

**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: **12 AUG 2014**

To

1. Dr. Krishna Biswas, Prof. & Head, Deptt. Of Endocrinology, Vardhman Mahavir Medical College & Safdarjung Hospital, Delhi.
2. Dr. Nikhil Tandon, Professor, Dept. of Endocrinology & Metabolism, AIIMS, New Delhi.
3. Dr. Anil Bansali, Addl. Prof. & Head, Deptt. Of Endocrinology, PGIMER, Chandigarh.
4. Dr. Neeraj Kumar Agrawal, Associate Professor, Dept. of Endocrinology and Metabolism, Institute of Medical Sciences (I.M.S.), BHU, Varanasi.
5. Dr. Shantanu Tripathi, Department of Clinical & Experimental Pharmacology, School of Tropical Medicine, Chittaranjan Avenue, Kolkata-700012.

**Subject-** Sixth Meeting of the Expert Committee on 27.08.2014 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 (Misc 13-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	1. Shield Healthcare	1. Benfotiamine 75mg + Metformin HCl 500mg Tablets
	2. Safetab Life Science	2. Benfotiamine 75 /100 mg + metformin HCl 500 mg tablets
	3. Goodman Pharmaceuticals	3. Metformin HCl 500mg + Benfotiamine 75mg Tablets
2	1. East West Pharma	1. Glibenclamide IP 5mg + Metformin HCl IP 850mg Uncoated Tablets
	2. Darwin Formulations	2. Metformin HCl 800mg + Glibenclamide 5mg Tablets
3	Sun Pharma	Glibenclamide + Metformin HCl + Pioglitazone HCl 5mg + 500mg + 7.5mg Tablets
4	1. Indu drugs pvt ltd	1. Gliclazide 80 mg + metformin hydrochloride 325 mg Tablets
	2. Dr. Reddy's Laboratories	2. Gliclazide 40mg + Metformin HCl 500mg Tablets
	3. Sun Pharmaceuticas	3. Gliclazine 1mg/2mg + Metformin HCl 850mg/850mg Tablets
	4. Ravian Life Science	4. Metformin HCl 500mg + Gliclazide 80mg Tablet

5	1. windlas biotech 2. Swiss Garnier 3. Glenmark Pharmaceuticals 4. Ordain Healthcare 5. ALCHEMIST Ltd., 6. Windlas Biotech 7. Akums Drugs Pharmaceuticals Ltd & 8. USV limited	1. glimepiride 3mg/4 mg + metformin hydrochloride 1000/1000 mg tablets 2. Glimepiride IP 2mg + Metformin HCl (ER) 850mg Film Coated Tablets 3. Glimepiride IP 3mg +Metformin HCl IP 1000mg Uncoated Bilayered tablet 4. Glimepiride IP 1mg/2mg +Metformin HCl (as sustained release) 500mg/500mg Tablets 5. Glimepiride IP 2mg +Metformin HCl IP 500mg Uncoated Tablets 6. Glimepiride 1mg/2mg/3mg +Metformin HCl 850mg/850mg/850mg Tablets 7. Glimepiride 4mg +Metformin HCl SR 1000mg tablet 8. metformin hydrochloride 500mg + glimepiride 0.5 mg tablet
6	1. Akums Drugs Pharmaceuticals Ltd & 2. Windlas Biotech 3. windlas biotech 4. M/s. Acme Formulation 5. Inventia Healthcare 6. Swiss Garnier 7. Swiss Garnier 8. USV Ltd. 9. USV Ltd	1. Glimepiride IP 1mg/2mg +Pioglitazone HCl IP 7.5mg/7.5mg +Metformin HCl IP 500mg/500mg Tablets 2. Glimepiride IP 1mg/2mg +Pioglitazone HCl IP 7.5mg/7.5mg +Metformin HCl IP 1000mg/1000mg Tablets 3. glimepiride 1mg/2mg + pioglitazone hydrochloride 15mg/15 mg + metformin hydrochloride 850 mg/ 850 mg tablets 4. Metformin HCL 1000/1000/500/500mg +Pioglitazone HCL 7.5/7.5/7.5/7.5mg + Glimepiride 1/2/1/2mg Tablets 5. Metformin HCL 500mg +Pioglitazone HCL 7.5mg + Glimepiride 1mg/2mg Tablets 6. Metformin HCl 850mg +Pioglitazone HCl 7.5mg +Glimepiride 1mg Tablets 7. Metformin HCl 850mg +Pioglitazone 7.5mg +Glimepride 2mg Tablets 8. Pioglitazone HCl 15mg +Metformin HCl 500mg +Glimepiride 1mg/2mg Tablets 9. Pioglitazone HCl 7.5mg +Metformin HCl 500mg +Glimepiride 1mg/2mg Tablets
7	Glenwell Pharma	Glipizide IP+Metformin HCl IP 2.5mg+400mg Uncoated tablet
8	1. Safetab Life Science 2. Inventia Healthcare 3. Goodman Pharmaceuticals	1. Mecobalamin JP 750mcg +Metformin HCl IP 500mg/1000mg Film Coated Tablets 2. Metformin HCl IP 500mg/1000mg +Methylcobalamin 750mcg/1500mcg Tablets 3. Metformin HCl IP 500mg +Methylcobalamin JP 500mcg Uncoated Tablets

	4.Aeon Formulations	Uncoated Tablets
	5.sunglow pharma	4.Metformin HCl IP 1000mg +Methylcobalamin JP 750mcg Film Coated Tablets 5.methylcobalamin 750 mcg/750 mg/1550 mcg + metformin HCL 500 mg/1000 mg/1000mg tablets
9	1.Savi Pharma	Metformin HCl ER 1000mg +Gliclazide MR 60mg +Voglibose 0.2mg uncoated bilayered tablet
10	GKM New Pharma	Metformin HCl IP 1000mg +Atorvastatin Calcium IP 20mg Film Coated Tablets

A meeting has been convened on **27.08.2014** to evaluate the above proposals.

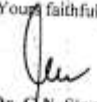
You are requested to kindly make it convenient to attend the said meeting on the said date.

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 is the authorized Govt. agent for this purpose.**

You are requested kindly to make it convenient to attend the said meeting on **27.08.2014** 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)  
Drugs Controller General (I)

**Copy to:**

1. M/s. Shield Health Care Pvt. Ltd., No: 66, Second Cross Street, Pallavan Nagar Extn, Maduravoyal, Chennai - 600095, Tamilnadu.
2. M/s. Safetab Life Sciences, Plot No. A-67 & 68, PIPDIC Electronic Park, Thirubuvanaï, Puducherry-605107.
3. M/s. Goodman pharmaceuticals, PLOT No. B3 To B8, PIPDIC Electronic Park, Thirubhuvanai, Pondicherry -605 107.
4. M/s. East West Pharma, No. 10, 2nd Cross, Maravaneri, Salem - 636007, Tamil Nadu.
5. M/s. Darwin Formulations Pvt Ltd., 54-18-374, A 1 R Colony, Benz Circle, Vijayawada, Andhra Pradesh 520008.
6. M/s. Sun Pharma Advanced Research Company Ltd., Tandalja, Vadodara, Gujarat.
7. M/s. Indu Drugs Pvt. Ltd., 5-35/278/279, Prasanthi Nagar, I D A, Kukatpally, Hyderabad, Andhra Pradesh 500072.
8. M/s. Dr. Reddy's Laboratories Ltd., 7-1-27, Ameerpet, Hyderabad-500016, A.P.

9. M/s. Raylan Life Science Pvt. Ltd, Vivek Anand Shahi, Plot No. - 34, Sector 8a, SIDCUL, IIE, Haridwar - 249403, Uttarakhand.
10. M/s. Windias Biotech Limited, 40/1 Mohabewala Industrial Area, S.B.I Road, Saharanpur Highway, Dehradun- 248002, Uttaranchal
11. M/s. Swiss Garnier Life Sciences, No. 21-23 Industrial Area Mehatpur, Dist. UNA, H.P. 174315.
12. M/s. Glenmark Pharmaceuticals Ltd., B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai-400026.
13. M/s. Ordain Health Care Global Private Limited, Sri Devi Temple Towers, No. 6, Second Main Road., Sembakkam, Chennai, Tamil Nadu 600073.
14. M/s. Alchemist Ltd., 23, Nehru Place NEW DELHI 110019.
15. M/s. Akums Drugs & Pharmaceuticals Ltd., 19 to 21, Sector 6-A, IIE, Ranipur, Haridwar.
17. M/s. USV Limited, Arvind Vithal Gandhi Chowk, BSD Marg, Station Road, Govandi East, Mumbai - 400 088.
18. M/s. Acme Formulations Pvt. Ltd., Ropar Road, Nalagarh, Distt. Solan, H.P.-174101.
19. M/s. Inventia Healthcare Pvt. Ltd., F1-F1/1, Additional Ambernath, M.I.D.C. Ambernath (East) 421506, Dist-Thane.
20. M/s. GLENWELL PHARMA, No. 52/7, Ramanathapuram Road, Ramanathapuram Village, Puducherry-605502
21. 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.
22. M/s. Sunglow Pharmaceuticals Pvt. Ltd., Plot No. 29-38, Opposite to Co-operative Milk Dairy (Ponlait), Kurumbapet, Pondicherry-605009.
- 23.
24. M/s. GKM New Pharma, Spl. Type Plot No. 5 to 8, PIPDIC Electronic Park, Thirubuvanal, Mannadipet Commune, Puducherry-605107.
25. M/s. Savi Pharma Limited.

**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 **27.08.2014** 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. G.N. Singh)

Drugs Controller General (I)