

**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. Dipankar Bhattacharyya, Prof. & Head, Dept. of Pharmacology, IPGMER & SSKM, Kolkata
2. Dr. Sudhir Gupta, Professor & Head, Dept. of Gastroenterology, Government Medical College & Super Speciality Hospital, Tukdoji Square, Nagpur, Maharashtra.
3. Dr. Goswami, Prof. & Head, Dept. of Hepatology, Guwhati Medical College, Guwhati
4. Dr. Sanjeev Sachdeva, Deptt. of Gastroenterology, G.B. Pant Hospital, New Delhi
5. Dr. K. Narayan, Prof. & Head, Dept. of Hepatology, Madras Medical College and Rajiv Gandhi General Council Hospital, Chennai.

**Subject:-** Seventh Meeting of the Expert Committee on 29.08.2014 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 (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	1.Vivimed labs	1.Magnesium hydroxide 98 mg + aluminium hydroxide 0.291 g + oxetacaine 10 mg oral liquid
	2.Restech pharma	2.Dried aluminium hydroxide gel 300 mg + magnesium hydroxide 100 mg + oxetacaine 10 mg Liquid suspension
	3.Acron Pharmaceutical	3.Oxetacaine 10mg +Aluminium Hydroxide 0.298mg +Magnesium Hydroxide 98mg Oral Suspension
	4.Skan research lab	4.Dried aluminium hydroxide gel 150 mg + magnesium hydroxide 150 mg + oxetacaine 5 mg suspension
	5.Selvok Pharmaceuticals	5.Oxetacaine BP 10mg +Aluminium Hydroxide eq. to dried Aluminium Hydroxide Gel IP 0.291gm eq. to 0.380gm +Magnesium Hydroxide IP 98mg Suspension
2	1.FDC Ltd	1.Aluminium hydroxide gel 250mg +Magnesium hydroxide 250mg +Simethicone 50mg +Oxetacaine 10mg Oral suspension
	2.Livin Formulations	2.Aluminium hydroxide paste+ Magnesium hydroxide Paste+Simethicone+Oxetacaine 1.57gm+1.25gm+50mg+10mg Suspension

3	<p>1.Espi Industries</p> <p>2.Espi Industries</p>	<p>1.Alginic Acid 200mg +Sodium Bicarbonate 70mg +Dried Aluminium Hydroxide 300mg +Magnesium Hydroxide 50mg Chewable Tablets</p> <p>2.Alginic Acid 200mg +Sodium Bicarbonate 70mg +Dried Aluminium Hydroxide 150mg +Magnesium Hydroxide 75mg Chewable Tablets</p>
4	<p>1.Pharma Synth Formulations</p> <p>2.Abaris Healthcare</p> <p>3.Indoco Remedies</p> <p>4.unibiotech formulations</p> <p>5.Indoco Remedies</p> <p>6.Dagon Pharmaceuticas</p> <p>7.Next Wave</p>	<p>1.Activated Dimethicone IP 40mg +Dill Oil BP 0.005ml +Fennel Oil 0.0007ml Oral Liquid</p> <p>2.Dill Oil 0.005ml +Fennel Oil 0.0007ml +Simethicone Emulsion USP 40mg Oral Liquid</p> <p>3.Dimethicone IP 40mg +Dill oil BP 0.005ml +Fennel oil USP 0.0007ml Syrup</p> <p>4.Simethicone emulsion 40 mg + fennel oil Dill oil 0.007 ml + 0.005 ml drop suspension</p> <p>5.Simethicone Emulsion USP eq. to Simethicone USP 40mg +Dil Oil BP 0.005ml +Fennel oil USP 0.0007ml Oral Drops</p> <p>6.Simethicone emulsion 40mg +Dill oil 0.005ml +Fennel oil 0.0007 ml Coligo drops</p> <p>7.Simethicone 40mg +Dill Oil 0.005ml +Fennel oil 0.0007ml Oral Liquid</p>
5	<p>1.Pharma Synth Formulations</p> <p>2.Espi Industries</p> <p>3.Galpa Laboratories</p> <p>4.Wallace Pharmaceuticals</p>	<p>1.Activated Dimethicone IP 50mg +Magnesium Hydroxide IP 250mg +Dried Aluminium Hydroxide Gel IP 250mg +Sorbitol Solution 1.25gm Suspension</p> <p>2.Activated Dimethicone 50mg++Magnesium Hydroxide 250mg +Dried Aluminium Hydroxide 250mg +Sorbitol Solution (70%) Non-Crystallizing 0.650gm Oral Liquid</p> <p>3.Aluminium Hydroxide Paste IP 300mg +Magnesium Hydroxide Paste IP 200mg +Activated Dimethicone IP 125mg +Sorbitol Solution 750mg Syrup</p> <p>4.Aluminium Hydroxide 300mg +Magnesium hydroxide 250mg +activated dimethicone 40mg +sorbitol solution 1000mg liquid oral</p>
6	<p>1.Shivalik Remedies</p> <p>2.Rexer pharma</p> <p>3.Livin Formulations</p>	<p>1.Activated Simethicone IP 40mg +Magnesium Hydroxide IP 400mg +DRIED Aluminium Hydroxide Gel IP400mg Suspension</p> <p>2.almunim hydroxide 250mg + magnesium hydroxide 250mg + simethicone 50 mg suspension</p> <p>3.Aluminium hydroxide Paste eq. to Dried Aluminium Hydroxide gel 1.57gm eq. to 250mg +Magnesium hydroxide Paste eq. to Maghesium Hydroxide IP 1.14gm eq. to 250mg +Simethicone IP</p>

	<p>4.RPG Lifesciences</p> <p>5.Cartel laboratories</p> <p>6.Hema Laboratories</p>	<p>50mg Oral Suspension</p> <p>4.Dried Aluminium Hydroxide BP 300mg +Magnesium Hydroxide BP 150mg +Simethicone BP 40mg Uncoated Tablets</p> <p>5.Simethicone 50 mg + magnesium hydroxide gel 250 mg + aluminium hydroxide gel 250 mg suspension</p> <p>6.Simethicone 50.0mg +Dried Aluminium Hydroxide Gel 250.0mg +Magnesium Hydroxide 250.0mg Monorin-MPS Suspension</p>
7	<p>1.Hippo Labs</p> <p>2.Unibiotech Formulations</p> <p>3.Shreya Life Sciences</p> <p>4.Cartel Laboratories</p> <p>5.Noel Pharma</p> <p>6.Laborate Pharmaceuticals</p> <p>7.Elan Pharma</p> <p>8.Sain Medicaments</p>	<p>1.Alpha Amylase (1:2000) 10mg +Papain 20mg Syrup</p> <p>2.Alpha Amylase IP 100mg +Papain IP 50mg Syrup</p> <p>3.Alpha Amylase IP 125mg +Papain IP 40mg Syrup</p> <p>4.Fungal Diastase IP 50mg +Papain IP 10mg Syrup</p> <p>5.Fungal Diastase IP 12.5mg +Papain IP 7.5mg Syrup</p> <p>6.Fungal Diastase IP 50mg +Papain IP 60mg Syrup</p> <p>7.Diastase IP 100mg +Papain IP 60mg Tablets</p> <p>8.Fungal Diastase (1:1200) IP 50mg +Papain IP 60mg Syrup</p>
8	<p>1.Darwin Formulations</p> <p>2.Shreya Life Sciences</p> <p>3.parnax lab ltd</p> <p>4.Sunrise International Labs</p> <p>5.Elder Pharmaceutical Ltd</p> <p>6.Noel Pharma</p> <p>7.GKM New Pharma</p> <p>8.Versatile Pharma</p> <p>9.P &amp; B Phameaceuticals</p> <p>10.Cartel laboratories</p> <p>11.BHC Lab</p>	<p>1.Alpha Amylase (1:2000 ) 50mg +Pepsin IP 10mg Syrup</p> <p>2.A-Amylase (Fungal Diastase 1:800 from Aspergillus oryzae) IP 62.5mg +Pepsin IP 20mg Solution for Oral administration</p> <p>3.alpha-amylase 62.5 mg + pepsin 20 mg oral syrup</p> <p>4.Diastase IP (Fungal Diastase derived from aspergillus oryzae digests not less than 60gms of cooked strach) 50mg + Pepsin IP 10mg Syrup</p> <p>5.Diastase IP 50mg + Pepsin 10mg Oral Liquid</p> <p>6.Diastase 33.33mg +Pepsin 5mg Drops</p> <p>7.Diastase 50mg +Pepsin 10mg Syrup</p> <p>8.Fungal Diastase (1:1200) IP 50mg +Pepsin (1:3000) IP 10mg Syrup</p> <p>9.Fungal Diastase (1:2500) 62.5mg +Pepsin IP 20mg Oral Liquid</p> <p>10.fungal diastase 50 mg + pepsin 10 mg syrup</p> <p>11.Fungal Diastase IP (1:1200) IP 50mg +Pepsin IP (1:2000) 10mg Hard Geletin Capsules</p> <p>12.Fungal Diastase IP (1:1200) IP 50mg +Pepsin IP (1:3000)</p>

12. Dr. Sain's Laboratories	10mg Syrup
13. Hippo Labs	13. Fungal Diatase (1:1200) 50mg + Pepsin (1:3000) 10mg Syrup

A meeting has been convened on **29.08.2014** to evaluate the above proposals.

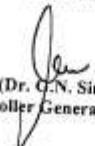
You are requested to kindly make it convenient to attend the said meeting on the said date.

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 **29.08.2014** 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 BaiBhawan, 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:**

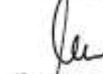
1. M/s. Vivimed Labs Ltd., D-9, Industrial Area, Haridwar, Uttarakhand.
2. M/s. Rstech Pharma, B-184/185, PIPDIC Industrial Estate, Mettupalayam, Pondicherry, P.C. 605009, Pondicherry.
3. M/s. Aeron Pharmaceuticals, 38/2, Main Road, G.I.D.C., Estate, Naroda, Ahmedabad-382330, Gujarat.
4. M/s. Skan Research Lab Pvt. Ltd., # 3/7-e, Thirubuvanai, Mahnadipet Commune, Villianur, Pondicherry, P.C. 605107, Pondicherry.
5. M/s. Selvok Pharmaceuticals, 147, G.I.D.C., Amalia, Billimora - 396 321, Dist. Navsari, Gujarat.
6. M/s. FDC Limited, 142-48, S.V. Road, Jogeshwari (W), Mumbai-400102.
7. M/s. Wallace Pharmaceuticals Ltd. B-307/312, Floral Deck Plaza, Off. Central MIDC Road, Andheri (East), Mumbai - 400 093.
8. M/s. Espi Industries & Chemicals Pvt. Ltd., Plot No. M-7/2, Kakatiya Nagar, Habsiguda, Hyderabad-500007.
9. M/s. **Pharmasynt Formulations Limited,** A-10/15, Jhilmil Industrial Area, Delhi-110095.
10. M/s. ABARIS HEALTHCARE PRIVATE LIMITED, 406, Saffron, Panchvati, Ambavadi, Ahmedabad - 380 006.
11. M/s. Unibiotech Formulations, Mr. J.K. Gulati, SCO-272, 1st Floor, Sector-32- D, Chandigarh - 160030.
12. M/s. Dagon Pharmaceuticals Pvt Ltd., Opp Gurdwara, Baddi - Nalagarh Road, Manpura P.O., Pinjore-Swarghat Rd, Baddi, Himachal Pradesh 174102.
13. M/s. Indoco Remedies Limited, Indoco House, 166, CST Road, Santa Cruz (East), Mumbai 400 098.
14. M/s. Next Wave (India), CORPORATE OFFICE, C 980 Sushant Lok, Phase I

- Gurgaon - (Haryana)- 122002.
15. M/s. Galpha Laboratories LtdG Babu Sakpal Marg, Worli, Mumbai, Maharashtra 400018.
  16. M/s. NOEL Pharma, 24-85/7, Laxminarayana Nagar Colony, New I.D.A., Uppal, Hyderabad - 500 039.
  17. M/s. Pro Laboratories Pvt. Pvt. Ltd., 140-141, Makkanpur, Bhagwanpur, Roorkee Dist Haridw Haridwar Ultrakhand, Haridwar - 249401.
  18. M/s. Shivalik Remedies Pvt. Ltd., Khasra No. 509/1-2 & 520, Village Bhagwanpur Mus, Roor Dehradun Road, Bhagwanapur. P.C. 247667, Roorkee.
  19. M/s. Rexer Pharma Pvt Ltd,Phase-II, Ida, Cherlapally, Cherlapally, 114/2/B, Telangana 500051.
  20. M/s. RPG Lifesciences Ltd., 25, MIDC Land, Thane Belapur Road, Navi Mumbai-400705.
  21. M/s. Cartel Laboratories, 24-112/4, Ln Colony, Near Gvk Bio, IDA, Uppal, Hyderabad - 500039
  22. M/s. Hema Laboratories Pvt. Ltd., Selaqui Industrial Area Pharma C Dehradun-248197, Uttarakhand.
  23. M/s. Hippo Labs PVT LTD., Goutham Nagar, 8 273 Old Air Port Road, Hyderabad, Hyderabad 500011.
  24. M/s. Shreya Life Sciences Private Limited, Shreya House 301/A, Parera Gill Road, Andheri E Andheri East, Mumbai, Maharashtra 400093.
  25. M/s. Laborate Pharmaceutical India Limited, E-11, Ind. Area, Panipat-132103.
  26. M/s. Elan Pharma India Pvt. Ltd., 501, Raikar Chamber, Govandi, Deonar E, Govandi, Muml Maharashtra 400088
  - 29.M/s. Sain Medicaments Pvt. Ltd., 10, HVES Building, Sultan Bazar, Hyderabad-500095.
  28. M/s. Darwin Formulations Pvt Ltd., 54-18-37/4, A I R Colony, Benz Circle, Benz Circle, Vijayawada, Andhra Pradesh 520008.
  29. M/s. Parmax Lab Private Limited, 104-107, Building, No-8, Jogani Industrial Estate, Chumabhatti Station, Sion, Sion, Mumbai, Maharashtra 400022.
  30. M/s. Sunrise International Labs, Plot No 100, Phase-II IDA, Cherlapally, Hyderabad 500051 AP.
  31. M/s. Elder Pharmaceuticals Pvt. Ltd., Elder House, Plot no. C-9, Dalia Industrial Estate, Off Veera Desal Road, Andheri (W), Mumbai-400053.
  32. M/s. GKM New Pharma, Spl. Type Plot No. 5 to 8, PIPDIC Electronic Park, Thirubuvanai, Mannadipet Commune, Puducherry-605107.
  33. M/s. Versatil Pharmaceuticals Pvt. Ltd. #5-62, Street No. 8, Habasiguda Hyderabad - 500007.
  34. M/s. P & B Pharmaceuticals Limited, A/09, Ashirwad,11 Lokhandwala Complex, Andheri (W), Mumbai-400 053.
  35. M/s. BHC Lab Private Ltd. Factory: Unit II, 91/2, D.I.C., Baddi, Distt. Solan (H.P.)
  36. M/s. Dr Sains Laboratories, 1054 N S Road Hariharpur, South Twenty Four Parganas, West Bengal.

**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 **29.08.2014** 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. C.N. Singh)  
Drugs Controller General (I)