

File No. 4-01/2013-DC (Misc. 13-PSC) (Pt. II)
Govt. of India
Directorate General of Health Services
Central Drugs Standard Control Organization
(FDC Division)

Dated: 22 MAY 2019

NOTICE

Subject: Procedure to be followed for subsequent applicants in respect of FDCs falling under category 'd' as per Prof. Kokate Committee report (i.e. FDCs which require generation of data)-regarding.

This is with reference to this office letter dated 15.01.2013 whereby all the State/UT Drugs Controllers were requested to ask the concerned manufacturers in their State to prove the safety and efficacy of FDCs within 18 months which were permitted by State Licensing Authorities without due approval from the office of DCG(I).

After examination of such applications in consultation with Prof. Kokate Committee constituted by Ministry of Health and Family Welfare, concerned manufacturers were earlier asked to conduct Phase IV study in post-market scenario for generation of data to decide further on such FDCs falling under category 'd' as per the report of the Committee.

Subsequently, this Directorate received representations from various stakeholders requesting for waiver of Phase IV clinical trial. The matter was examined by this Directorate in consultation with Prof. Kokate Committee and after due deliberation, the Committee recommended for categorization of these FDCs into following sub-groups:-

- I. FDCs which require Phase IV trial (Post-Marketing Trial/Bioequivalence Study) as per Drugs & Cosmetics Rules, 1945.
- II. FDCs for which Active Post Marketing Surveillance shall be conducted under intimation to DCG (I) and report shall be submitted for further evaluation.

Further, this Directorate also received representations from the subsequent applicants for obtaining NOC for manufacturing and marketing w.r.t. FDCs falling under category 'd' to have a level playing field. The list of FDCs falling under category 'd' is enclosed as **Annexure A**.

With the approval of Ministry, it has been now decided to follow the pathway for clearance of such subsequent applications as under:-

1. Documents required in case of manufacturers already holding licenses from State Licensing Authority (SLA) before 01.10.2012 for the proposed FDCs shall at least contain:-
 - a) Form CT 21(duly filled, signed and stamped)

- b) Fees as specified in sixth schedule of New Drugs and Clinical Trials Rules 2019 through Bharatkosh.
 - c) Name and composition of the FDC
 - d) Product Permission issued by SLA
 - e) Copy of Manufacturing license in Form 25/28
 - f) Sl. no. and name of FDC as per the "**Annexure A**" and
 - g) Phase IV trial protocol/commitment for conducting Active Post Marketing Surveillance study/Bio-equivalence study protocol, as the case may be.
2. Documents required in case of new manufacturers for the proposed FDCs shall at least contain:-
- a) Form CT 21(duly filled, signed and stamped)
 - b) Fees as specified in sixth schedule of New Drugs and Clinical Trials Rules 2019 through Bharatkosh.
 - c) Name and composition of the FDC
 - d) Product Permission issued by SLA in Form 29
 - e) Copy of Manufacturing license in Form 25/28
 - f) Sl. no. and name of FDC as per the "**Annexure A**"
 - g) Stability studies data (06 months accelerated)
 - h) Test Specifications of the FDC alongwith Method of Analysis
 - i) Phase IV trial protocol/commitment for conducting Active Post Marketing Surveillance study/Bio-equivalence study protocol, as the case may be.
3. All the manufacturers who are already holding licenses from State Licensing Authorities for such FDCs before 01.10.2012 and did not apply to DCG (I) are required to submit their applications to this Directorate at the earliest but not later than 6 months, failing which their applications will not be considered and their licenses will be considered as without legal validity.

In view of above, all concerned stakeholders are required to follow above procedure for clearance of such cases.

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

To:-

All State/UT Drugs Controllers/All Zonal/Sub Zonal offices of CDSCO.

Copy to:-

- 1. PS to JS(R), Ministry of Health and Family Welfare, Nirman Bhawan, New Delhi.
- 2. Drug Manufacturing Associations: IDMA/OPPI/IPA/CIPI/FOPE etc.

List of FDCs falling under category "d" as per Prof. Kokate Committee Report

ANNEXURE A

Sr.No.	Name of FDC	Final recommendation
1	Diastase (Fungal Diastase IP (1:2000)+Cinnamon Oil BP+Caraway Oil BP+Cardamom Oil BP)(40mg+250mcg+500mcg+500mcg) Solution each 10 ml	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
2	Paracetamol Ip+ phenylephrine Hydrochloride + chlorpheniramine maleate(250 mg+ 5 mg+ 2 mg) syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation, if the formulation is in oral dosage form.
3	Acebrofylline 100mg + Acetylcysteine BP 600mg film coated bilayer tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
4	Aceclofenac + Thiocolchicoside + Methyl Salicylate + Menthol + Camphor liniment (15mg+0.25mg+250mg+50mg+10mg)	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
5	Aceclofenac IP 100mg+Pregabalin IP 75mg film coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
6	Aceclofenac IP 200mg+Misoprostol 200mg hard gelatin capsules	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
7	Acetyl Cysteine BP 300mg +Ambroxol HCl IP 30 mg tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
8	Acetylcysteine 300mg + Ambroxol hydrochloride 60mg hard gelatin capsules	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
9	Activated Dimethoicone 40mg+Dill Oil 0.005ml+Fennel Oil 0.0007ml liquid orals	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
10	Alpha Amylase (Bacterial 1:800) IP 100mg + Papain IP 50mg +Dil Oil BP 10 mg +Anise Oil BP 10mg +Caraway Oil BP 10 mg drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

11	Alpha amylase (bacterial 1:800) IP 20 mg + Papain IP 10 mg +Dil oil BP 2 mg +Anise Oil BP 2mg +Caraway Oil BP 2mg drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
12	Alpha Amylase (Fungal 1:800) IP 20mg+Papain IP 10mg+Dill Oil IP 2mg+Anise Oil IP 2mg+Caraway Oil IP 2mg drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
13	Alpha Amylase 20mg+Papain 10mg+Dil oil 2mg+Anise oil 2mg+Caraway oil 2mg syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
14	Alpha Amylase 20mg+Papain 10mg+Dill Oil 2mg+Anise Oil 2mg+Caraway Oil 2mg oral Liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
15	Alpha Galactosidase 150mg+Lipase Enzyme 3mg+Alpha Amylase 50mg+Protease Enzyme 25mg+Lactase USP 7mg hard gealtin capsules	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
16	Alpha-Amylase (Fungal Diastase 1:800 from Aspergillus oryzae) IP 20mg+Pepain IP 10mg+Dill Oil BP 2mg+Anise Oil BP 2mg+Caraway Oil BP 2mg drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
17	Alpha-Amylase (Fungal Diastase 1:800 from Aspergillus oryzae) IP 31.25mg+Pepsin IP 10mg+Cardamom Oil BP 0.4mg+Cinnamon Oil BP 0.4mg drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
18	Alpha-Amylase IP 20mg+Papain IP 10mg+Dill Oil BP 2mg+Anise Oil BP 2mg+Caraway BP 2mg oral drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
19	Alpha-Amylase IP 9mg+Papain IP 5mg+Thiamine HCl IP 1mg +Riboflavin 5-phosphate sodium IP 1mg +Pyridoxine HCl IP 1 mg +Cyanocobalamin IP 1.0mcg + Niacinamide IP 10mg +Cyproheptadine HCl IP 0.5 mg Drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
20	Alprazolam 0.25mg+Fluxeotine HCl 20mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
21	Ambroxol HCl IP 30mg+N-Acety L-Cyteine USP 200mg film coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

22	Ambroxol Hydrochloride + salbutamol Sulphate IP Eq. to Salbutamol + Guaiphenesin+ mentholated flavoured syrup base (7.5 mg+ 0.5 mg+12.5 mg per ml drops)	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
23	Amitriptyline HCl IP 10mg/25mg+Mecobalamin (SR) 1500mcg film coated bilayered tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
24	Amitryptilline IP 12.5mg/25mg/25mg + Chlordiazepoxide IP 5mg/5mg/10mg tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
25	Amoxicillin Trihydrate eq. to Amoxycillin 250mg+Cloxacillin Sodium eq. to Cloxacillin 250mg hard gelatin capsule	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
26	Amoxicillin Trihydrate IP 250mg + Cloxacillin Sodium 250 mg + Saccharomyces Boulardii 40 million spores hard gelatin capsules	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
27	Amoxycillin Trihydrate IP eq. to Amoxycillin 200mg + Potassium Clavulanic Diluted IP eq. to Clavulanic acid 28.5 mg dispersible tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
28	Arginine IP 500mg+Folic Acid IP 500mcg+Pyridoxine HCL IP 1.5mg+Ubidecarenone USP 15mg+Vitamin B12 IP 205mg+Lycopene USP 2.5mg+Piperine 2.5mg soft gelatin capsules	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
29	Betahistine Dihydrochloride 16mg + Domperidone 10mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
30	Betahistine Hcl 24mg+Ginkgo biloba extract 60mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
31	Bismuth Citrate USP126mg + Belladonna dry Extract IP 9mg oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
32	Brimonidine 0.2%w/v+Timolol 0.5%w/v+BKC 0.02%w/v eye drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

33	Brimonidine 0.2%w/v+Timolol 0.5%w/v+BKC 0.2%w/v eye drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
34	Chlordiazepoxide 10mg/5mg/5mg + Trifluoperazine 1mg/1mg/0.5mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
35	Chlordiazepoxide 10mg+Trifluoperazine Hcl 1mg sugar coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
36	Chlordiazepoxide IP 10 mg + Amitriptyline Hydrochloride IP (in extended release form)25mg uncoated bilayered tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
37	Chlordiazepoxide IP 10 mg + Trifluoperazine Hydrochloride IP eq. to Trifluoperazine 1mg + Trihexyphenidyl Hydrochloride IP 2mg film coated tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
38	Chlordiazepoxide IP10 mg/10 mg + Trifluoperazine HCl IP Eq. to Trifluoperazone 1mg/2mg film coated tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
39	Chlorpheniramine maleate 2 mg + Phenylephrine HCl 5 mg + PCM 250 mg + Menthol IP Syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
40	Chlorpheniramine maleate 2 mg + Phenylephrine HCl 2.5 mg + PCM 125 mg per 5 ml syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
41	Chlorpheniramine Maleate 4 mg + Phenylephrine HCl 5 mg + Paracetamol 325 mg tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation . however the dose of paracetamol should be 500 mg.
42	Chlorpheniramine Maleate IP 1.0 mg+Paracetamol IP 125 mg+Phenylephrine HCl IP 2.5 mg Oral liquid each ml	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
43	Chlorpheniramine Maleate IP 1.5mg+Phenylephrine Hcl IP 2.5mg+Paracetamol IP 125mg+Menthol IP 1mg suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

44	Chlorpheniramine Maleate IP 2mg+Phenylephrine HCl IP 5mg+Paracetamol IP 325mg uncoated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation . However the dose of paracetamol dose should be 500 mg.
45	Chlorpheniramine maleate IP+Paracetamol IP+Phenylephrine Hydrochloride IP (2mg+250mg+5mg) syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
46	Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Paracetamol IP (4mg+5mg+500mg) tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
47	Chlorpheniramine maleate+Phenylephrine HCl +Paracetamol IP(2mg+2.5mg+125mg) suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
48	Clomiphene Citrate IP 100mg+N-Acetylcysteine USP 600mg+Astaxanthin 4mg combi pack of tablets & capsules	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
49	Clomiphene Citrate IP 50mg+N-Acetyl Cysteine USP 600mg+Astaxanthin 4mg combipack tablets /capsules	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
50	Clonazepam 0.25 mg/0.25mg + Propranolol Hcl 10 mg/20 mg each film coated tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
51	Clonazepam IP 0.5mg/0.5mg/0.25mg+Propranalol HCl IP 20mg/10mg/20mg uncoated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
52	Desvenlafaxine 50mg+Clonazepam IP 0.5mg film coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
53	Desvenlafaxine Succinate eq. to Desvenlafaxine 100mg/50mg + Clonazepam 0.5mg/0.5mg uncoated bi-layered tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
54	Diastase (1:2000) (fungal derived from aspergillus oryzae)+ Cardamom oil+Caraway oil+Cinnamon oil (40mg+500mg+500µg+250µg) per 10 ml syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

55	Diastase (1:2000) IP (derives from fungal-Aspergillus oryzae) + Cinnamon Oil BP+Caraway Oil BP+Cardamom Oil BP (20mg+0.2mg+0.4mg+0.4mg) per ml oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
56	Diastase (1:800) IP 50mg(Fungal Diastase derived from aspergillus Oryzae) IP+Pepain IP 50mg+Cardamom Oil BP 0.4mg+Caraway Oil BP 0.4mg, Cinnamon Oil BP 0.2mg oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
57	Diastase (1:800) IP(derived Aspergillus Oryzae)+Papain IP+Cinnamon Oil BP+Caraway Oil BP+Cardamom Oil BP (50mg+30mg+0.2mg+0.4mg+0.4mg) oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
58	Diastase (1:800) IP(Fungal Diastase derived Aspergillus Oryzae digest 40gm of coocked starch) + Papain IP + Cinnamon Oil BP + Caraway Oil BP + Cardamom Oil BP (50mg+50mg+0.2mg+0.4mg+0.4mg) liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
59	Diastase (1:800) (DERIVED FROM Aspergillus oryzae) + Cinnamol+ Caraway+ Cardamom Oil (50 mg+ 250 mcg+ 500 mcg + 500 mcg) per 5 ml oral liquid)	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
60	Diastase IP (1:1200)+Pepsin IP (1:3000)+Simethicon Emulsion USPeqvt. To Simethicone (33.33mg+5mg+40mg) drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
61	Diazepam 2.5mg+Propranolol Hcl 20mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
62	Diclofenac Diethylamine BP 1.16%w/w eq. to Diclofenac Sodium 1.0%w/w + Thiocolchicoside IP 0.125%w/w + Linseed Oil BP 3.0%w/w + Methyl Salicylate IP 10%w/w + Menthol IP 5%w/w + Benzyl Alcohol IP 1%w/w gel	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
63	Diclofenac Sodium 100mg+Misoprostol 100mcg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
64	Diclofenac sodium 100mg+Misoprostol 200 mcg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
65	Diclofenac Sodium 50mg+Misoprostol 100mcg enteric coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

66	Diclofenac Sodium IP 32.10mg + Thiocolchicoside IP 0.125 % w/v + menthol IP 1% w/v topical solution	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
67	Dimethicone IP 40 mg + Dill Oil BP 0.005ml +Fennel Oil 0.0007 ml oral drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
68	Dried Extract of Gingo Biloba 60 mg + Vinpocetine 10 mg film coated tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
69	Dried extract to Ginkgo Biloba 60mg+Piracetam IP 400mg hard gelatin capsules	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
70	Epalrestat 150mg+Pregabalin 150mg film coated bilayered sustained release tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
71	Escitalopram 5mg/10mg+Etizolam 0.5mg film coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
72	Etizolam 1mg + Escitalopram Oxalate eq. to Escitalopram 10mg film coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
73	Flupirtine maleate 100mg/100mg+Thiocolchicoside IP 4mg/8mg film coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
74	Fungal Diastase (1:1200) IP (Derived from Aspergillus Oryzae) 40mg+Caraway Oil BP 500mcg+Cardamom Oil BP 500mcg+Cinnamon Oil BP 250mcg per 10ml syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
75	Fungal Diastase (1:1200) IP 50 mg (derived from aspergillus Oryzae)+Cinnamon Oil BP 125 mg +Caraway Oil BP 250 mg +Cardamom Oil BP 250 mg oral liquid per 5 ml	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
76	Fungal Diastase (1:1800) + Caraway Oil BP+Cinnamon Oil BP+Cardamom Oil BP+Papain IP(20mg+400mcg+200mcg+400mcg) ORAL DROPS	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

77	Fungal Diastase (1:2000) IP 40 mg derived from aspergillus oryzae) + Cinnamon oil 250 mcg + Cardamom oil 500 mcg + caraway oil 500 mcg per 10 ml syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
78	Fungal Diastase (1:2000) IP 40 mg+Cinnamon Oil BP 250 mcg+Caraway Oil BP 500 mcg+Cardamon Oil BP 500 mcg liquid oral	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
79	Fungal Diastase (1:2000)IP 18.75mg+Pepsin (1:3000) IP 12.5mg+Thiamine HCL IP 2mg+Riboflavine IP 1mg+Pyridoxine HCL IP 1.5mg+Niacinamide IP 5mg+D-Panthenol IP 1.5mg+Cyanocobalamin IP 1mcg syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
80	Fungal Diastase (1:2000)IP 50mg+Pepsin IP 10mg+Simethicone 50mg hard gelatin capsules	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
81	Fungal diastase (1:800) IP 40 MG (DERIVED FROM Aspergillus oryzae) + Papain 60mg + Cardamom BP 0.5mg + caraway Oil BP 0.5mg + cinamon oil BP 0.5mg + anise oil BP 7.5mg + ajowan oil BP 10mg per 5 ml oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
82	Fungal Diastase (1:800) IP 50 mg(derived Aspergillus Oryzae) + Pepsin (1:3000) IP 12.5 mg+Compound cardamom 0.075mL+Strong ginger 0.0125 mL Syrup each 5 mg	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
83	Fungal Diastase (1:800) IP+Dill Oil BP+Caraway Oil BP+Anise Oil BP (20mg+2mg+2mg+2mg) drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
84	Fungal Diastase IP (1:2000) IP+Cinnamon OilBP+Caraway Oil BP+Cardamom Oil BP (40mg+250µg+500µg+500µg) oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
85	Fungal Diastase IP (1:800)+Caraway Oil BP+Cinnamon Oil BP+Cardamom Oil BP+Simethicone + Papain IP (20mg+400mcg + 200mcg+400mcg+40mg+10mg) per ml oral drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
86	Fungal Diastase IP 40mg +Cinnamon oil 250mcg + Caraway oil 500mcg solution	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
87	Gabepentin USP 300mg+Methylcobalamin JP 500mcg+Alpha Lipoic Acid USP 100mg film coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

88	Lecithin IP 125mg+Silymarin 35mg per 5ml syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
89	Liquor Bismuth Ammonium Citrate 2.5 ml + Belladonna dry extract 9 mg + Thymol 0.15 mg + Menthol 0.2 mg oral liquid.	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
90	L-Ornithin L-aspartate 150mg+Pancreatin IP 100mg enteric coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
91	Magladrage IP eq. to anhydrous magaldrate + Domperidone(480mg+10mg per 10ml)Oral suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
92	Mecobalamin JP 500mcg+Gabapentin USP 100mg+Alpha Lipic Acid IP100mg film coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
93	Mepyramine Maleate IP 2.0%w/v+Zinc Oxide IP 15.0%w/v cream	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
94	Montelukast Sodium IP eq. to Montelukast 10mg+Ebastine BP 10mg film coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
95	Moxonidine 0.2mg+Amlodipine 5mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
96	Moxonidine BP 0.2mg + Hydrochlorothiazide IP 12.5mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
97	Octinoxate 7.5 % w/w + Avobenzone 2 % w/w + Oxybenzone 3 % w/w + Octocrylene 3 % w/w + Zinc oxide 2 % w/w gel	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
98	Octinoxate USP 7.5%w/w + Avobenzone USP 2%w/w + Oxybenzone USP 3%w/w + Processed Zinc Oxide (nanozided) 2%w/w + Phenoxyethanol IP (Preservative) suncross gel and aqua gel	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

99	Octyl Methoxy Cinnamate USP (OMC) 8%w/w+Oxybenzole USP5%w/w+Vitamin E Acetate IP0.5%w/w+MBBT(Methylene Bis-Benzotriazolyl Tetramethylbutylphenol) 10%w/w Cream	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
100	Octyl methoxycinnamate 3 % w/w + oxybenzole 2 % + vitamin E acetate 0.5 % + MBBT 4 % cream	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
101	Octyl Methoxycinnamate USP 7.5%w/w + Oxybenzone USP 3.0%w/w + Avobenzone USP 3.0%w/w + Zinc Oxide IP 2.0%w/w sunscreen lotion	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
102	Papain IP 60mg+Alpha Amylase IP 20mg+Simethicone IP 25mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
103	Papain IP 60mg+Fungal Diastase IP (1:2000) 20mg+Simethicone IP 25mg effervescent tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
104	paracetamol + chlorpheniramine maleate + phenylephrine hydrochloride (125 mg+ 1 mg+ 2.5 mg)oral drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
105	Paracetamol + phenylephrine Hydrochloride + chlorpheniramine maleate + sodium citrate+ menthol (125 mg+ 2.5 mg+ 1 mg+ 60 mg+ 0.5 mg) oral syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
106	Paracetamol 125 mg + phenylephrine 2.5 mg + CPM 1 mg oral tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation . However the dose of paracetamol dose should be 500 mg.
107	Paracetamol 325 mg+Phenylephrine HCl 10 mg+Chlorpheniramine maleate 2 mg tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation . However the dose of paracetamol dose should be 500 mg.
108	Paracetamol IP + Chlorpheniramine Maleate IP + Phenylephrine HCl IP (125mg/125mg/125mg/250mg + 5mg/5mg/2mg/2mg+ 5mg/2.5mg/5mg/5mg) Surup/Suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
109	Paracetamol IP 125 mg + Phenylephrine HCL 2.5mg + Chlorpheniramine maleate 1 mg suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

110	Paracetamol IP 125 mg +Phenylephrine HCl IP 5 mg +Chlorpheniramine Maleate IP 2 mg flavoured syrup each 5 ml contains	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
111	Paracetamol IP 125 mg+Phenyephine hydrochloride IP 2.5 mg+Chlorpheniramine maleate IP 1.5 mg + Methanol IP Syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
112	paracetamol IP 125mg +CPM IP 1 mg + Phenyl ephedrine IP 5mg + Sodium Citrate IP suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
113	Paracetamol IP 125mg/250mg+Phenylephrine Hcl IP 2.5mg/5mg+Chlorpheniramine Maleate IP 1mg/2mg per 5ml suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
114	Paracetamol IP 125mg+Chlorpheniramine Maleate IP 2mg+Phenylephrine HCl IP 2.5mg per ml oral drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
115	Paracetamol IP 125mg+Phenylephrine HCl IP 5mg+Chlorpheniramine Maleate IP 1mg+Sodium Citrate IP 60mg+Menthol IP 0.5mg per 5ml oral suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
116	Paracetamol IP 125mg+Phenylephrine HCl IP 2.5mg+Chlorpheniramine Maleate IP 1mg per 5ml oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
117	Paracetamol IP 125mg+Phenylephrine Hcl IP 2.5mg+Chlorpheniramine Maleate IP 1mg per 5ml syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
118	Paracetamol IP 125mg+Phenylephrine Hcl IP 2.5mg+Chlorpheniramine Maleate IP 2mg per 5ml oral drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
119	Paracetamol IP 125mg+Phenylephrine Hcl Ip 5mg+Chlorpheniramine Maleate IP 1 mg per 5ml syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
120	Paracetamol IP 125mg+Phenylephrine Hcl IP 5mg+Chlorpheniramine Maleate IP 1mg+Sodium Citrate 60mg per 5ml syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

121	Paracetamol IP 250mg/125 mg +Phenylephrine HCl IP 5mg/2.5 mg +Chlorpheniramine Maleate IP 2mg/1 suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
122	Paracetamol IP 250mg+Phenylephrine HCl IP 2.50mg+Sodium Citrate IP 60mg+Chlorpheniramine Maleate IP 1mg per 5ml oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
123	Paracetamol IP 250mg+Phenylephrine Hcl IP 2.5mg+Chlorpheniramine Maleate IP 1mg uncoated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation . However the dose of paracetamol should be 500 mg.
124	Paracetamol IP 250mg+Phenylephrine Hcl Ip 5mg+Chlorpheniramine Maleate IP 2mg+Sodium Citrate IP 60mg per 5ml suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
125	Paracetamol IP 325mg + Phenylephrine HCl IP 10 mg + Chlorpheniramine maleate IP 4mg uncoated tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation . However the dose of paracetamol should be 500 mg.
126	paracetamol IP 325mg +CPM IP 4 mg + Phenyl ephedrine IP 10mg uncoated tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation . However the dose of paracetamol should be 500 mg.
127	Paracetamol IP 325mg+Phenylephrine HCl IP 2.5mg+Chlorpheniramine Maleate IP 1mg per 5ml liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
128	Paracetamol IP 500 mg +Phenylephrine Hydrochloride IP 5 mg+Chlorpheniramine Maleate IP 2 mg each uncoated tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
129	Paracetamol IP 500mg + Thiocolchicoside IP 8mg tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
130	paracetamol IP 500mg +Serratiopeptidase IP 10mg, tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
131	Paracetamol IP 500mg+Phenylephrine Hcl IP 10mg+Chlorpheniramine Maleate IP 2mg uncoated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

132	Paracetamol IP 500mg+Thiocolchicoside IP 4mg uncoated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
133	paracetamol IP 650mg +Serratiopeptidase IP 10mg (as enteric coated granules) eq. to 20,000 Serratiopeptidase units) tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
134	Paracetamol IP+Chlorpheniramine HCl IP+Phenylephrine HCl IP(125mg+1.0mg+2.5mg) oral suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
135	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Sodium Citrate IP+Menthol IP (125mg/125mg/125mg/250mg+2mg/1mg/1mg/2mg+5mg/2.5mg/5mg/2.5mg+60mg/60mg/60mg/60mg + 1mg/1mg/1mg/1mg) oral suspension)	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
136	Paracetamol IP+Phenylephrine HCL IP+Chlorpheniramine Maleate IP+Sodium Citrate IP+Menthol IP (250mg+5mg+2mg+60mg+1mg) suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
137	Paracetamol IP+Phenylephrine Hcl IP+Chlorpheniramine Maleate IP (125mg+2.5mg+1mg) syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
138	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP (125mg+2.5mg+2mg) per 5 ml liquid for oral use	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
139	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP (125mg+5mg+1mg) metholated syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
140	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Sodium Citrate IP+Menthol IP (250mg+5mg+2mg+60mg+1mg) suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
141	Paracetamol IP+Phenylephrine HCL IP+Chlorpheniramine Maleate (250mg+5mg+2mg) liquid oral	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
142	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Menthol IP(250mg+5.0mg+2.0mg+1.0mg) oral suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

143	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Sodium Citrate (125mg+5mg+1mg+60mg) 5ml syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
144	Paracetamol IP+Phenylephrine HCL IP+Chlorpheniramine Maleate IP+Sodium Citrate IP+Menthol IP(250mg+5mg+2mg+60mg+1mg)	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
145	Paracetamol IP+Phenylephrine HCL IP+Chlorpheniramine Maleate suspension (250mg+5mg+2mg)	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation, if the formulation is in oral liquid form.
146	Paracetamol+Chlorampheniramine maleate+Phenylephrine HCL syrup (125mg+1mg+5mg)	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation, if the formulation is in oral dosage form.
147	Paracetamol+Phenylephrine HCL+Chlorampheniramine Maleate(250mg+2.5mg+1mg) uncoated dispersible tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
148	Paracetamol+Phenylephrine HCL+Chlorpheniramine Maleate suspension (125mg+5mg+1mg each 5 ml) oral suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
149	Paracetamol+Phenylephrine HCl+Chlorpheniramine maleate+Sodium Citrate(125mg+5mg+1mg+60mg) ORAL SYRUP	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
150	Paracetamol+Phenylephrine HCl+chlorpheniramine Maleate+Sodium Citrate+Menthol (125mg+5mg+1mg+60mg+1mg) per 5 ml syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
151	PCM 250 mg + Phenylephrine HCl 5 mg + Chlorpheniramine maleate 2 mg + NaCl 60 mg + Menthol 1 mg suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
152	PCM 250 mg + Phenylephrine HCl 5 mg + Chlorpheniramine maleate 2 mg + NaCl 60 mg + Menthol 1 mg syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
153	Phenylephrine HCl IP 2.5mg+Chlorpheniramine Maleate IP 1 mg+Paracetamol IP 125 mg Syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

154	Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Paracetamol IP syrup (5mg+2mg+125mg) Syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation, if the formulation is in oral liquid form.
155	Phenylephrine IP 2.5mg +Chlorpheniramine Maleate IP 1.5mg + Paracetamol IP 125mg + Menthol IP 1mg Syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
156	Piracetam 500mg + Methylcobalamin 500 mcg syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
157	Pregabalin 75mg+Nortriptyline 10mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
158	Pregabalin IP (SR) 100mg+Mecobalamin JP 1500mcg film coated modified release tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
159	Propranolol HCl IP 20mg+Alprazolam IP 0.25mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
160	Propranolol HCl IP40mg/40mg + Flunarizine 5mg/10mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
161	Ramipril IP 2.5/5/10mg + Clinidipine 10/10/10mg capsule	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
162	Salbutamol Sulphate eq. to Salbutamol 2mg/4mg/4mg + Theophylline anhydrous 100mg/200mg/300mg, tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
163	Salbutamol Sulphate IP 1mg+Theophylline IP 50mg syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
164	Salbutamol Sulphate IP Eq. to Salbutamol 1 mg + Choline Theophylline BP BP 50 mg, oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

165	Salbutamol Sulphate IP eq. to Salbutamol 1mg+Choline Theophylline BP 60mg syrup	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
166	Sertraline Hydrochloride Eq. to Sertraline 25mg + Alprazolam IP 0.5mg (in sustained release form) uncoated bilayered tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
167	Sertralline HCl BP eq. to Sertralline 50mg + Alprazolam IP 0.25mg film coated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
168	Sildenafil 8mg+ Dutasteride (uncoated tablet) 0.5mg hard gelatin capsules	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
169	Simethicone 40 mg + Dill oil 0.005 ml + fennel oil 0.0007 ml drops	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
170	Simethicone emulsion + fennel oil Dill oil (40 mg+ 0.007 ml+ 0.005 ml) drop suspension	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
171	Simethicone Emulsion USP Eq. to Simethicone+Dill Oil+Fennel oil (40mg+0.005ml+0.0035ml) oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
172	Simethicone Emulsion USP (30%) Eq. to Simethicone + Dill Oil BP + Fennel Oil USP-NF (40mg+0.005 ml+.0007 ml) ORAL DROPS	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
173	simethicone emulsion USP Eq. to Simethicone 40mg + Fennel oil USP 0.0007ml + dill oil 0.005 ml per ml of oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
174	Simethicone emulsion USP Eq. to Simethicone IP 40 mg+Dill Oil BP 0.005ml +Fennel Oil USP 0.0007 ml per ml of Syrup base	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
175	Simethicone Emulsion USP eq. to Simethicone USP+Dil Oil BP+Fennel oil USP (40mg+0.005ml+0.0007ml) ORAL DROPS	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .

176	Sodium Bicarbonate BP-0.05 g + Dill Oil BP-0.005g oral liquid	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
177	Sodium citrate 70 mg + citric acid monohydrate 35 mg (Flavoured With Cardamom Oil, Caraway Oil , Cinnamon Oil, Clove Oil, Ginger Oil) +Acohol content 4%v/v per 5ml liquid oral	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
178	Sodium Citrate IP 60 mg +Citric Acid Monohydrate IP 30 mg (oral liquid)	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
179	Trifluoperazine 2.5mg/5mg+Trihexyphenidyl Hcl 1mg/2mg tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
180	Trifluoperazine HCl IP 5 mg + Trihexiphenidyl HCl IP 12mg tablet	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
181	Tripolidine Hydrochloride IP2.5 mg +Phenylephrine HCl IP 5mg uncoated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
182	Tripolidine Hydrochloride IP2.5 mg +Pseudophedrine Hydrochloride IP 60mg uncoated tablets	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
183	Water soluble Azulene (Sodium Azulene Sulfonate) JPC 2.01mg + L-Glutamine JPC 663.030 mg sachet of 0.67gm	Active Post Marketing Surveillance shall be conducted under intimation to DCGI. Report shall be submitted for evaluation .
184	50,000 Armour units of enzymatic activity of Trypsin chymotrypsin+Diclofenac Potassium 50mg sugar coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
185	50,000 armour units Enymatic Activity. Supplied by purified concentrate which has specific trypsin and chymotrypsin activity in ratio of approximately six to one Diclofenac Potassium BP 50 mg each enteric coated tablet	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
186	50,000 Armour units of enzymatic activity (supplied by a purified concentrate which has specified trypsin and Chymotrypsin activity in a ratio of approximetly six to one) enteric coated + Diclofenac Potassium BP 50 mg + Paracetamol IP325 mg film coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.

187	Acebrophylline 50mg + Guaiphenesin IP 50mg + Terbutaline Sulphate IP 1.25 mg per 5ml syrup	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
188	Acebrophylline 200mg +Montelukast Sodium IP eq. to Montelukast 10mg Tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
189	Aceclofenac 100mg + paracetamol 500mg + Thiocolchicoside 4mg/8mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
190	Aceclofenac 100mg/100mg + Paracetamol 325mg/325mg + Thiocolchicoside 4mg/8mg film coated tablet	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
191	Aceclofenac IP 100mg + Paracetamol IP 500mg + Trypsin Chymotrypsin 150000AU film coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
192	Aceclofenac IP 100mg +Tizanidine HCl IP Eq. to Tiznadine 2mg +Paracetamol IP 325 mg film coated tablets.	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
193	Aceclofenac IP 100mg/100mg/100mg+Paracetamol IP 325mg/325mg/500mg+Chlorzoxazone USP 500mg/250mg/250mg tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
194	Aceclofenac IP 100mg+Paracetamol IP 325mg+Trypsin & Chymotrypsin 150000AU film coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
195	Aceclofenac IP 100mg+Paracetamol IP 500mg+Tolperisone 150mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules. The strength of Paracetamol should be 325 mg.
196	Aceclofenac IP 100mg+Paracetamol IPO 325mg+Trypsin/Chymotrypsin 15000 IU Tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
197	Aceclofenac IP 200mg + Cyclobenzaprine HCl 15 mg sustained release bilayered tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules

198	Atorvastatin Calcium 10mg/20 mg/40mg/10mg/20mg/40 mg/10mg/20mg + Vitamin D3 IP 2000IU/2000IU/800IU/800IU/800IU/1000IU/1000IU tablet	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
199	Atorvastatin calcium 10mg/20mg/40mg/80mg+Cholecalciferol 1000IU film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
200	Atorvastatin Calcium IP 10mg/20mg+Cholecalciferol 1000IU+Fenofibrate 45mg/135mg hard gelatin capsules	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
201	Balofloxacin 200mg+Phenazopyridine HCl USP 200mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
202	Bismuth Citrate USP 0.23gm+Ammonia solution strong IP 0.11ml+Nux Vomica IP 30mg+Chloroform IP 0.01ml+Glycerin IP 0.03ml+Hydrochloric Acid IP 0.007ml solution	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
203	Bismuth Citrate USP 130mg+Nux Vomica IP 5mg+Dill Oil BP 0.004ml+Chloroform IP 0.01ml	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
204	Bismuth Citrate USP 70mg+Aluminium Citrate 60mg+Nux Vomica IP 5mg+Dill Oil BP 0.004ml+Chloroform IP 0.01ml	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
205	Bismuth Citrate USP 70mg+Aluminium Citrate 60mg+Nux Vomica IP 5mg+Opium IP 15mg+Dill Oil BP 0.003ml+Chloroform IP 0.01ml	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
206	Bromhexine Hydrochloride IP 4 mg + Guaiphenesine IP 50 mg + Phenylephrine Hydrochloride IP 5 mg syrup	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
207	Camylofin dihydrochloride 12.5 mg+Paracetamol IP 125 mg Syrup each 5 ml	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
208	Camylofin dihydrochloride 25 mg+ Diclofenac Sodium 25mg + Benzyl alcohol I.P. 2.0%W/v per ml injection	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules

209	Camylofin dihydrochloride 50 mg + Mefenamic acid IP 250 mg + colour: Tartrazine Blue, Black Iron Oxide, Titanium dioxide IP & Cardamom flavour Film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
210	Camylofin Dihydrochloride 50 mg + Mefenamic Acid IP 250 mg each film coated tablet	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
211	Camylofin dihydrochloride 50 mg + nimesulide 100 mg tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
212	Camylofin dihydrochloride 50 mg+Paracetamol IP 325 mg tablet	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
213	Camylofine Dihydrochloride 50mg+Diclofenac Potassium 50mg Film Coated Tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
214	Clindamycin 1.0%w/w+Nicotinamide 4.0%w/w+Allantoin 0.5%w/w Gel	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
215	Clindamycin phosphate BP eq. to Clindamycin 100mg + Clotrimazole IP 200 mg vaginal suppository	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
216	Clindamycin Phosphate USP eq. To Clindamycin 100mg + Clotrimazole IP 200mg soft gelatin vaginal suppositories	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
217	Clindamycin phosphateBP eq. to Clindamycin 100mg + Clotrimazole IP 100 mg vaginal suppository	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
218	Dapoxetine HCl 30/60/60 mg + Sildenafil Citrate IP 50/50/100 mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
219	Diclofenac Potassium BP 50mg+Trypsin & Chymotrypsin 50000 armour units enteric coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.

220	Ebastine BP 10mg+Phenylephrine Hcl 10mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
221	Etoricoxib 60 mg + Serratiopeptidase IP 10mg film coated tablet	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
222	Gabapentin 300mg+Amitriptyline Hcl 10mg tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
223	Gabapentin USP 400mg +Nortriptyline Hydrochloride IP Eq. to Nortriptyline 10 mg tablet	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
224	Gabapentin USP 300 mg + Nortriptyline HCl IP 10 mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
225	Hydrochlorothiazide IP 12.5 mg + Amlodipine Besylate IP eq. to Amlodipine 5mg + Losartan Potassium IP 50 mg film coated tablet	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
226	Levocetirizine HCl IP 5mg + Montelukast Sodium IP Eq. to Montelukast 10mg +Ambroxol HCl IP 75 mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules.
227	Levocetirizine Dihydrochloride IP 5mg + Montelukast Sodium IP Eq. to Montelukast 10mg + Ambroxol hydrochloride IP 75mg (as sustained release) uncoated bilayered tablet	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
228	Levocetirizine hydrochloride IP 5mg + Montelukast Sodium IP Eq. to Montelukast 10mg + Ambroxol hydrochloride IP 75mg film coated tablet	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
229	Metadoxine 250mg+Silymarin 70mg+L-ornithine L-Aspartate 75mg+Folic Acid IP 1mg+Pyridoxine Hydrochloride IP 3mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
230	Montelukast Sodium IP 10mg+Doxophylline IP 400mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules

231	Nortriptylline HCl 5mg/10mg+Gabepentin 300mg/400mg capsules	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
232	Olmесartan 20mg/40mg+Clindipine 10mg + Chlorthalidone IP 6.25 mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
233	Pamabrom USP 25mg+Dicyclomine IP 10mg+Paracetamol IP 325mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules.
234	Paracetamol IP 325mg+Aceclofenac IP 100mg+Trypsin Chymo Trypsin 50000 AU tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
235	Paracetamol IP 500mg+Diclofenac Potassium BP 50mg tablets with proteolytic enzymes Trypsin & Chymotrypsin in the ratio 6:1 and provided enzymes activity eq. to 1,50,000 international units tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
236	Paracetamol IP 500mg+Pitofenone HCl 5mg+Fenpivirinium Hydrobromide 0.1mg uncoated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
237	Pregabalin 75mg/150mg+Dosulepin 75mg/75mg+Mecobalamin 1500mcg/1500mcg hard gelatin capsules	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
238	Rosuvastatin Calcium IP 5mg/10mg+Cholecalciferol (Vitamin D3) IP 1000IU tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
239	Rosuvastatin Calcium IP 5mg/10mg+Clopidogrel Bisulphate IP 75mg+Cholecalciferol (Vitamin D3) IP 1000IU hard gelatin capsules	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
240	Serratiopeptidase IP 10mg+Diclofenac Sodium IP 50mg+Tizanidine HCl IP 2mg film coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
241	Serratiopeptidase IP 15mg+Diclofenac Potassium IP 50mg+Tizanidine HCl IP 2mg film coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.

242	Sildenafil citrate 50mg+Dapoxetine Hcl 30mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
243	Sildenafil Citrate IP eq. to Sildenafil 100mg+Dapoxetine Hydrochloride eq. to Dapoxetine 30mg film coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
244	Tadalafil 10mg+Dapoxetine 30mg tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
245	Terbutaline Sulphate IP 1.25mg + Etofylline IP 50mg syrup	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
246	Terbutaline Sulphate IP 1.25mg+Choline Theophyllinate BP 50mg oral liquid	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
247	Terbutaline Sulphate IP 1.25mg+Choline Theophyllinate BP 50mg syrup	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
248	Terbutaline Sulphate IP 2.5mg+Etophyline BP 100mg tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
249	Thiocolchicoside IP 4 mg/8mg+Diclofenac SodiumIP 50 mg(As enteric coated tablet)+Paracetamol IP 325 mg tablet	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
250	Tizanidine Hydrochloride IP 2mg + Diclofenac Potassium BP 50mg + Paracetamol 325 mg tablet	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
251	Tramadol 50mg + Dicyclomine 10mg + Acetaminophen 325mg hard gelatin capsules	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
252	Tramadol HCl 37.5 mg +Drotaverine HCl 80 mg tablet	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.

253	Tramadol HCl 37.5 mg +Thiocolchicoside IP 4mg tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
254	Tramadol HCl 37.5mg+Paracetamol IP 325mg+Serratiopeptidase 15.0mg film coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
255	Tramadol HCL Eq. to Tramadol +Dicyclomine HCL+Paracetamol IP (37.5mg+20mg+500mg) uncoated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
256	Tramadol HCl IP 37.5mg + Paracetamol IP 325mg + Serratiopeptidase 15 mg (as enteric coated granules Eq. to enzyme activity 30,000 units) film coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
257	Tramadol HCL+Paracetamol +Dicyclomine HCL (37.5 mg+ 325 mg+ 10 mg) capsules	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
258	Trypsin & Chymotrypsin 50000 armour units+Diclofenac Potassium IP 50mg tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
259	Trypsin 48mg+Bromelain 90mg+Rutoside Trihydrate 100mg+Zinc Sulphate Monohydrate 5mg enteric coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
260	Trypsin BP 48 mg/96mg+Bromelain 90 mg/180mg + Rutoside Trihydrate BP 100mg/200mg film coated tablet	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
261	Trypsin BP 48mg + Bromelain 90mg + Rutoside Trihydrate BP 50mg enteric coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
262	Trypsin BP 48mg + Rutoside Trihydrate BP 100mg + Papain IP 60mg enteric coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
263	Trypsin BP 48mg/96mg+Bromelain 90mg/180mg+Rutoside Trihydrate BP 100mg/200mg enteric coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules.

264	Trypsin BP 48mg+Bromelain 90mg+Rutoside trihydrate 100mg+Aceclofenac sodium 50mg enteric coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
265	Trypsin BP 48mg+Bromelain 90mg+Rutoside Trihydrate BP 100mg+Diclofenac Sodium IP 50mg enteric coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
266	Trypsin BP 48mg+Bromelain 90mg+Rutoside Trihydrate BP 100mg+Diclofenac Sodium IP 50mg tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
267	Trypsin BP 48mg+Bromelain 90mg+Rutoside Trihydrate BP 100mg+Papain 120mg+Pancreatin 200mg enteric coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
268	Trypsin BP 96mg + Bromelain 180mg + Rutoside Trihydrate BP 1200mg enteric coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
269	Trypsin BP+Bromelain+Rutoside Trihydrate BP+Harpagophytum dry Extract (96mg+180mg+200mg+5mg) enteric coated tablet	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
270	Trypsin Chymotrypsin 50000 AU++Diclofenac Potassium IP 50mg+Paracetamol IP 50mg enteric coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
271	Trypsin-Chymotripsin 1,00000 AU of enzymatic activity + Diclofenac Potassium BP 50mg (Immediate release) sugar coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
272	Trypsin-Chymotripsin Eq. to Trypsin-Chymotripsin 50,000AU+Aceclofenac Eq. to Aceclofenac 100mg+Paracetamol IP Eq. to Paracetamol 125mg film coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
273	Trypsin-Chymotrypsin (6:1) 50000AU + Diclofenac Potassium 50mg tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
274	Trypsin-Chymotrypsin 150000 AU+Diclofenac Potassium 50mg tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.

275	Trypsin-Chymotrypsin 50000 AU + Bromelain 90mg +Rutoside Trihydrate 100mg entric coated tablets	Phase IV shall be conducted as per provisions of Drugs and Cosmetics Rules
276	zolpidem tartrate 5 mg/10mg + melatonin 3 mg film coated tablets	Phase IV trial shall be conducted as per Drugs & Cosmetics Act and Rules.
277	Clonazepam IP 0.5mg/0.5mg + Paroxetine HCl Hemihydrate BP eq. to Paroxetine 12.5mg/25mg film coated bilayered tablet	BE study shall be conducted.
278	Paroxetine Hydrochloride hemihydrate BP eq. to Paroxetine(As Controlled release form) 12.5mg/25mg/37.5mg+Clonazepam IP (As Immediate release form) 0.5mg film coated tablets	BE study shall be conducted.