

F.No. 4-01/2013-DC (Misc. 13-PSC -Pt-Meeting)  
Directorate General of Health Services  
Office of Drugs Controller General (India)  
(FDC Division)

FDA Bhawan,  
Kotla Road, New Delhi

Dated: **26 MAY 2014**

To

1. Dr. Kamlakar Tripathi, Prof., Dept. of Medicine, Institute of Medical Sciences, BHU, Varanasi – 221 005
2. Dr. T.K. Dutta, Prof. & Head, Dept. of Medicine, JIPMER, Puducherry
3. Dr. B.Gupta, Prof. in General Medicine, North Delhi Medical College & Hindu Rao Hospital, Malkaganj, New Delhi – 110 007.
4. Dr. Manjula Bhargava, Prof. & Head, Dept. of Pharmacology, SMS Medical College, Jaipur – 302 004
5. Dr. Sayed Moeid Ahamed, Associate Professor, Dept. of Anaesthesia and critical care, Alligarh Muslim University, Aligarh, UP
6. Dr. Buddhadar Chowdhury, Addl. Professor, Dept. of Orthopaedic, JPNATC, AIIMS, Main Hospital, Ansari Nagar, Infront of Safdarjung Hospital, New Delhi - 110 029

**Subject:-** Third Meeting of the Expert Committee on 04.06.2014 at 11:00 a.m. to 6:00 p.m. in the Conference Room, 1<sup>st</sup> floor, FDA Bhawan, Kotla Road, Near National Bai Bhawan, New Delhi-110002, to examine the matters related to approval of the safety and efficacy of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG(I) – regarding.

Sir,

Reference is invited to this Directorate's Office Memorandum No. 4-01/2013-DC (Misc13-PSC) dated 03.02.2014 on the subject cited above.

This office in the following proposals for approval of Fixed Dose Combinations seeks your expert opinion of Expert Committee as to whether based on the data submitted by the firm, these proposals can be approved.

S.No.	Name of firm/ Institute	Drug
1	BRD Medilabs	3 tablets of Serratiopeptidase (enteric coated 20000 units) IP 10mg +Diclofenac Potassium BP 50mg & 2 tablets of Doxycycline HCL IP 100mg Kit
2	1.Life Care Formulations 2.Macsur Pharma India Pvt Ltd 3.Synokem Pharmaceutical Ltd 4.Akums Drugs & Pharmaceuticals Ltd 5.Talent Healthcare	1.Aceclofenac 100mg + paracetamol 325 mg + thiocolchicoside 4 mg film coated tablet 2.aceclofenac 100 mg + paracetamol 325 mg + thiocolchiside 4 mg/8 mg film coated tablet 3.Aceclofenac 100mg +Paracetamol 325mg +Thiocolchicoside 4mg Film coated Tablet 4.Aceclofenac 100mg/100mg +Paracetamol 325mg/325mg +Thiocolchicoside 4mg/8mg Tablets 5.Aceclofenac 100mg +Paracetamol 325mg +Thiocolchicoside 8mg Film Coated Tablets

	6.Embiotic Laboratories 7.Acme Formulations	6.Aceclofenac 100mg +Paracetamol 500mg +Thiocolchicoside 4mg/8mg Film Coated Tablets  7.Aceclofenac 100mg +Paracetamol 325mg +Thiocolchicoside 4mg/8mg Tablets
3	Wockhardt Ltd	aceclofenac IP 200 mg + rabeprazole sodium 20 mg Tablet
4	Akums Drugs & Pharmaceuticals Ltd	Aceclofenac IP 100mg +Paracetamol IP 325mg +Rabeprazole Sodium IP 10mg Enteric Coated tablets
5	Aeon Formulations	Drotaverine HCl IP 80mg + Clidinium Bromide USP 2.5mg + Chlordiazepoxide IP 5mg Film Coated Tablets
6	1.Talent Healthcare  2.Windlas Biotech	1.Lornoxicam IP 8mg +Paracetamol IP 325mg +Serratiopeptidase IP 15mg Film Coated tablets  2.Lornoxicam 8mg +Paracetamol IP 325mg +Serratiopeptidase IP 15mg Tablets
7	1 Talent Healthcare  2.Windlas biotech.	1.Lornoxicam IP 100mg +Paracetamol IP 325mg + Tramadol IP 37.5mg Film Coated tablets  2.Tramadol hydrochloride 37.5 mg + paracetamol 325 mg + lornoxicam 8 mg film coated bilayered tablet
8	Orbit Lifesciences	Lornoxicam 8mg +Paracetamol 325mg +Trypsin150000 AU Tablets
9	Akums Drugs & Pharmaceuticals	Paracetamol IP 300mg +Mefenamic Acid IP 150mg +Ranitidine HCL 100mg +Dicyclomine HCl IP 10mg Tablets
10	1.Vivimed labs  2.Psychotropics India Ltd  3.Wockhardt Ltd	1.Tramadol HCl 37.5 mg + paracetamol 325 mg + dicyclomine HCl 10 mg capsules  2.Tramadol HCl 37.5mg +Dicyclomine HCl 20mg +Paracetamol IP 500mg Uncoated Tablets  3.Dicyclomine hydrochloride 10 mg/20 mg + tramadol hydrochloride 50 mg/ 37.5 mg + Acetaminophen 325 mg capsule
11	Macsur Pharmaa	Naproxen 300mg/550mg +Paracetamol IP 325mg Film Coated Tablets
12	Acme Formulations	Tapentadol 50mg +Paracetamol 325mg Tablets

A meeting has been convened on 04.06.2014 to evaluate the above proposals.


You are requested to kindly make it convenient to attend the said meeting on the said date.

TA/DA for attending the meeting as well as honorarium will be paid as per this Directorate's Office Memorandum No. 4-01/2013-DC (Misc13-PSC) dated 03.02.2014. If travelled by Air, it should be by Indian Airlines only and the air tickets, if purchased through agent, should be purchased through M/s Balmaer Laurie & Co. who are the authorized Govt. agent for this purpose.

You are requested kindly to make it convenient to attend the said meeting on 04.06.2014 at 11:00 a.m. to 6:00 p.m. in the Conference Room, 1<sup>st</sup> floor, FDA Bhawan, Kotla Road, Near National BalBhawan, New Delhi-110002.

You are requested to confirm your participation by e-mail at [fdedivision@gmail.com](mailto:fdedivision@gmail.com).

Yours faithfully,

  
(Dr. G.N. Singh)  
Deputy Drugs Controller General (I)


Copy to:

1. M/s. BRD MediLabs, Mr. Rahul Bansal, No. 23, DIC Industrial Area, Baddi, Himachal Pradesh - 173 205.
2. Lifecare Formulations Pvt. Ltd. Plot No. 2 & 3, 91/5, Link Road, Sonia Gandhi Nagar Extn. Near Mettupalayam Industrial Estate, Mettupalayam, Puducherry – 605 009.
3. M/s. Synokem Pharmaceuticals Pvt. Ltd. Plot No. 35/36, Sector 6A, IIE, SIDCUL, Ranipur, Haridwar-249403, Uttrakhand.
4. Macsur Pharmaa India Private Limited, 361, A, Vazhudavur Main Road, Mathirayar Palayam, Pondicherry.
5. M/s. Talent healthcare, 66,67 sector 6A, SIDCUL, Haridwar, Uttarakhand-249403.
6. M/s. Akums Drugs & Pharmaceuticals Ltd., 19 to 21, Sector 6-A, IIE, Ranipur, Haridwar.
7. M/s. Embiotic Laboratories (P) Ltd. #20C, Ist Phase, Kumbalgodu Industrial Area, Mysore Road, Kumbalgodu, Bangalore – 560 074.
8. M/s. Acme Formulations Pvt. Ltd., Ropar Raod, Nalagarh, Distt. Solan, H.P.-174101.
9. M/s. Wockhardt Limited, Wockhardt Towers, BandraKurla Complex, Bandra (East), Mumbai-400051.
10. M/s. Windlas Healthcare (P) Ltd., Plot No. 183 & 192, Mohabewala Industrial Area, Dehradun-248110, Uttarakhand.
11. M/s. Aeon Formulations Pvt. Ltd., R.S. No. 515/2 & 515/2 & 514, no. 152/7, Vinayagar Koil Stret, Thirubuvanaipalayam, Mannadipet Commune, Puducherry-605107.
12. M/s. Orbit Lifescience Pvt. Ltd. 13, kailash Darshan, 4th Floor, Nana Chowk, Mumbai – 400007.
13. M/s. Psychotropics India Limited, A-32, Sector -11, Opposite G. E. Motors, Faridabad, Haryana – 121007.
14. M/s. Vivimed Labs Ltd., D-9, Industrial Area, Haridwar, Uttarakhand.

**Note for Firms:**

- You are requested to depute your technical team for presentation. As application for same FDC have been received from multiple applicants, you are requested to be present at CDSCO on 04.06.2014 at 11:00 a.m. to 6:00 p.m. in the Conference Room, 1<sup>st</sup> floor, FDA Bhawan, Kotla Road, Near National Bal Bhawan, New Delhi - 110 002 to make presentation as considered necessary by the committee.
- Also requested to submit the copy of the presentation of the respective proposals before 3 days of the meeting date.
- Also requested to bring Drug Samples in original pack as well as package insert while coming for presentation.
- Any other manufacturer who have applied above FDC's may also present their case before the committee.

Yours faithfully,

  
(Dr. C.N. Singh)  
Drugs Controller General (I)