions • Shampoo
12.	M/s Lisko Pakistan (Pvt.) Ltd, L-10-D, Block No. 21, Shaheed Rashid Road, Karachi	DML No. 000110 (Formulation)	**The Board decided and suspended the renewal of DML of the firm for a period of three months according to Rue 13 of Drugs (Licensing, Registering & Advertising) Rules 1976 due to following observations made by the panel during inspection:** i) HVAC system was partially effective due to light break ups and monitoring was also below satisfactory. ii) Penicillin & Cephalosporin areas were devoid of proper dispensing booths iii) Microbiology must be more compliant as per guidelines. iv) HVAC system should also be provided in corridors of manufacturing unit v) Sufficient persons are hired but a few are advised to be hired as per DRAP requirement. vi) To do further improvements in documentation, calibration and training in Q.C Laboratory. The Board directed the firm to rectify the above mentioned shortcomings within a period of three months.

13.	M/s Weather Folds Pharmaceuticals 69/2 Phase-2 Industrial Estate Hattar.	DML NO. 000644 (Formulation)	While discussing the case: - Prof. Dr. Muhammad Saeed, Member CLB apprised the Board that he was also the member of the panel but he was not the part of panel inspection of the firm for which this report has been submitted for consideration of CLB. He further added that previously an inspection for renewal of DML of the firm was conducted in the month of September 2014. Accordingly report was written and signed by some members in which renewal of DML was not recommended due to serious violation of GMP. The said inspection report has not been submitted to CLB as yet. Prof. Dr. Muhammad Saeed apprised the Board that Q.C Incharge of the firm was absent from last 06 months as informed by production Incharge. Q.C Lab was totally out of order. The material of another company was placed in the premises. The HVAC system was out of order in Oral Solid Dosage section. There was extreme violation of GMP practices. Prof. Dr. Muhammad Saeed excused for being the panel member of this firm. **Keeping in view the above serious observations1 of one of the panel member of inspection team (also member of CLB), the Board discussed and deliberated the case thoroughly and unanimously decided as under:** **"Deferred the for renewal of DML for re-inspection by the following panel:** **1. Prof. Dr. Gul Majeed Khan, Member CLB.** **2. Chief Drug Inspector, KPK** **3. Director DTL, Peshawar** **4. Mr. Muhammad Arif Chaudhary, DDC (Reg-I), DRAP, Islamabad.** **5. Area FID, DRAP, Peshawar** **6. Area ADC, DRAP, Peshawar.** **The Board has desired to seek that inspection report from area FID wherein Dr. Saeed has signed for submission to CLB.** **The Board expressed its displeasure about such practices of field offices.**

ITEM NO. V MISCELLANEOUS CASES.

<u>Case No. 1.</u> Request for approval to produce Pseudoephedrine Hcl from semi basic process i.e. by using Intermediate (+)-(IS, 2S)-2-Methylamino-1-Phenylpropan-1-OL Base by M/s Alpha Chemicals (Pvt.) Ltd, Lahore. (DML NO. 000373 -Basic Manufacturing)

The case was placed before the Board as under:

M/s. Alpha Chemicals (Pvt.) Ltd, DML NO. 000373 (Basic Manufacturing) has requested to grant approval to produce **Pseudoephedrine Hcl** from semi basic process i.e. by using Intermediate (+)-(IS, 2S)-2-Methylamino-1-Phenylpropan-1-OL Base.

Firm has already approval for manufacturing Pseudoephedrine Hcl by Basic Manufacturing as verified vide record of Licensing Division DRAP, Islamabad vide in recent renewal of DML of the firm for the period **08-01-2011 to 07-01-2016.**

Firm has explained their reasons for adopting semi basic manufacturing method for Pseudoephedrine Hcl from Intermediate i.e. (+)-(IS,2S)-2-Methylamino-1-Phenylpropan-1-OL Base, due to unavailability / shortage and import of **Acetic anhydride** and procuring Pharma grade molasses from the year of 2005 onwards

The firm has license to manufacture drugs by way of Basic Manufacture, so under provision of Rule 15(g)(iv) of the Drugs (Licensing, Registering and Advertising) Rules, 1976, the firm may manufacture drugs by way of Semi Basic Manufacture. The said rule is reproduced as under: -

"[provided that where a person possesses or applies for a license to manufacture by way of basic and he also intends to conduct semi basic manufacture of drugs, he may conduct such manufacture under the same license, subject to the approval of, and under such conditions as, Central Licensing Board may specify.]"

<u>Decision of CLB</u>

The Board after thorough discussion and deliberation decided to ask the firm to submit:-

- Five years track record of production, sale and purchase of Pseudoephedrine HCl.
- Justification for change of manufacturing process in detail with documentary evidence of the said drug substance.

The Board constituted following panel for inspection of the firm in this context: -

i). Dr. Ikram-Ul-Haque, Member CLB (will head the panel)
ii). Prof. Dr. Muhammad Saeed, Member CLB
iii). Area Federal Inspector of Drugs
iv). Salateen Waseem Philip, ADC / DDC (Lic)

The Board authorized the Chairman CLB to dispose of the case accordingly.

The above panel inspected the premises on 30-06-2014 and gave its recommendations as under:

The panel of inspectors examined the production and sale record provided by the firm. The firm is engaged in the manufacturing of ephedrine and pseudoephedrine by way of basic

manufacturing. The firm is manufacturing pseudoephedrine HCl by way of semi basic manufacturing as well by getting allocation of special quota of base/intermediate from the competent authorities from time to time.

In view of the above and international strict control on controlled substances like acetic anhydride, the panel of inspectors is of the opinion to also recommend the grant of permission for manufacturing of pseudoephedrine HCL by way of Semi Basic manufacturing to the M/s Alpha Chemical (Pvt) Ltd, 65-KM, Multan Road, District Kasur.

The firm provided the following documents / information as per decision of CLB to the members of the inspection panel which are enclosed with report: -

- Details of inspection of the premises.
- Five years record of sale & manufacturing of Pseudoephedrine HCL by using Acetic Anhydride & Intermediate.
- List of equipment in the premises.
- List of approved technical experts.
- Justification of production by semi basic process.

Decision of CLB

The Board after thorough discussion and deliberation, keeping in view the recommendations of panel and facts on ground, allowed the permission to manufacture Pseudoephedrine HCl by way of semi basic manufacturing method from Intermediate i.e. (+)-(IS,2S)-2-Methylamino-1-Phenylpropan-1-OL Base also.

Case No. 2. Time extension for packaging material usage up to 31st March 2015 of M/s. Martin Dow Ltd, Plot No. 37, Sector-19, Korangi Industrial Area, Karachi DML No.000267 Formulation)

The case was placed before the Board as under:

Brief Background of the case:-

Central Licensing Board in its 235th meeting held on 15th May 2014 has considered and approved the change of name of the firm from M/s Martin Dow Pharmaceuticals Limited to M/s Martin Dow Limited. The Board has further directed to consume/dispose of printed packaging material with previous name within 03 three months of issuance of this letter.

Now firm has requested in continuation to previous letter dated 29th September, 2014 for subject matter. They further explained that it is to bring in kind notice that although they have utilized about 90% of the printed packaging material with old name but still few unutilized packaging material are lying with them so it is requested to please grant us time extension for materials usage up to 31st March 2015.

As desired details of unutilized printed packaging material is attached.

Decision of CLB

The Board after thorough discussion and deliberation, keeping in view the facts on ground decided to allow firm to use already printed packaging material with previous name till 31-12-2014.

<u>Case No. 3</u>. **Regularizations of Layout Plans of M/s. Hilton Pharma, Plot No.13&14 Sector 15, Korangi Industrial Area, Karachi.**

The case was placed before the Board as under:

M/s. Hilton Pharma, Plot No.13&14 Sector 15, Korangi Industrial Area, Karachi. DML No.000136 (Formulation) has applied for regularization of their following existing sections: -

1. Tablet Section
2. Capsule Section
3. Oral Liquid Section
4. Injectable Section (Vial & Ampoule)
5. Dedicated Cephalosporin Section containing products including Capsules, Oral Suspension & Injection.
6. Dedicated section for Biotech products
7. Dedicated veterinary section for powders & liquid

Accordingly, layout plan of firm was approved and panel was requested to verify the above sections of firm as per approved layout plan.

The panel visited the firm on 05 & 06-11-2014. The Recommendations of panel comprising of (i). Sheikh Ansar Ahmed, Director Biological, DRAP, Islamabad, (ii). Syed Muied Ahmed, Member CLB. (iii).Dr. Saifur Rehman Khattak, Director CDL, Karachi. (iv) Dr. Abdul Rasool Shaikh, Area FID-III, DRAP, Karachi. (v) Dr. Shoaib Ahmed, ADC, DRAP, Karachi are as under: -

<u>Recommendations of Panel</u>: The panel further confirms the availability of following sections as aligned with approved DRAP drawing:

1. Dedicated biotech section,
2. Dedicated cephalosporin sections (sterile dry powder injection, capsules and Oral Dry Powder (suspension).
3. Dedicated veterinary section (Liquid syrups (General) and Dry powder (General).
4. Dedicated sections for sterile liquid sections (ampoule and vials).
5. Dedicated section for ENFLOR containing Saccharomyces Boulardii.
6. Tablet (General), Capsule (General), Oral Dry Powder Suspension (General), Liquid Syrup and Sachet sections.
7. Dedicated facilities for primary blistering and packing.

The Area FID has also submitted details of sections on evaluation form

<u>Decision of CLB:</u>

The Board after discussion / deliberations has approved the regularization/ authentication of existing facility of M/s. Hilton Pharma, Plot No.13 & 14 Sector 15, Korangi Industrial Area, Karachi (DML No.000136 - Formulation) according to approved layout plan for the following sections:

1. Tablet (General)	**6. Oral Dry Powder Suspension (Cephalosporin)**
2. Capsule (General)	**7. Dry Powder Injectable (Cephalosporin)**
3. Oral Liquid (General)	**8. Veterinary Liquid (General)**
4. Injectable Vials & Ampoules (General)	**9. Veterinary Powder (General)**
5. Capsule (Cephalosporin)	

Case No. 4 Regularization of Layout Plans of M/s CKD Pharmaceuticals (Pvt) Ltd, 50/28, Korangi Industrial Area, Karachi

The case was placed before the Board as under:

M/s CKD Pharmaceuticals (Pvt) Ltd, DML NO. 000144 (Formulation), 50/28, KIA, Karachi has applied for regularization of layout plan of running facility for their following existing sections which were being licensed before the promulgation of S.R.O. 470/98 dated 15th May 1998 when approval of layout plan was not mandatory: -

1.Tablet (General) Section 2.Cream / Ointment / Gel (General) Section 3.Oral Liquid (General) Section 4.Capsule (General) Section 5.Capsule (Cephalosporin) Section	6.Oral Dry Suspension (Cephalosporin) 7.Capsule (Penicillin) Section 8.Tablet (Penicillin) Section 9.Oral Dry Powder Suspension (Penicillin) Section

Later on, layout plan of firm for above mentioned sections was pproved/regularized/authenticated and Area FID was requested to verify the above sections of firm as per approved layout plan. Accordingly, area FID has inspected the premises and verified all the above mentioned sections.

Decision of CLB in its 237th meeting held on 01-10-2014.

The Board considered and deferred for the verification of sections through a panel.

2. In the light of above decision of Board a panel was then again constituted comprising of (i) DDG (E&M), DRAP Karachi, (ii) Area FID, DRAP, Karachi , (iii) Area ADC, DRAP, Karachi. The report of the panel is as under:-

Observations of Panel:-

1. During the inspection it was observed that the firm has following sections, which are in accordance with approve layout plan i.e. Tablet (General), Capsule (General), Dry Powder (General), Cream/Ointment/Gel Section (General), Liquid Syrup (General), Dedicated Cephalosporin (Capsule, Dry Powder Suspension) and Penicillin (Capsule, Tablet & Dry Powder Syrup)

2. It is an old unit but found well maintained. Previously the layout plan was not regularized but as the new management has taken over the charge of the facility they were advised to go it thus management has submitted the revised layout plan the existing facilities for consideration with recommended from Drug Licensing Directorate Islamabad, require for approval

3. The existing layout plan was approved by the concerned quarter DRAP Islamabad . The panel further observed that above mentioned sections are re-modified , up graded and renovated as per current approved layout plan, which is checked and complied verified.

4. Only dedicated penicillin section was under renovation and up gradation, found closed. Rest of the sections were observed under active production with good GMP Compliance.

5. Q.C Lab is located at mezzanine floor with required equipment and well trained staff. It was also reset as per approved layout plan. QA/QC require further improvement for effective control

Conclusion

Based on the above observations the panel unanimously confirmed the availability of above sections as per approved layout plan and recommended to the worthy CLB for regularization of the same.

Decision of CLB

The Board after discussion / deliberations has approved the regularization/authentication of existing facility as per approved layout plan for following sections: -

1. **Tablet (General) Section**
2. **Capsule (General) Section**
3. **Cream / Ointment / Gel (General) Section**
4. **Oral Liquid (General) Section**
5. **Capsule (Cephalosporin) Section**
6. **Oral Dry Powder Suspension (Cephalosporin)**
7. **Capsule (Penicillin) Section**
8. **Tablet (Penicillin) Section**
9. **Oral Dry Powder Suspension (Penicillin) Section**

===== The End =====