

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: 04 APR 2014

To

1. Dr. Santanu Tripathi, Prof. & Head, Dept. of Clinical & Experimental Pharmacology, School of Tropical Medicine, Chittaranjan Avenue, Kolkata - 700 012.
2. Dr. Surendra K. Sharma, Prof. & Head, Dept. of Medicine, AIIMS, Main Hospital, Ansari Nagar, Infront of Safdarjung Hospital, New Delhi - 110 029
3. Dr. Rajender Prasad, Prof. & Head, Dept. of Pulmonary Medicine, Vallabh Bhai Patel Chest Institute, Guru Tegh Bahadur Road, University Enclave, New Delhi - 110 007
4. Dr. A.U. Athavale, Professor & Head of Chest Medicine & Chief of E.P.R.C, Seth GS Medical College & KEM Hospital, Mumbai
5. Dr. Usha Acharya, Prof. & Head, Dept. of Paediatrics, SMS Medical College, Jaipur

Subject:- Second Meeting of the Expert Committee on 23.04.2014 at 11:00 a.m. to 6:00 p.m. in the Conference Room, 1st 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.

S.No.	Name of firm/ Institute	Drug
1	Restech pharma	chlorpheniramine maleate 2.5 mg + dextromethophan 5mg + dextromethophan HBr 50 mg + guaiphenesin 60 mg + ammonium chloride + menthol 1 mg Syrup
2	Naxpar pharma	dextromethorphan hydrobromide 5 mg + phenylephrine HCl 5 mg + ammonium chloride 50 mg + menthol 2.5 mg syrup
3	1.DM pharma	1.levocetizine HCl 2.5 mg + ambroxol HCl 60 mg + phenylepherineHCl 5 mg + paracetamol 325 mg tablets
	2.BRD Medilabs	2.LevoCetizine Dihydrochloride IP 5mg +Phenylephrine HCl IP 5mg +Ambroxol IP 30mg +Paracetamol IP 325mg Tablets
	3.Tee & TEE Health care	3.LevoCetizine Dihydrochloride 2.5mg +Phenylephrine HCL 5mg +Paracetamol 325mg +Ambroxol 60mg Uncoated Tablet
	4.Rivpra Formulations	4.LevoCetizine HCl IP 5mg +Ambroxol HCl IP 30mg +Phenylephrine HCL IP 5mg +Paracetamol IP 325mg Tablets
	5.Arion Healthcare	5.LevoCetizine HCl IP 2.5mg/5mg +Paracetamol IP 325mg/500mg +Ambroxol Hclp IP 30mg/60mg +Phenylephrine HCl IP 5mg Uncoated tablet

	6.Akums Drugs & Pharmaceuticals 7.Noel Pharma 8.Unix Biotech 9.Windlas Biotech 10.Cipla Ltd., 11.Logos Pharma 12.Akums Drugs & Pharmaceuticals Ltd	6.LevoCetrizine HCl IP 2.5mg/2.5mg +Phenylephrine HCl IP 5mg/10mg +Ambroxol HCl IP 60mg/60mg +Paracetamol IP 500mg/325mg Tablets 7.LevoCetrizine HCl IP 5mg +Phenylephrine HCl IP 5mg +Ambroxol HCl IP 30mg +Paracetamol IP 325mg Uncoated Tablets 8.LevoCetrizine HCl IP 5mg +Phenylephrine HCl IP 5mg +Ambroxol HCl IP 60mg +Paracetamol IP 325mg Tablets 9.LevoCetrizine HCl 2.5mg +Paracetamol 325mg +Phenylephrine HCl 10mg +Ambroxol HCl 30mg Tablets 10.LevoCetrizine HCl 5mg +Phenylephrine HCl 5mg +Ambroxol HCl 30mg +Paracetamol 325mg Tablets 11.LevoCetrizine IP 2.5mg +Phenylephrine IP 5mg +Ambroxol IP 60mg +Paracetamol IP 325mg Uncoated Tablets 12.Paracetamol IP 500mg/325mg +Levocetizine HCl IP 2.5mg/5mg +Phenylephrine HCl IP 5mg/5mg +Ambroxol HCl IP 60mg/30mg Tablets
4	Akums Drugs & Pharmaceuticals Ltd	LevoCetrizine Hcl IP 2.5mg +Ambroxol Hcl IP 30mg +Phenylephrine Hcl IP 5mg +Paracetamol IP 250mg per 5ml Suspension
5	1.Akums Drugs & Pharmaceuticals 2.Suncare Formulations 3.Ravian life science 4.Wallace Pharmaceuticals 5.Swiss Garnier	1.Paracetamol IP 325mg +Chlorpheniramine Maleate IP 2mg +Phenylephrine HCl IP 5mg Tablets 2.Paracetamol IP 325mg +Phenylephrine HCl IP 5mg +Chlorpheniramine Maleate IP 2mg Solid Oral/Tablets 3.phenylephrine hydrochloride 5 mg + chlorpheniramine maleate 4 mg + paracetamol 325 mg uncoated tablet 4.Paracetamol 325mg +Phenylephrine HCL 10mg +Chlorampheniramine Maleate 2mg Tablet 5.Paracetamol 250mg +Phenylephrine HCL 2.5mg +Chlorampheniramine Maleate 1mg Tablet
6	1.Akums Drugs & Pharmaceuticals Ltd 2.Aeon Formulations	1.Acebopphylline 50mg +Guaiphenesin IP 50mg +Terbutaline Sulphate IP 1.25mg per 5ml Syrup 2.Terbutaline Sulphate 1.25mg +Acebopphylline 50mg +Guaiphenesin 50mg Syrup
7	Phoenix Biologicals	Acebopphylline 200mg +Montelukast Sodium IP 10mg +Desloratadine 5mg Film Coated Bilayered Tablets
8	Sun Pharmaceuticals Industries	Acebopphylline 200mg +Montelukast Sodium IP eq. to Montelukast 10mg Tablets
9	Psychotropics India	Acetaminophen 125mg +Guaiphenesin 25mg +Dextromethorphan Hydrobromide 7.5mg +Chlorpheniramine Maleate 5mg/1mg Syrup
10	1.RPG life science 2.Pro Laboratories	1.Acetaminophen 500mg +Phenylephrine HCL 10mg +Chlorpheniramine Maleate 2mg +Caffeine 30mg Tablet 2.Caffeine (Anhydrous) IP 30mg +Paracetamol IP 35mg +Phenylephrine HCl IP 2.5mg +Chlorpheniramine Maleate IP

		2mg Uncoated tablet
3.Acme Lifesciences		3.Caffeine IP 30mg +Chlorpheniramine Maleate IP 2mg +Paracetamol IP 500mg +Phenylephrine HCl IP 5mg Uncoated Tablets
4.CIAN Healthcare		4.Chlorpheniramine Maleate IP 2mg +Phenylephrine HCl IP 5mg +Paracetamol IP 325mg +Caffeine Anhydrous IP 30mg Uncoated Tablets
5.Micro labs ltd		5.paracetamol 325mg + phenylephrine HCL 10 mg+ chlorpheniramine Maleate 2 mg + caffeine 30 mg tablets
6.AGIO pharmaceuticals		6.paracetamol 500 mg + phenylephrine hydrochloride 10 mg + caffeine 30 mg + chlorpheniramine maleate 2mg uncoated tablet
7.Alembic Pharmaceuticals		7.Paracetamol IP 500mg/500mg +Chlorpheniramine Maleate IP 2mg/2mg +Phenylephrine HCl IP 10mg/5mg +Caffeine IP 30mg/30mg Uncoated Tablets
8.Akums Drugs & Pharmaceuticals		8.Paracetamol IP 500mg/500mg +Phenylephrine HCl IP 10mg/10mg +Caffeine IP 32mg +Chlorpheniramine Maleate IP 2mg Combikit (Film Coated Tablets)
9.Kaizen Pharmaceuticals		9.Paracetamol IP 325mg +Phenylephrine HCl IP 5mg +Caffeine IP 16mg +Chlorpheniramine Maleate IP 2mg Uncoated Tablets
10.BRD Medilabs		10.Paracetamol IP 325mg +Phenylephrine HCl IP 10mg +Chlorpheniramine Maleate IP 2mg +Caffeine anhydrous IP 30mg Tablets
11.Sain Medicaments		11.Paracetamol IP 325mg +Phenylephrine HCl IP 5mg +Chlorpheniramine Maleate IP 2mg++Caffeine anhydrous IP 30mg Film Coated Tablets
12.Swiss Garnier		12.Paracetamol IP 325mg +Phenylephrine HCL IP 10mg +Chlorpheniramine Maleate IP 2mg +Caffeine IP 30mg Uncoated tablets
13.GENPHARMA		13.paracetamol 325mg + phenylephrine hydrochloride 10 mg + chlorpheniramine maleate 2 mg + caffeine 30 mg uncoated tablet
14.Noel Pharma		14.Paracetamol 325mg +Phenylepherine HCl 10mg +Chlorpheniramine Maleate 2mg +Caffeine 30mg Uncoated tablet
15.Agron Remedies		15.Paracetamol 500mg +Phenylepherine HCl 5mg +Chlorpheniramine Maleate 2mg +Caffeine 30mg Tablets
16.Akums drugs & pharmaceuticals		16.Paracetamol 500mg/500mg/325mg +Phenylephrine HCL 10mg/10mg/10mg +Chlorpheniramine Maleate 2.5mg/5mg/5mg + caffeine 30mg/30mg/30mg Film coated tablet
17.Akums Drugs & Pharmaceuticals		17.Paracetamol 500/500/325/325/325/325mg +Phenylephrine HCL 5/5/5/10/10/10mg +Chlorpheniramine Maleate 2/2/2/4/2/4mg + caffeine 15/20/30/16/30/15mg Tablet

	18.RIVPRA Formulations	18.Paracetamol 325mg +Phenylprine HCl IP 10mg +Chlorpheniramine Maleate IP 4mg +Caffeine 20mg Uncoated Tablets
	19.Shiva Biogenetic Pharmaceutica	19.Phenylephrine HCl IP 5mg +Chlorpheniramine Maleate IP 2mg +Caffeine IP 20mg/30mg +Paracetamol IP 325mg Tablets
11	1.MDC Pharmaceuticals 2.Symbiotic Drugs & Diabetic 3.Akums Drugs & Pharmaceuticals Ltd 4.Healer's Lab	1.Acetyl Cysteine BP 300mg +Ambroxol HCl IP 30mg Film Coated Tablets 2.Ambroxol HCl IP 30mg +Acetyl-Cysteine USP 300mg Film Coated Tablets 3.Ambroxol Hydrochloride IP 30mg +N-Acetyl L-Cysteine USP 300mg Tablets 4.Acetylcysteine BP 300mg +Ambroxol HCl IP 30mg Uncoated Tablets
12	swiss garnier	Acetylcysteine 300mg + ambroxol hydrochloride 60 mg hard gelatin capsules
13	1.Prim research laboratories 2.Safetab Life Science 3.GKM New Pharma 4.Sozin Flora Pharma	Montelukast sodium 10 mg + levocetirizine dihydrochloride 5mg + ambroxol hydrochloride 60 mg film coated tablet Montelukast Sodium IP 10mg +LevoCetirizine Dihydrochloride IP 5mg +Ambroxol HCl IP 75mg Uncoated Bilayered Tablets Montelukast Sodium 10mg +LevoCetirizine HCl IP 5mg +Ambroxol HCL IP 75mg Uncoated Tablets LevoCetirizine HCl 5mg +Montelukast Sodium IP eq. to Montelukast 10mg +Ambroxol HCl IP 75mg Tablets

A meeting has been convened on 23.04.2014 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 23.04.2014 at 11:00 a.m. to 6:00 p.m. in the Conference Room, 1st 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.

Yours faithfully,


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

Copy to:

1. M/s. Restech Pharma, B-184/185, PIPDIC Industrial Estate, Mettupalayam, Pondicherry. P.C. 605009, Pondicherry.
2. M/s. Naxpar Pharma Pvt. Ltd. 104-107, Bldg. No.8, Jogani Industrial Complex, Chunabhatti, Sion, Mumbai- 400 022.
3. M/s. DM Pharma, NH 21-A, Bhud, Baddi, Soian (H.P.) 173205.
4. M/s. BRD MediLabs, Mr. Rahul Bansal, No. 23, DIC Industrial Area, Baddi, Himachal Pradesh - 173 205.
5. M/s Rivpra Formulation Pvt Ltd, Plot No. 08, Sec- 6A, IIE SIDCUL, BHEL Industrial Area, Ranipur, Haridwar - 249403, Uttranchal.
6. M/s. Arion Healthcare Private Limited, Mr. Abhay Jain, SCO 907, 2nd Floor, N.A.C., Manimajra, Chandigarh - 160017, Chandigarh.
7. M/s. Akums Drugs & Pharmaceuticals Ltd., 19 to 21, Sector 6-A, IIE, Ranipur, Haridwar.
8. M/s. NOEL Pharma, 24-85/7, Laxminarayana Nagar Colony, New I.D.A., Uppal, Hyderabad - 500 039.
9. M/s. Unix Biotech, Mr. Asif Ali, Plot No. 27, Phase No. 1, E. P. I. P., Jharmajari, Baddi District, Solan - 173205, Himachal Pradesh.
10. M/s. Windlas Healthcare (P) Ltd., Plot No. 183 & 192, Mohabewala Industrial Area, Dehradun- 248110, Uttarakhand.
11. M/s. Cipla Limited, Mumbai Central, Mumbai-400008.
12. M/s. Logos Pharma Village Maissa Tibba, Tehsil Nalgarh, District-Solan -174 101, Himachal Pradesh.
13. M/s. Suncare Formulations Pvt. Ltd., E-20, UPSIDC Industrial Area, Selakai, Dehradun - 248007, Uttarakhand.
14. M/s. Ravian Life Science Pvt. Ltd. Vivek Anand Shahi, Plot No. - 34, Sector 8a, SIDCUL, IIE, Haridwar - 249403, Uttarakhand
15. M/s. Wallace Pharmaceuticals Ltd. B-307/312, Floral Deck Plaza, Off. Central MIDC Road, Andheri (East), Mumbai - 400 093.
16. M/s. Swiss Garnier Life Sciences, No. 21-23 Industrial Area Mehatpur, Dist. UNA, H.P. 174315.
17. 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.
18. M/s. Phoenix Biologicals Pvt Ltd., R.S No. 135/2B, Kotha Puri, Natham Road, Thiruvondar Koil, Puducherry, 605107.
19. M/s. Psychotropics India Limited, A-32, Sector -11, Opposite G. E. Motors, Faridabad, Haryana - 121007.
20. M/s. Sun Pharmaceuticals Industries Ltd., Tandalja, Vadodara-390020.
21. M/s. RPG Lifesciences Ltd., 25, MIDC Land, thane Belapur Road, Navi Mumbai-400705.
22. M/s. Pro Laboratories Pvt. Pvt. Ltd., 140-141, Makkanpur, Bhagwanpur, Roorkee Dist Haridwar, Haridwar Uttrakhand, Haridwar - 249401.
23. M/s Rivpra Formulation Pvt Ltd, Plot No. 08, Sec- 6A, IIE SIDCUL, BHEL Industrial Area, Ranipur, Haridwar - 249403, Uttranchal.
24. M/s. Shiva Biogenetic Pharmaceuticals Pvt. Ltd., Village Manpura, Nalagarh, District Solan, Near Le Meriot Hotel, Baddi - 174101, Himachal Pradesh.
25. M/s. MDC Pharmaceuticals Pvt. Limited, Plot No. 213, Industrial Area, Phase I, Chandigarh-160002.
26. M/s. Symbiotic Drugs & Diabetic Care Pvt. Ltd., Jharmajri Baddi, Dist. Solan, Himachal Pradesh-173205.
27. M/s. Healers Lab, Plot No. 112, HPSIDC, Baddi - 173205, Himachal Pradesh.
28. Safetab Life Sciences, Plot No. A-67 & 68, Electronic Park, Thirubuvanai, Tamil Nadu.
29. Prim Research Laboratories, Sujam Formulations Pvt Ltd, No 68/137, 2nd floor, Kundrathur Road, Porur, Chennai - 600 116, Tamil nadu,
30. Sozin Flora, Nr. Govt. School , Nahan Road , Village Moginand, Kala Amb, Distt. Sirmour,- 173030 , Himachal Pradesh.

31. M/s. GKM New Pharma, Spl. Type Plot No. 5, 6, 7 and 8, PIPDIC Electronic Park, Thirubuvanai, Mannadipet Commune, Puducherry-605107.

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 23.04.2014 at 11:00 a.m. to 6:00 p.m. in the Conference Room, 1st 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 manufacturers who have applied above FDC may also present their case before the committee.

Yours faithfully,

(Dr. G.N. Singh)

Drugs Controller General (I)