

No. F. 12-05/2015-DDC (Health & OTC)  
Government of Pakistan  
Ministry of National Health Services, Regulations & Coordination  
Drug Regulatory Authority of Pakistan  
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Islamabad, the 7<sup>th</sup> December, 2015.

**MINUTES OF 5TH MEETING OF THE ENLISTMENT EVALUATION  
COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH  
PRODUCTS.**

5<sup>th</sup> meeting of the Enlistment Evaluation Committee, constituted under 7 of the Alternative Medicines and Health Products (Enlistment) Rules, 2014, was held in the office of the Chairman of the committee on 7<sup>th</sup> December, 2015.

Meeting of Committee was attended by the following:-

<b>S. #.</b>	<b>Name &amp; Designation</b>	<b>Position in the Committee</b>
1.	Dr. Noor Muhammad Shah, Director Health & OTC	Ex-Officio Chairman
2.	Abdul Sattar Sohrani, Deputy Drug Controller Health & OTC	Ex-Officio Member / Secretary
3.	Homeopathic Dr. Muhammad Tariq Khan, Assistant Professor, Department College of Pharmacy, Margalla Institute of Health Sciences, Rawalpindi.	Expert Member
4.	Hafiz Muhammad Asif, Assistant Professor Faculty of Health and medical Sciences Department of Eastern Medicines and Surgery, University of Poonch (Rawala Kot), AJ&K.	Expert Member Absent
5.	Dr. Lajbar Khan, Ex-Chief Scientific Officer, Medicinal Botanic Centre, PCSIR Laboratories Complex, Peshawar.	Expert Member

6.	Dr. Farnaz Malik, Chief, DC & TMD, NIH	Ex-Officio Member Absent
7.	Dr. Amjad Ali, Chief, Nutrition Division, NIH	Ex-Officio Member

**Item No. 1.** The meeting started with recitation of the Holy Quran and Darud on the Prophet (PBUH). Secretary of the committee presented agenda of the meeting and following decisions were made by the committee.

**Item No. 2. GRANT OF ENLISTMENT CERTIFICATE TO THE MANUFACTURERS.**

The Enlistment Evaluation Committee examined and discussed the record / panel inspection reports of the following firms and on the basis of recommendations of the panel of inspections approved grant of enlistment certificates for manufacturing authorization to them.

S. No.	Name and address of the Manufacturer	Name of approved Sections
1.	M/s. EmmEss Nutraceuticals, 227-Kararwala, 10-Km, Jaranwala Road, Faisalabad.	1. Tablet Section 2. Dry Powder Sachet Section 3. Oral Liquid Section Manufacturing facility was also approved for enlistment as Contract Acceptor as recommended by the panel.
2.	M/s. Warsan Homoeopathic Laboratories, Qasim Zia Industrial Estate, 23-KM, Link Ferozepur Road, Lahore.	1. Oral Liquid 2. Cream and Ointment 3. Dry Powder (Trituration) 4. Encapsulation 5. Tablet (Biochemics) 6. Homoeopathic Dilution 7. Mother Tincture
3.	M/s. A. R. Nutraceutical Pharma (Pvt) Limited, Plot No. F-4/C, S.I.T.E., Phase-II, Super Highway, Karachi.	1. Syrup Section 2. Tablet Section 3. Sachet Section 4. Ointment & Cream Section
4.	M/s. Neuvic Pharma (Pvt) Ltd. 15-KM, Raiwind Road, (Rayan Pind), Lahore.	1. Tablet & Capsules Section 2. Sachet Section

		Panel do not recommend for contract manufacturing.
5.	M/s. Apple Laboratories, National Industrial Zone, RCCI Road, 1.5-KM, Rawat, Rawalpindi.	<ol style="list-style-type: none"> <li>1. Tablet Section</li> <li>2. Sachet / Powder Section</li> <li>3. Cream / Ointment</li> <li>4. Syrup Section</li> </ol> <p>Recommended for contract manufacturing of upto six contract givers only as recommended by the panel.</p>
6.	M/s. Hi-Nutrition, Hashim Park, 9.5-KM, Sheikhpura Road, Lahore.	<ol style="list-style-type: none"> <li>1. Soft Gel Capsules</li> <li>2. Sachet (Powder)</li> <li>3. Tablets &amp; Capsules</li> <li>4. Oral Liquids (Syrup &amp; Suspension)</li> </ol> <p>The panel recommended for contract manufacturing as contract acceptor.</p>
7.	M/s. Nutrimed Laboratories, Plot No. B-42, S.I.T.E., Super Highway, Karachi.	<ol style="list-style-type: none"> <li>1. Tablet</li> <li>2. Capsule</li> <li>3. Liquid</li> <li>4. Sachet (General)</li> <li>5. Sachet (Probiotics)</li> <li>6. Ointment / Cream</li> </ol> <p>Panel recommended contract manufacturing as contract acceptor.</p>
8.	M/s. Kent Homoeopathic Pharmacy, Plot No. 30/D, Sector-15, Korangi Industrial Area, Karachi, Pakistan. Homoeopathic manufacturing facility.	<ol style="list-style-type: none"> <li>1. Syrup Section</li> <li>2. Tablet Section</li> <li>3. Encapsulation</li> <li>4. Cream / Ointment Section</li> <li>5. Sachet Section</li> <li>6. Mother Tincture &amp; Potency Drops</li> <li>7. Dry Powder Section</li> </ol>
9.	M/s. Capex Cosmetic & Pharmaceuticals Experts, Plot No. 119, Kahuta Industrial Triangle, Islamabad.	<ol style="list-style-type: none"> <li>1. Tablet Section</li> <li>2. Capsule Section</li> <li>3. Sachet Section</li> <li>4. Topical. a Cream b. Lotion)</li> <li>5. Syrup Section</li> </ol> <p>Panel recommended contract manufacturing as contract acceptor under Rule 6</p>
10.	M/s. Periodic International, Plot No. RS-23, Street No. 1, Sector 19, Korangi Industrial Area, Karachi.	<ol style="list-style-type: none"> <li>1. Sachet</li> <li>2. Liquid Syrup</li> </ol>

11.	M/s. Orbit Naturals (Pvt) Ltd., 22-KM, Adyala Road, Rawalpindi.	<ol style="list-style-type: none"> <li>1. Tablet Section</li> <li>2. Capsule Section (Hard Gelatine)</li> <li>3. Liquid Syrup Section</li> <li>4. Sachet / Powder Section</li> <li>5. Cream / Ointment Section</li> </ol> <p>Panel recommended the firm as contract acceptor.</p>
12.	M/s. Glorious Laboratories, Plot No. 136, Industrial Triangle, Kahuta Road, Islamabad.	Additional Section of Disinfectant approved subject to submission of application on prescribed Form with Fee.

Item:-II **DISCREPANCIES IN THE IMPORT DOCUMENTS OF TWO FIRMS FROM ONE PRINCIPAL MANUFACTURER:-**

(i). M/s. Graton Pharma, Suit#102, 1<sup>st</sup> Floor, The Plaza, Block-09, Clifton 2-Talwar, Karachi, Pakistan. (Agent of M/s. ESSENTIAL PHARMACEUTICAL, CORP. 1906 W. Holt Avenue Pomona, CA 91768 Dist: Los Angeles, USA).

(ii). M/s. Nutralake Healthcare, Plot # C-105, KDA Scheme # 01, Off Karsaz Road, Karachi-Pakistan. (Agent of M/s. ESSENTIAL PHARMACEUTICAL, CORP. 1906 W. Holt Avenue Pomona, CA 91768 Dist: Los Angeles, USA).

Both the firms have filed applications from the same principal manufacturer however import documents like Site Master File, Manufacturing License etc have variable contents in these documents. Site Master File of M/s. Graton Pharma and M/s. Nutralake Healthcare have same document number QA 205, revision no. 01, same effective date and review date but differing in number of pages and name of principal manufacturer. In the document of M/s. Nutralake Healthcare Life Saver Solutions, Inc. has been included as prefix to the M/s. ESSENTIAL PHARMACEUTICAL, CORP. in the Site Master File as principal manufacturer Same is included as suffixed in the Free Sale Certificate and Department of Public Health Food and Drug Branch Registration Certificate.

2. It is astonishing that both the firms have filed these documents as legalized by the Notary Public and attested by the Consulate General of Pakistan at Los Angeles and Embassy of Pakistan at Washington DC. It is interesting that Site Master File of M/s. Graton Pharma contains signatures purported to be made by the qualified technical personnel as a confidential document. Where as the Site Master File of the M/s. Nutralake Healthcare doses not bear such

signature. Agency Agreement of the M/s. Nutralake Healthcare has been signed by Mr. Justin Dam on behalf of Life Saver Solutions, Inc. while distribution agreement for USA Health Supply, Inc. has been signed by Dr. Bruce Y Lin as CEO of M/s. ESSENTIAL PHARMACEUTICAL, CORP.

**Decision:-**

The Committee after going through the variability in the import documents of one principal manufacturer i.e. M/s. ESSENTIAL PHARMACEUTICAL, CORP. 1906 W. Holt Avenue Pomona, CA 91768 Dist: Los Angeles, USA presented by the two different agents i.e. (I). M/s. Graton Pharma, Suit#102, 1<sup>st</sup> Floor, The Plaza, Block-09, Clifton 2-Talwar, Karachi, Pakistan and (II). M/s. M/s. Nutralake Healthcare, Plot # C-105, KDA Scheme # 01, Off Karsaz Road, Karachi-Pakistan is astonishing because both are presented as attested by the Notary Public and Counter Signed by the Embassy or Consulate of Pakistan. It is concluded that after such verification there exist gray areas which are being manipulated and miss used because one manufacturer registered with same registration No could not have two different particulars. This tantamounts that misrepresentation could exist even after present mechanism of attestations. The committee made following decisions.

- (i). Counter verification mechanism by any means and mechanism should be evolved for validation of attested documents.
- (ii). Both the firms who presented documents shall be asked to explain their position and their reply shall be placed before the committee for examination and if required firms shall be called upon in the forthcoming meeting of the EEC.
- (iii). Cases of importer included in the agenda item III are deferred for further evaluation.

Item:- IV **MISCELLANEOUS CASES:-**

**1. Change of Company's Name:-**

- (i). M/s. NovaMed Healthcare (Pvt) Ltd., 28-Km, Ferozpur Road, Lahore-Pakistan has requested to change their company name from NovaMed Pharmaceuticals (Pvt) Ltd (Health Care Division), 28-Km, Ferozpur Road, Lahore-Pakistan to NovaMed Healthcare (Pvt) Ltd, 28-Km, Ferozpur Road, Lahore-Pakistan in Provisional Enlistment Certificate i.e. Form-6 (E. No. 0018).
- (ii). M/s. Don Valley Phyto Pharma, 31-KM, Main Ferozpur Road, Lahore-Pakistan has requested to change their company name from Don Valley Phyto Pharma 31-KM, Main

Ferozpur Road, Lahore-Pakistan to “Don Valley (Health Division)” 31-KM, Main Ferozpur Road, Lahore-Pakistan in Provisional Enlistment Certificate i.e. Form-6 (E. No. 0037).

(iii). M/s. Bayer Pakistan (Pvt) Ltd, C-21, S.I.T.E., Karachi has requested to change their company name from M/s. Bayer Health Care, to M/s. Bayer Pakistan (Pvt) Ltd, C-21, S.I.T.E., Karachi in Provisional Enlistment Certificate i.e. Form-6 (E. No. 0027 & 0028).

**Decision:-**

The requests of the firms will be entertained for change in title subject to the following conditions:-

- (i). Application on prescribed Form with prescribed fee.
- (ii). Firm registration or company incorporation certificates which ever applicable.
- (iii). Partnership deed or Form-29 which ever applicable.
- (iv). National Tax Certificate.
- (v). Undertaking on stamp paper that the contents are true and accurate.

**2. Request for withdrawal of Applications:-**

M/s. Jasons Homoeo Pharma, Multan, Pakistan has requested for withdrawal of their application submitted before the authority for enlistment certificate due to their own problems.

**Decision:-**

Request of the firm acceded to.

**3. Incomplete Applications:-**

List of firms / companies whose applications for local manufacturing and import which are incomplete. (**Annex-D**)

**Decision:-**

The Committee after examination of cases decided to reject the applications under Rule 7 on the grounds that applicant failed to complete their applications as per prescribed criteria under the Rules despite notices of shortcomings / deficiencies.

**4. PRODUCTS ENLISTMENT OF ENLISTED MANUFACTURERS AND IMPORTERS:-**

To expedite the product enlistment before the closing date of 31<sup>st</sup> December, 2015, it is suggested that applications for enlistment of the products of those firms already enlisted are evaluated through the sub-committee constituted by EEC. Recommendation regarding products evaluation will be submitted before the EEC for final decision. This committee may be empowered to evaluate products applied by the enlisted firms and its recommendation may be placed before the enlistment evaluation committee for final decision.

**Decision:-**

Enlistment Evaluation Committee agreed to the proposal for quick disposal of product enlistment applications.

**Pakistan Zindabad**

**Disclaimer: -**

Any mistake or omission or correction may be reported to the Director (Health & OTC Division) 2<sup>nd</sup> Floor, TF Complex, Islamabad.