

No. F. 12-06/2015-DDC (Health & OTC)
Government of Pakistan
Ministry of National Health Services, Regulations & Coordination
Drug Regulatory Authority of Pakistan

Islamabad, the 31st December, 2015.

**MINUTES OF 6TH MEETING OF THE ENLISTMENT EVALUATION
COMMITTEE FOR ALTERNATIVE MEDICINES AND HEALTH
PRODUCTS.**

6th 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 31st December, 2015.

Meeting of Committee was attended by the following:-

S. #.	Name & Designation	Position in the Committee
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
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. Phytocon International (Pvt) Ltd., 339-A, Sunder Industrial Estate, Raiwind Road, Lahore.	1. Tablet 2. Capsule 3. Oral Liquid 4. Ointment / Cream 5. Sachet
2.	M/s. ZAHl Nutraceutical Laboratories, C-61, Hayatabad Industrial Estate, Peshawar.	1. Oral Liquid 2. Tablet 3. Ointment / Cream 4. Sachet 5. Capsule
3.	M/s. Tarrot Health Care, 595, Sunder Industrial Estate, Raiwind Road, Lahore.	1. Cream / Ointment 2. Sachet 3. Oral Liquid
4.	M/s. Faran Pharmacy, 14-KM, Multan Road, Near Pakistan Communication Industry, Lahore. (Homoeopathy)	1. Homoeopathic Mother Tincture 2. Homoeopathic Potencies / Dilution / Combinations 3. Tablet / Trituration / Granules 4. Oral Liquid (Syrup / Emulsion / Suspension / Drops) 5. Semi Solid (Cream / Ointment / Gel)

5.	M/s. MSG Nutraceuticals, Plot No. 32, I-9/2, Industrial Area, Islamabad.	<ol style="list-style-type: none"> 1. Tablet 2. Sachet 3. Cream / Ointment 4. Oral Liquid
6.	M/s. Paul Brooks Homoeo Labs, Plot No. A-69, S.I.T.E., Super Highway Phase-I, Karachi. (Homoeopathy)	<p>(Homoeopathic & Biochemic Sections):-</p> <ol style="list-style-type: none"> 1. Syrup 2. Tablet 3. Encapsulation 4. Cream / Ointment 5. Sachet 6. Oral Drops 7. Dry Powder <p>Herbal Sections:-</p> <ol style="list-style-type: none"> 1. Tablets 2. Capsules 3. Syrups 4. Cream / Ointments 5. Semi-Solids (Khamirah Majoons) 6. Dry Powder (Granules) 7. Distillates (ARQs)
7.	M/s. ALAQ Laboratories, 5-Main Road, Amir Town, Lahore-Pakistan.	<ol style="list-style-type: none"> 1. Tablet 2. Capsule 3. Sachet 4. Cream / Ointment 5. Oral Liquid
8.	M/s. SOIS Life Sciences (Pvt) Limited, Plot No. A-84, S.I.T.E., Phase-I, Super Highway, Karachi.	<ol style="list-style-type: none"> 1. Tablet 2. Capsules 3. Soft Gel 4. Liquid / Suspension 5. Sachet 6. Ointment / Cream
9.	M/s. Greektec (Pvt) Limited, Plot No. D-30/A (First Floor), S.I.T.E.-II, Phase-I, Super Highway, Karachi.	<ol style="list-style-type: none"> 1. Tablet 2. Capsule 3. Sachet
10.	M/s. EON PHARMACY, Plot No. A/150, Sector 11-E, New Karachi.	<ol style="list-style-type: none"> 1. Oral Liquid 2. Tablet 3. Capsule 4. Cream / Ointment 5. Sachet
11.	M/s. Rafay Laboratories (Pvt) Limited, Plot No. F/46, S.I.T.E.-II, Phase-II, Super Highway, Karachi.	<ol style="list-style-type: none"> 1. Sachet (Probiotics & Prebiotics) 2. Tablet 3. Capsule 4. Syrup 5. Ointment / Cream

12.	M/s. Biozone International, Plot No. 8, Bhengrail Road, Rawat, Islamabad.	<ol style="list-style-type: none"> 1. Tablet 2. Capsule 3. Sachet 4. Dry Powder 5. Liquid / Drop 6. Semi Solid
13.	M/s. Hinucon, Plot No. 12/1, Sector-15, Korangi Industrial Area, Karachi.	<p>After revised layout and inspection by the panel firm's following changes were approved.</p> <ol style="list-style-type: none"> 1. Chewable Tablet Section changed to Tablet Section. 2. Sachet Section changed to Capsule Section.

2. **INSPECTION REPORT WITH RESERVATION OF RESIDENTIAL AREA:-**

1.	<p>M/s. Calgan Phyto Pharma (Pvt) Ltd., Plot No. 2, Green Park Road, Near Band Road Grid Station, Lahore.</p> <p>Sections:-</p> <ol style="list-style-type: none"> 1. Tablet 2. Sachet 3. Cream / Lotion 4. Herbal Extract 5. Oral Drops 	11-11-2015	<p>01. Dr. Zaka-ur-Rehman, Chief Drug Controller, Punjab, Lahore.</p> <p>02. Mr. Asim Rauf, FID, DRAP, Lahore.</p>	<p>The firm M/s. Calgan Phyto Pharma (Pvt) Ltd was inspected in the light of letter No. F. 1-983/2015-DDC (Health & OTC) dated 29-09-2015. The firm is located at Plot No. 2, Green Park Road, Near Band Road, in a residential locality and was two storeys building approx less than 2 kanal (as per management claim.</p> <p>2. The firm possess basic manufacturing, Q.C. facilities with a suitable team of technical persons. Some of the sections were better than others liquid syrup section needed improvements in terms of walks, flooring &</p>
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					<p>atmospheric conditions etc.</p> <p>3. Keeping in view the observation facilities required at the moment for enlistment of such type of manufacturing units. Panel recommends to consider for enlistment of following sections subject to taking into consideration by the board regarding residential area policy for such type of units, as the above unit is located in residential area.</p> <p>(i). Tablet (ii). Sachet (iii). Cream / Lotion (iv). Herbal Extract (v). Oral Drops.</p>
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Decision

EEC approved the above sections subject to verification of history of the premises built in as commercial manufacturing unit and its utility connections like electricity, gas and water etc are also commercial instead of domestic.

3. **INSPECTION REPORT WITH NOT RECOMMENDED BY THE PANEL:-**

5.	<p>M/s. Alpha Neutraceuticals Research Laboratories, 21-S, Quaid-e-Azam Industrial Estate, Kot Lakhpat, Lahore.</p> <p>Sections:-</p> <ol style="list-style-type: none"> 1. Tablet 2. Oral Liquid 3. Capsule 4. Ointment / 	18-11-2015	<p>01. Dr. Sheikh Akhtar Hussain, DDG (E&M), DRAP, Lahore.</p> <p>02. Mr. Muneeb Ahmed Cheema, ADC, DRAP, Lahore.</p>	Not Good	Panel not recommended grant of enlistment certificate for manufacturing authorization.
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	Cream				
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Decision

EEC rejected the application because panel did not recommend the facility due to the reasons given in the inspection report presented by the Secretary (EEC).

Item No. 4. GRANT OF ENLISTMENT CERTIFICATES TO IMPORTERS AS AN AGENT OF PRINCIPLE MANUFACTURER.

The Enlistment Evaluation Committee considered and evaluated the case of enlistment of the following firms and granted approval

1. M/s. Base6 Private Limited, E-216, Street # 5, Cavalry Grounds, Lahore. (Agent of M/s. NATURAL FACTORS NUTRITIONAL PRODUCTS LTD. 1550, United Boulevard, Coquitlam, British Columbia, Canada, V3K 6Y2).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

2. M/s. Ferozsons Laboratories Limited, P.O. Ferozsons Amangarh Nowhshera, Khyber-Pakhtunkhwa. (Agent of M/s. Hygenic Corporation, 1245 Home Avenue, Akron Ohio 44310, U.S.A).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

3. M/s. Medinostic Health Care (Pvt) Ltd., B-18, S.I.T.E., Karachi. (Agent of M/s. Hydrachem Limited, Unit 11, Gillmans Industrial Estate, Billingshurst, West Sussex RH14 9EZ, UK).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

4. M/s. Rana Shaukat Ali, P-130/6, St-06, Fatehabad-East, Satiana Road, Faislabad-Pakistan. (Agent of M/s. Shanghai Niu Beile Bio-tech Co., Ltd., No. 2, Lane 1200, Xiechun Road, Huangdu Town, Jiading District).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

5. M/s. Al-Hamd Poultry & LiveStock Services, 31-U-Block, Khuda Bukhsh Colony, New Airport Road, Lahore Cantt. (Agent of M/s. DORADZTWO CHEMICZNE s.c. Katarzyna Łuczyńska I Michał Łuczyński ul. Jacka Kuronia, 10-165 Olsztyn, POLAND.)

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

6. M/s. TABROS PHARMA (PVT) LTD., Essa House 32-1-C, Block 6, P.E.C.H.S., Karachi.
(Agent of M/s. ANA Bio Stock Company, Lo 7, Lien ke 22, KDT Van Khe, ha Dong,Ha Noi, Viet Nam).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

7. M/s. Genetics Healthcare, 537-A, Sundar Industrial Estate, Lahore.
(Agent of M/s. Shandong Yuwang Pharmaceutical Co., Ltd., No. 2731 Tongqu Road, Yucheng City, Shandong. China).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

8. M/s. Genetics Healthcare, 537-A, Sundar Industrial Estate, Lahore.
(Agent of M/s. Hatops Corporation, Ltd. No. 28, Heng Jiang Village, Shi Qiao Town, PanYu, Guangzhou, Guang Dong, China).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

9. M/s. Genetics Healthcare, 537-A, Sundar Industrial Estate, Lahore.
(Agent of M/s. BioGrowing Co., Ltd. No. 10666, Songze Rd, Qingpu, Shanghai, 201700, China).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

10. M/s. Mass Pharma (Private) Limited, 17-KM, Ferozepur Road, Lahore-Pakistan.
(Agent of M/s. Shandong Yuwang Pharmaceutical Co., Ltd., No. 2731 Tongqu Road, Yucheng City, Shandong. China).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

11. M/s. Care Marketing, 173 (2) Block G, Model Town, Lahore.
(Agent of M/s. BIOZYME BIOTECHNOLOGY CORP. 10F., No. 10, Ln. 16, Sec. 2, Sichuan Rd., Banqiao Dist., New Taipei City 220, Taiwan (R.O.C.).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

12. M/s. ICI Pakistan Limited, Life Sciences, Pharmaceuticals, ICI House, 5 West Wharf, Karachi.
(Agent of M/s. Sirio Pharma Co., Ltd. No. 83 Taishan Rd, Shantou, Guangdong, China: No. 11, Zhuye St. (S), Huangshan Rd. Shantou, Guangdong, China).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

13. M/s. The Searle Company Limited, First Floor, N.I.C.L Building, Abbasi Shaheed Road, P.O. Box 5696, Karachi-75530.
(Agent of M/s. Chr. Hansen A/S BogeAlle 10 - 12 DK-2970 Hørsholm Denmark).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

14. M/s. Fartal Pharmaceuticals, Plot # 9, Street # 1, Model Colony, Karachi-Pakistan.
(Agent of M/s. ARVET, P.O. Box (56) Al-Hassan Industrial Estate (2146) Ramtha - Jordan).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

15. M/s. Cutis Cosmeceutical, H. No. 1177, B-Block, Satellite Town, Rawalpindi, Pakistan.
(Agent of M/s. MBH Cosmeceutical Sdn Bhd (858877-T) No. 12, Jalan Meru Indah 20, Taman Perindustrian Meru Indah, 42200 Kapar, Klang, Selangor, Malaysia).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

16. M/s. Hassan Poultry Services, 59-Kehkashan Street # 10, New North Gulgasht Colony, Multan.
(Agent of M/s. Shijiazhuang Jiangshan Animal Pharmaceutical Co., Ltd. Shangzhuang century industrial park, Luquan country, Shijiazhuang city, Hebei, China).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

17. M/s. Curative Pharmaceuticals, 285/2, House # 2, Raja Akram Road, Rawalpindi. 46000.
(Agent of M/s. Pronova Laboratories Co. Ltd, 88/100, Moo 5 Tambon Lamlukka, Pathumthani, Post Code 12150 Thailand).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

18. M/s. LACHMAN Pharmaceuticals, 2nd Floor, Pak Chambers, 5 – Temple Road, Lahore-Pakistan.
(Agent of M/s. LABORATORIOS OVEJERO, S.A. Ctra. Leon – Vilecha No 30 24192 – Leon (Spain).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

19. M/s. SHS NUTRITION, Shireen Arcade, Mezzanine Floor, Suite # 3, Plot # A-41, K.C.H.S.U Block 7/8, Karachi, Pakistan.
(Agent of M/s. Shanghai QiangSheng Wanshineng Health Co., Ltd., No. 315 Fengpao Rd, Haiwan Tourism, Fengxin Town, Fengxian District, Shanghai, China).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

20. M/s. Maxitech Pharma (Pvt) Ltd., F-55, Block-F, North Nazimabad, Karachi.
(Agent of M/s. Weihai Baihe Biology Technological Co., Ltd., No. 522, Chengda Road, Swan Lake Economic Technology Development Zone, Rongcheng, Shandong, China, 264321).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

21. M/s. MPC Health & Food, SF-13, 5th Floor, Shahnaz Arcade, Main Shaheed-e-Millat Road, Karachi-Pakistan.
(Agent of M/s. Weihai Baihe Biology Technological Co., Ltd., No. 522, Chengda Road, Swan Lake Economic Technology Development Zone, Rongcheng, Shandong, China, 264321).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

22. M/s. JAWAD IMPEX INTERNATIONAL, 21-Iftikhar Building, Chouburji, Lahore.
(Agent of M/s. INTRACARE BV Voltaweg 4, 5466 AZ VEGHEL The Netherlands).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

23. M/s. JAWAD IMPEX INTERNATIONAL, 21-Iftikhar Building, Chouburji, Lahore.
(Agent of M/s. Zagro Singapore Pte Ltd Zagro Global Hub 5 Woodlands Terrace Singapore 738460).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

24. M/s. Pak Medicine Corner, 01 & 1A Hilal-e-Ahmer Building, B.B Block, Dabgari Garderns, Peshawar Cantt.
(Agent of M/s. Principle Healthcare International Ltd., Airedale Business Centre, Millennium Road Skipton, North Yorkshire BD23 2TZ, United Kingdom).

Decision

Committee approved the grant of enlistment certificate as agent of above mentioned principal manufacturer.

Item No. 5:-

1. **ABROAD CONTRACT MANUFACTURING CASES:-**

- (i). M/s. PHAR-MAN SERVICES, Plot # 226, Sector 27, Korangi Industrial Area, Karachi.
(Agent of M/s. Gehrlicher Pharmazeutische Extrakte GmbH, Robert-Koch-Str. 5 D-82547 Eurasburg/Obb. Germany). (Contract manufacturing agreement with the Principal Manufacturer and Drug Sale License of the importer but without Agency Agreement as required under the Rules).
- (ii). M/s. PHAR-MAN SERVICES, Plot # 226, Sector 27, Korangi Industrial Area, Karachi.
(Agent of M/s. Weber & Weber International GmbH & Co. KG Herrschinger Str. 33 82266 Ommomg a, A,,ersee – Germany). (Contract manufacturing agreement with the Principal Manufacturer and Drug Sale License of the importer but without Agency Agreement as required under the Rules).

2. **DRUG MANUFACTURING LICENSE INSTEAD OF DIETARY SUPPLEMENT MANUFACTURER REGISTRATION.**

Following firms have submitted attested copies of Drug Manufacturing License. FDA was requested through email that whether Drug Manufacturing License could be use for manufacturing for Dietary Supplement. FDA responded that FDA grants registration certificate to the manufacturers of dietary supplement under the food category and drug manufacturing license is not valid for such products. They also said that they not issue any GMP Certificate nor rely on the GMP Certificate issued by the private sectors.

- (i). M/s. Heal The World, City Centre Suite 107, Marston Road, Karachi-Pakistan.
(Agent of M/s. Robinson Pharma, Inc. 3330 South Harbor Boulevard, Santa Ana, California 92704, U.S.A.).
- (ii). M/s. AAN NUTRA CARE PVT. LTD, 611, 612 & 613 Caeser Tower Opp: Ayesha Bawani School Main Shahrah-e-Faisal, Karachi, Pakistan.
(Agent of M/s. Robinson Pharma, Inc. 3330 South Harbor Boulevard, Santa Ana, California 92704, U.S.A.).
- (iii). M/s. Route2 Health (Pvt) Limited, 229-Sundar Industrial Estate, Lahore.
(Agent of M/s. GOOD N NATURAL Manufacturing Corporation, NBTY, 2100 Smithtown Avenue, Ronkonkoma, NY 11779, U.S.A.).
(Without Dietary Supplement Manufacturing License of Principal Manufacturer).
- (iv). M/s. Sigma Pharma International, 46-E/3, Block-6, P.E.C.H.S. Karachi-Pakistan.
(Agent of M/s. NBTY Manufacturing LLC 105 Orville Drive, Bohemia, NY 11716 U.S.A.). (Without Dietary Supplement Manufacturing License of Principal Manufacturer).

Decision

Agenda item No. 5 (1 & 2) is deferred for further evaluation on the basis of Principal decision given below.

Basic decision:-

- 1. Exclusive Sole Agency Agreement shall be provided from the Principal Manufacturer for the products / formulations which are on Free Sale and authorized to be marketed in the local market.**
- 2. Countries like USA where Nutraceutical products or Dietary Supplements or Health Supplements are categories separate from the Allopathic Drugs, Drug Manufacturing License will not be acceptable as manufacturing authorization. Relevant manufacturing authorization from the regulatory authority shall be submitted by the applicant.**

3. **Manufacturing Authorization as drug shall be submitted by the applicants from the regulatory authorities where the Herbal products are categorized as drugs like EU Countries.**
4. **Manufacturing units having both type of facilities shall be required to submit both authorizations, otherwise only the products of the facility whose manufacturing authorization have been submitted will be entrained for enlistment.**
5. **Only applicants having Sole Agency Agreement for the product with Principal Manufacturer / Legal Owner abroad will be entrained.**
6. **Valid GMP Certificate issued by the regulatory authority based on inspection report shall be sufficient to replace inspection report. Otherwise inspection report by the regulatory authority shall be required to be submitted for enlistment.**
7. **This decision will be applicable on all the applicants, in item 4, item 5 sub item 1 & 2 and already enlisted firms.**

Item No. 6:- MISCELLANEOUS CASES:-

1. Incomplete Applications:-

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

Decision:-

Deferred as the notices issued to the firms were late dispatched by the section and time period given to the applicants have not been fulfilled.

2. Change of Company's Name:-

Reference to the 5th Meeting of EEC M/s. NovaMed Healthcare (Pvt) Ltd., 28-Km, Ferozepur Road, Lahore-Pakistan has requested to change their company name from NovaMed Pharmaceuticals (Pvt) Ltd (Health Care Division), 28-Km, Ferozepur Road, Lahore-Pakistan to M/s. NovaMed Healthcare (Pvt) Ltd, 28-Km, Ferozepur Road, Lahore-Pakistan in Provisional Enlistment Certificate i.e. Form-6 (E. No. 0018).

2. M/s. NovaMed Healthcare (Pvt) Ltd, 28-KM, Ferozepur Road, Lahore-Pakistan has submit the requisite information. Application of M/s. Bayer and Don Valley are awaited.

Decision:-

The change of name of M/s. NovaMed Healthcare (Pvt) Ltd., 28-KM, Ferozepur Road, Lahore-Pakistan approved. Similarly other firms will be entrained accordingly.

Item No. 7:- MISCELLANEOUS CASES:-

1. 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. Aulton Neutraceuticals, Plot 84/1, Block A/1, Phase V, Industrial Estate, Hattar.	1. Tablet 2. Capsule 3. Sachet 4. Oral Liquid
2.	M/s. ALAST Phytoceuticals, First Floor, SF, Unit No. 40-41, S.I.T.E. Area, Karachi.	1. Tablet 2. Capsule 3. Oral Liquid 4. Ointment / Cream 5. Sachet / Powder 6. Majoon
3.	M/s. Stiflex Pharmaceuticals (Consumer Healthcare Division), 33-B, Small Industrial Estate, Bahtar Road, Wah Cantt.	1. Tablet 2. Capsule 3. Sachet 4. Cream / Ointment 5. Oral Liquid (Syrup)

Pakistan Zindabad

Disclaimer: -

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