

**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. Renuka Kulkarni Munshi, Associate Prof. & Incharge, Clinical Pharmacology, TN Medical College & BLY Nair Charitable Hospital, Mumbai
2. Dr. Iqbal Kaur, Prof. & Head, dept. of Microbiology, UCMS, New Delhi
3. Dr. Subhash Giri, Dept. of Medicine, UCMS, New Delhi
4. Dr. Niranjana Mohanty, Prof. & Head, Dept. of Paediatrics, SCB Medical College, Cuttack-753014.
5. Dr. B.Gupta, Prof. in General Medicine, North Delhi Medical College & Hindu Rao Hospital, Malkaganj, New Delhi – 110 007.

**Subject:-** Fourth Meeting of the Expert Committee on 11.06.2014 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-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.

Age nda no.	Name of firm/ Institute	Drug
1	1.Hetero Labs 2. Valence Healthcare 3. Relax Pharmaceuticals 4. East West Pharma 5. FDC Ltd 6. Akums Drugs & Pharmaceuticals Ltd	1. Azithromycin 125mg/250mg/500mg + Cefixime 100mg/200mg/200mg Tablets 2.Cefixime (As Trihydrate) 200mg +Azithromycin Drihydrate IP 250mg Film Coated Tablets 3. Cefixime 200/200mg + azithromycin 250/500mg Tablet 4. Cefixime Trihydrate IP 200mg +Azithomycin Dihydrate IP 500mg Film Coated tablets 5. Cefixime 100mg +Azithromycin 125mg Dispersible tablets 6. Azithromycin 250mg/500mg +Cefixime 200mg/200mg Tablets
2	MDC Pharmaceuticals	Cefixime IP eq. to anhydrous Cefixime 200mg +Acetyl Cysteine USP 300mg Film Coated Tablets
3	Akums Drugs & Pharmaceuticals	Cefixime IP eq. to anhydrous Cefixime 400mg +levofloxacin Hemihydrate IP eq. to Levofloxacin 500mg Tablets

4	1.Talent Healthcare 2.Macleods Pharmaceuticals 3.Aeon Formulations 4.Aeon Formulations 5.Orbit Lifesciences	1. Cefpodoxime Proetile IP 200mg +Azithromycin Dihydrate IP 250mg Film Coated tablets 2. Cefpodoxime Proxetil 200mg +Azithromycin 250mg Film Coated Tablets 3. Cefpodoxime 320mg +Azithromycin 500mg Tablets 4. Cefpodoxime 100mg +Azithromycin 125mg Dispersible tablet 5. Azithromycin Dihydrate IP eq. to Azithromycin 250mg/500mg +Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg Film Coated tablets
5	Orbit Life Science	cefpodoxime proxetil 200 mg + dicloxacillin sodium 500 mg tablets
6	Relax pharmaceuticals Pvt. Ltd	Cefpodoxime proxetil 200 mg + levofloxacin hemihydrate 250 mg tablets
7	1.Akums Drugs & Pharmaceuticals 2.Gelnova laboratories 3.Synokem pharma 4.Hetero Labs	1.Levofloxacin 250mg/500mg +Azithromycin 250mg/500mg Tablets 2.Anhydrous Azithromycin 250mg/500mg + Anhydrous Levofloxacin 250mg/500mg Tablets 3.Azithromycin 250 mg/500 mg + Levofloxacin 250 mg/500 mg film coated tablet 4.Azithromycin 250mg/500mg +Levofloxacin 250mg/500mg Tablets
8	Arion Healthcare	Beclomthasone Dipropionate 0.025%w/v + Clotrimazole 1%w/v + Chloramphenicol 5%w/v +Gentamycin Sulpahte 0.3%w/v + Lignocaine HCl 2%w/v Ear Drops
9	Aeon Formulations	Ciprofloxacin HCl IP 250mg +Phenazopyridine HCl USP 200mg Film Coated Tablets
10	Alembic Pharmaceuticals	Roxithromycin IP 150mg +Serratiopeptidase 10mg Film Coated Tablets
11	1.Akums drugs & pharmaceuticals limited 2.Bushal Healthcare	1.Sulphadiazine sodium 100 mg + trimethiprim 20 mg oral powder 2.Trimethoprim IP 200mg +Sulphadiazine IP 1000mg Uncoated Tablets

A meeting has been convened on 11.06.2014 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 Ministry of health & Family Welfare order No. X.19029/5/2011-DFQC dated 31.3.2011. 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 11.06.2014 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 [fdcddivision@gmail.com](mailto:fdcddivision@gmail.com).

Yours faithfully,



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

Copy to:

1. M/s. Hetero Labs Ltd., Hetero Corporate, Industrial Estates, H. No. 7-2-A2, Sanathnagar, Hyderabad-500018, Andhra Pradesh.
2. M/s. East West Pharma, No. 10, 2nd Cross, Maravaneri, Salem – 636007, Tamil Nadu.
3. M/s. Akums Drugs & Pharmaceuticals Ltd., 19 to 21, Sector 6-A, IIE, Ranipur, Haridwar.
4. M/s. MDC Pharmaceuticals Pvt. Limited, Plot No. 213, Industrial Area, Phase I, Chandigarh-160002.
5. M/s. FDC Limited, 142-48, S.V. Road, Jogeshwari (W), Mumbai-400102.
6. M/s. Talent healthcare, 66,67 sector 6A, SIDCUL, Haridwar, Uttarakhand-249403.
7. M/s. Relax Pharmaceuticals, 48-B, Industrial Area, Comdpur Paonta Sahib, Himachal Pradesh.
8. M/s. Valence Healthcare, Plot No. 8 & 9, New Industrial Area, Village Bai Attarian, P.O. Kandrori, (Near Pathankot) Tehsil: Indrora, Dist. Kangra, Himachal Pradesh
9. M/s. Macleods Pharmaceuticals Ltd., Atlanta Areade, 3 rd Floor, Church Road, Near Leela Hotel, Andheri-Kurla Road, Andheri (E), Mumbai-400059.
10. 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.
11. M/s. Orbit Lifescience Pvt. Ltd. 13, kailash Darshan, 4th Floor, Nana Chowk, Mumbai – 400007.
12. M/s. Synokem Pharmaceuticals Pvt. Ltd. Plot No. 35/36, Sector 6A, IIE, SIDCUL, Ranipur, Haridwar-249403, Uttrakhand.
13. Gelnova Laboratories (I) Pvt. Ltd., C-125 TTC Industrial Area,, Mahape (Pawane), Pawane Midc Road Number 7, Electornic Zone, Mahape, Navi Mumbai, Maharashtra 400705.
14. M/s. Arion Healthcare Private Limited, Mr. Abhay Jain, SCO 907, 2nd Floor, N.A.C., Manimajra, Chandigarh - 160017, Chandigarh.
15. M/s. Alembic Pharmaceuticals Ltd., Alembic Road, Vadodara-390003, Gujarat.
16. M/s. Relax Pharmaceuticals Pvt. Ltd. (Unit-11), 49-A-B, Gomdipur Industrial Area, Paonta Sahib, Distt. Sirmour (H.P.)-173025.

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 11.06.2014 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 - 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. G.N. Singh)  
Drugs Controller General (I)