To,

27 MAY 2015

The Secretary
Ministry of Health & Family Welfare,
Govt. of India,
Nirman Bhawan, New Delhi-110001.

Subject: Submission of report by Expert Committee constituted for examination of Fixed Dose Combinations (FDCs) permitted for manufacture for sale in the country without due approval from office of DCG (I)-regarding.

Sir,

This has reference to Ministry of Health and Family Welfare order No. X11035/53/2014-DFQC dated: 16.09.2014 whereby the Ministry has constituted the Committee under the Chairmanship of Prof. C.K. Kokate, VC, KLE University, Belgaum with the approval of Hon'ble Minister of Health and Family Welfare, Government of India.

The Expert Committee evaluated the FDCs categorized under category 'b' earlier in its assessment report dated 19.1.2015. Committee evaluated these proposals by inviting various subject experts of relevant therapeutic areas before concluding the report. The Committee will evaluate Vitamins and Minerals related preparations separately including micronutrients and report in this regard will be submitted separately in due course of time.

In continuation with earlier 3 reports of the Committee, the detailed report along with the recommendations of the Committee with respect to FDCs categorized under category 'b' is enclosed herewith.

The Committee also reviewed its earlier recommendations with respect to the FDCs which were prohibited by Central Government recently and found that there were some typographical errors in respect of 5 FDCs. The recommendations in this regard are also included in the minutes for re-consideration by the Ministry.

We would like to acknowledge with thanks the support received from Dr. G.N. Singh, DCG (I) and his colleagues at CDSCO.

(Prof. C.K. Kokate)

REPORT OF EXPERT COMMITTEE

ON

Evaluation of Cases of Fixed Dose Combinations (FDCs) except Vitamins and Minerals preparations categorized under category 'b' i.e. FDCs requiring further deliberation with subject experts

CENTRAL DRUGS STANDARD CONTROL ORGANIZATION

DIRECTORATE GENERAL OF HEALTH SERVICES

MINISTRY OF HEALTH & FAMILY WELFARE

GOVT. OF INDIA

Date: May'2016

Table of Contents

Report of Expert Committee

Ministry of Health & Family Welfare vide order No. X11035/53/2014-DQC dated: 16.09.2014 constituted a Committee under the Chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka for examining the safety and efficacy of unapproved FDCs which were licensed by State Drug Licensing Authorities without due approval of DCG(I).

After a series of meetings of the Committee, the Committee categorized these FDCs into four categories as under :

i. FDCs considered as Irrational by the Committee were categorized under category 'a'.
ii. FDCs requiring further deliberation with subject experts were categorized under category 'b' and further deliberations are in progress.
iii. FDCs considered as rational by the Committee were categorized under category 'c'.
iv. FDCs requiring further generation of data were categorized under category 'd'.

Based on the report of the Committee, CDSCO has already taken various actions like issuance of approval or otherwise. However in cases of FDCs categorized under category 'b', it was considered by the Committee to have further deliberations with subject experts to further categorize these FDCs into categories 'a', 'c' or 'd' based on the rationality, safety and efficacy. The Committee conducted a series of meetings and discussed each FDC in detail. Committee further categorized these FDCs during the meeting accordingly. Further certain applications of the FDCs which were left un-discussed inadvertently during first assessment due to their non inclusion in the list were also discussed by the Committee and were categorized accordingly.

The Committee also reviewed its earlier recommendations with respect to the FDCs which were prohibited by Central Government recently and found that there were some typographical errors in respect of 5 FDCs. The recommendations in this regard are also included in the minutes for re-consideration by the Ministry.

While reviewing these FDCs, the Committee considered various criteria viz Patient safety, Drug Toxicity/Adverse effect, Misuse of drug/ Prescription error, Abuse potential, Pk and Pd interaction/compatibility, Dosage compatibilities of FDC vis a vis that of single ingredients, issue of Anti-microbial resistance, Latest standard treatment guidelines, Risk/Benefit ratio, Patient compliance, international status.

The detailed recommendations of the Committee have been given against each FDC in the report. The Committee will evaluate Vitamins and Minerals related preparations separately including micronutrients and report in this regard will be submitted separately in due course of time.

The Committee is of the opinion that these FDCs wherever recommended as Irrational should not be allowed for their continued manufacturing and marketing in the country. The detailed recommendations are as under:

Final Recommendations of the Experts Committee in respect of FDCs categorized under 'b' category for proving safety and efficacy					
Sr.No.	Sr. No. of main list	Name of FDC	Strength	Dosage Form	Final Categorization of the FDC/comments by the Expert Committee after deliberation with subject experts
1	3	Paracetamol IP+Nimesulide BP	150mg+100mg per ml	Injection	a already recommended as "a"
2	7	Diclofenac Sodium IP+Paracetamol IP	25mg +75mg/ml	Injection	a There is no scientific rationale for this FDC.Dosage of ingredients are subtherapeutic.
3	8	Paracetamol IP+Mefenamic Acid IP	125mg+50mg per 5ml	Syrup	c
4	14	Diacerin IP+Glucosamine Sulphate Potassium Chloride USP+MSM (Methylsulfonylmethane) USP+Cetyl Myristoleate (20%)	50mg+750mg+ 250mg+175mg	Tablets	a There is no scientific evidence of addition of Cetyl Myristoleate in FDC
5	17	Trypsin-Chymotripsin Eq. to Trypsin-Chymotrissin+Aceclofenac Eq. to Aceclofenac+Paracetamol IP Eq. to Paracetamol	500000 AU+100mg+3.2 5mg	Film Coated Tablets	d
6	33	Paracetamol IP+Mefenamic Acid IP	125mg+50mg per 5ml	Syrup	c
7	41	Paracetamol IP+Mefenamic Acid IP	250mg+100mg	Meftagesic DS Suspension	c
8	60	Paracetamol+Mefenamic acid	325mg+500mg	Tablets	c
9	63	Camylofin+Paracetamol	25mg+300mg	Tablets	a Subtherapeutic dose of Paracetamol
10	66	Paracetamol+Phenylephrine HCl+Caffeine	325mg+10mg+ 32mg	Tablets	already categorized as 'a'
11	67	Paracetamol+Diclofenac Sodium+Benzyl Alcohol	75mg+25mg+1 %w/v	Injection	a There is no scientific rationale for this FDC.Dosage of ingredients are subtherapeutic.
12	75	Tramadol HCL+Dicyclomine HCL+Paracetamol IP	37.5mg+20mg+ 500mg	Uncoated Tablets	d paracetamol dose should be 325 mg
13	78	Tramadol HCL+Dicyclomine HCL+Paracetamol IP	37.5mg+20mg+ 500mg	Uncoated Tablets	d paracetamol dose should be 325 mg
14	89	Mefenamic Acid IP+Paracetamol IP	500mg+350mg	Uncoated Tablets	c, if paracetamol dose is 325 mg

15	93	Paracetamol IP+Mefenamic Acid IP	125mg+50mg+	suspension	c
16	96	Mefenamic Acid IP+Paracetamol IP	100mg+250 mg	suspension	c
17	97	Etodolac IP+Paracetamol IP+Serratiopeptidase IP	400mg+500mg/ 325mg+15mg	Film Coated TAblets	a There is no rationale for use of serratiopeptidase.
18	105	Thiocolchicoside IP+Aceclofenac IP+Paracetamol IP	4mg/8mg+100mg+500mg	Tablets	d Already categorize as d
19	111	Mefenamic Acid IP+Paracetamol IP	100mg/50mg+250mg/125mg	suspension	c
20	126	Paracetamol+ caffeine anhydrous + chloropheniramine maleate	650 mg+ 30 mg+ 4 mg	tablets	a
21	139	Flupirtine maleate +paracetamol	100mg+ 325 mg	film coated tablet	a There is no scientific rationale.
22	142	Tranexamic acid+ mefenamic acid	500 mg + 250 mg	tablets	c
23	145	Aceclofenac + paracetamol	50 mg+ 125 mg	oral suspension	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
24	147	Aceclofenac + Paracetamol	50mg+125mg	Oral Suspension	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
25	148	Paracetamol+Phenylephrine HCL+Chlorpheniramine Maleate suspension	125mg+5mg+1 mg	Oral Suspension	d Similar FDC is already discussed by 10 expert Committee
26	157	Diclofenac sodium+famotidine	75mg+20mg	Tablet	Sub-judice
27	160	Mefenamic Acid IP+Paracetamol IP	50mg+125mg	Syrup	c
28	162	Paracetamol IP+Mefenamic Acid IP	125mg+50mg	Tablets	c For peadiatric use
29	172	Tranexamic Acid IP+Mefenamic Acid IP	500mg+250mg	Film Coated Tablets	c
30	176	Mefenamic acid+Paracetamol	50mg+125mg	Suspension	c
31	181	Diclofenac sodium+ pantoprazole sodium sesquihydrate	75 mg+ 40 mg	capsules	a It is an irrationale FDC .The dosing schedule of Diclofenac and pentaprazole is different.
32	186	Aceclofenac+Paracetamol	50mg+125mg	Syrup	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
33	192	Aceclofenac+ paracetamol	50 mg+ 125 mg	liquid oral dose	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
34	195	Flupirtine Maleate+Paracetamol IP	100mg+325mg	Uncoated Bilayered Tablets	a There is no scientific rationale.
35	198	Lornoxicam+Thiocolchicoside	8mg+4mg	Film Coated Tablets	c
36	205	Mefenamic acid+paracetamol	100mg/100mg+125mg/250mg	Oral suspension	c

37	206	Paracetamol+Chloramipheniramine maleate+Phenylephrine HCL	125mg+1mg+2.5mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
38	207	Paracetamol+Mefenamic acid	125mg+50mg	Suspension	c
39	208	Paracetamol+Phenylephrine HCL+Chloramphenicol Maleate	250mg+2.5mg+1mg	Tablet	d Similar FDC is already discussed by 10 expert Committee
40	209	paracetamol + phenylephrineHCL+ chlorpheniramine maleate+ sodium citrate	125 mg+ 5 mg+ 1 mg+ 60 mg	syrup	d Similar FDC is already discussed by 10 expert Committee
41	216	Tramadol HCL+ paracetamol+ taurine+ caffiene	37.5 mg+ 325 mg+ 250 mg+ 30 mg	film coated tablet	a There is no scietific rationale for this FDC
42	217	hyoscine butylbromide + mefenamic acid	10 mg+ 250 mg	film coated tablet	c
43	218	Phenylephirine HCl IP+Chlorpheniramine Maleate IP+Paracetamol IP	5mg+2mg+125 mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
44	219	Paracetamol IP+Phenylephirine HCl IP+Chlorpheniramine Maleate IP	125mg+2.5mg+1mg	Drops	d Similar FDC is already discussed by 10 expert Committee
45	222	Cetirizine HCL IP+Phenylephirine HCl IP+Paracetamol IP	5mg+5mg+500 mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
46	223	Paracetamol IP+Phenylephirine HCl IP+Chlorpheniramine Maleate IP	325mg+5mg+2 mg	Solid Oral/Tablets	d Similar FDC is already discussed by 10 expert Committee
47	224	Aceclofenac IP+Paracetamol IP	50mg+125mg	Suspension	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
48	235	Tranexamic acid + mefenamic acid + vitamin K1	500 mg+ 325 mg+ 5 mg	film coated tablet	a irrationale combination, addition of Vit-K without coagulation profile is not justified
49	248	Tramadol HCL+ paracetamol + dicyclomine HCL	37.5 mg+ 325 mg+ 10 mg	capsules	d
50	254	Flupirtine maleate+Thiocolchicoside	100/100mg+4/8 mg	Film coated Tablet	a There is no scientific rationale.
51	257	Flupirtine maleate+paracetamol	100mg+325mg	Tablet	a There is no scientific rationale.
52	262	Paracetamol IP+Ergotamine tyartrate IP+Caffeine IP+Prochlorperazine Maleate IP	250mg+1mg+100mg+2.5mg	Tablets	a There is no scientific rationale for this FDC.
53	276	Paracetamol+Chlorpheniramine Maleate+Phenylpherine HCl+Sodium Citrate	125mg+1mg+2.5mg+60.0mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
54	277	Cetrizine Dihydrochloride+Phenylpherine HCl+Paracetamol	2.5mg+2.5mg+125mg	Liquid	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.

55	282	Dicyclomine HCl+Tramadol HCl	20mg+50mg	Capsule	c
56	283	Medizine HCl+Paracetamol+Caffeine	25mg+500mg+50mg	Tablets	a Pharmacodynamically irrational
57	284	Aceclofenac+Thiocolchicoside+Methyl Salicylate+Menthol+Camphor	15mg+0.25mg+250mg+50mg+10mg	Liniment	d
58	285	Paracetamol+Mefenamic Acid	250mg+100mg	Suspension	c
59	286	Sucralfate USP+Aceclofenac IP	500mg+100mg	Film Coated Tablets	a pharmacodynamic irrelevant
60	295	Paracetamol IP+Diclofenac Sodium IP	75mg+25mg per ml	injection	a There is no scientific rationale for this FDC.
61	297	Flupirtine Maleate+Paracetamol IP	400mg+325mg	Uncoated Tablets bilayered	a There is no scientific rationale.
62	300	Diacerein IP+Glucosamine Sulphate Potassium Chloride+Methylsulphonylmethane	750mg+446mg+250mg	Film Coated Tablets	c Already approved by DCGI
63	301	Aceclofenac IP+Paracetamol IP	50mg/250mg+250mg/0.650gm	Oral Liquid	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
64	302	Doxycycline HCl IP+Betacyclodextrin USP+Serratiopeptidase IP	100mg+50mg+15mg	Film Coated Tablets	a There is no scientific rationality of combining antibiotic with serratiopeptidase whichca cause peptic ulcer and serious gastro intestinal bleeding.
65	305	Aceclofenac IP+Paracetamol IP	100mg+250mg/10 ml	Oral Liquid	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol is subtherapeutic for adult population. Hence FDC is irrationale
66	309	Mefenamic Acid+Paracetamol IP	500mg+400mg	Uncoated Tablets	c if paracetamol dose is 325 mg
67	312	Etodolac IP+Paracetamol IP+Serratiopeptidase IP	400mg+500mg+15mg	Film Coated Tablets	a There is no rationale for use of serratiopeptidase.
68	316	Drotaverine HCl+Mefenamic Acid IP	80mg+250mg	Film Coated Tablets	subjudice
69	319	Cetyl Myristoleate+Glucosamine Sulphate Potassium+Methyl Sulfonyl Methane	102.5mg eq. to 20.5mg+500mg+200mg	Film Coated Tablets	a There is no scientific evidence of this FDC. The dose of Glucosamine is subtherapeutic.
70	327	Thicolchicoside IP+Diclofenac Diethylammonium BP eq. to Diclofenac Sodium+Oleum Lini+Methyl Salicylate IP+Menthol IP	0.125%w/w + 1%w/w + 3%w/w + 10%w/w + 5%w/w	Gel	a There is no scientific rational for this FDC
71	334	Aceclofenac IP+Paracetamol IP	50mg+125mg/5 ml	Suspension	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
72	336	Aceclofenac IP+Paracetamol IP	50mg+125mg	Suspension	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
73	338	Mefenamic Acid IP+Paracetamol IP	250mg+325mg	Uncoated Tablets	c

74	345	Mefenamic Acid IP+Paracetamol IP	50mg+125mg/5 ml	Oral Liquid	c
75	349	Mefenamic Acid IP+Paracetamol IP	50mg+125mg	Liquid	c
76	356	Hyoscine Butylbromide IP+Mefenamic Acid IP	10mg+250mg	Film Coated Tablets	c
77	372	Paracetamol IP+Mefenamic Acid IP	125mg+50mg	Suspension	c
78	375	Paracetamol IP+Phenylphirine HCl IP+Chlorpheniramine Maleate IP	125mg/250mg+ 2.5mg/5mg+1m g/2mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
79	376	Paracetamol IP+Pentazocin HCl IP	500mg+15mg	Tablets	a FDC is not rationale. Addition of Paracetamol with pentazocin is not proven to increase efficay but can increase the side effects.
80	392	Aceclofenac+Paracetamol	50mg+125mg	Syrup	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
81	395	Mefenamic Acid+Paracetamol	50mg+125mg	Oral Liquid	c
82	418	Mefenmic Acid+Dicyclomine HCl	250mg+10mg	Uncoated tablet	c
83	424	Thiocolchicoside IP+Aceclofenac IP+Paracetamol IP	4mg+100mg+3 25mg	Film Coated Tablets	d Already categorize as d
84	432	Paracetamol IP+Aceclofenac IP	125mg+50mg	Liquids	a Aceclofenac is not recommended paediatric population . Dosage of parscetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
85	439	Paracetamol IP+Diclofenac Potassium BP+ Caffeine Anhydrous IP	325mg+50mg+ 30mg	Uncoated Tablets	a There is no scientific rationale for this FDC.Addition of caffein does not add any therapeutic benefit.
86	441	Paracetamol IP+Caffeine IP+Diphenhydramine HCl IP	320mg+30mg+ 12.5mg	Uncoated Tablets	c If paracetamol dose is 500 mg,and FDC is indicated for symptomatic treatment of viral upper respiratory tract infection.
87	446	Mefenamic Acid+Paracetamol IP	50mg+125mg	Tablets	c for peadiatric use.
88	454	Flupirtine Maleate IP+Paracetamol IP	100mg+325mg	Film Uncoated bilayered tablets	a There is no scientific rationale.
89	470	Dicyclomine HCl+Mefenamic Acid	20mg+500mg	Film Coated Tablets	c
90	484	Mefenamic Acid+Paracetamol+Benzyl Alcohol	50mg+150mg+ 2%w/v	Liquid Injection	a FDC is not rationale in this dosage form.
91	497	Paracetamol+Phenylephrine HCl+Chlorpheniramine maleate	325mg+10mg+ 2mg	Uncoated tablet	d Similar FDC is already discussed by 10 expert Committee
92	498	Ergotamine tartrate+Caffeine+Paracetamol+Prochlorpe razine maleate	1mg+100mg+2 50mg+2.50mg	Tablets	a Irrationale FDC. Safer and efficasious drugs are available.
93	516	Ergotamine tartrate+Caffeine+Paracetamol+Prochlorpe razine maleate	1mg+100mg+2 50mg+2.5mg	Uncoated tablet	a Irrationale FDC. Safer and efficasious drugs are available.
94	517	Flunarizine Di HCl+Domperidone+Paracetamol	5mg+10mg+50 0mg	Uncoated tablet	a Already declared as " a" category
95	518	Paracetamol+Mefenamic Acid	125mg+50mg	Oral liquid	c
96	519	Mefenamic Acid+Paracetamol	50mg+125mg	Suspension	c
97	520	Mefenamic Acid+Paracetamol	50mg+125mg	Oral liquid	c
98	521	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephirine HCl IP+Bromhexine HCl IP	125mg+1.25mg g+2.5mg+4.0m g	Oral Liquid	a There is no pharmacodynamic relevance of adding so many ingredients which does not have any added therapeutic advantage.
99	522	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephirine HCl IP	125mg+1.0mg+ 2.5mg	Oral Liquid	d Similar FDC is already discussed by 10 expert Committee

100	523	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephirine HCl IP+Bromhexine HCl IP	125mg+1.25mg +2.5mg+4.0mg	Oral Liquid	a There is no pharmacodynamic relevance of adding so many ingredients which does not have any added therapeutic advantage
101	528	Paracetamol IP+Diclofenac Sodium IP+Magnesium Trisilicate IP	325mg+50mg+ 150mg	Uncoated Tablets	a Already categorise as "a"
102	534	Paracetamol IP+Mefenamic Acid IP	325mg+500mg	Uncoated Tablets	c
103	536	Tramadol HCl BP+Paracetamol IP+Caffeine IP+Taurine USP	37.5mg+325mg +30mg+250mg	Film Coated Tablets	a There is no scietific rationale for this FDC.
104	541	Tramadol HCl BP+Dicyclomine HCl IP+Domperidone BP	50mg+10mg+10mg	Uncoated Dispersible tablets	a There is no scietific rationale for combining domperidone in the present FDC.
105	551	Diclofenac Sodium IP+Paracetamol IP	50mg+325mg	Uncoated Dispersible tablets	c
106	556	Novomal Plus Tablet IP, Diclonov Plus Tablets, N-CT Tablet, Parallkin Syrup, Stomacid, DEC Syrup (Essofi), Novacid, Novo Carmin, Romandyl, Novormon, Kofolax (Cough Expectorent), Novorex Forte, Calciferol	1.160%w/w + 0.025%w/w + 1.000%w/w + 3.000%w/w +	Topical Aerosol	Incomplete iformation
107	575	Diacerein IP+Glucosamine Sulphate Potassium Chloride USP 750mg+Methyl Sulphonyl Methane	50mg+750mg+ 200mg	Film Coated Tablets	c Already approved by DCGI
108	579	Drotaverine HCl+Mefenamic Acid	80mg+250mg	Oral Tablet	subjudice
109	591	Paracetamol IP+Diclofenac Sodium IP+Magnesium Trisilicate IP	300mg+50mg+ 100mg	Uncoated Tablets	a Already categorise as "a".
110	593	Paracetamol IP+Diclofenac Sodium IP+Magnesium Trisilicate IP+Chlorpheniramine Maleate IP	500mg+50mg+ 100mg+2mg	Uncoated Tablets	a There is no pharmacodynamic relevance of adding so many ingredients which does not have any added therapeutic advantage.
111	595	Diclofenac pottasium +Pitofenac HCL+Fenpiverinium Bromide	50 mg+ 5 mg+ 0.1 mg	Tablet	Sub-judice
112	597	Novomal Plus Tablet IP, Diclonov Plus Tablets, N-CT Tablet, Parallkin Syrup, Stomacid, DEC Syrup (Essofi), Novacid, Novo Carmin, Romandyl, Novormon, Kofolax (Cough Expectorent), Novorex Forte, Calciferol	Nil	Nil	Incomplete
113	606	Mefenamic Acid IP+Paracetamol IP	50mg+125mg	Suspension	c
114	614	ParacetamolIP+Mefenamic Acid IP	125mg+50mg	Suspension	c
115	616	Paracetamol IP+Mefenamic Acid IP	125mg+50mg	Suspension	c
116	618	Aceclofenac+Paracetamol IP	50mg+125mg	Suspension	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
117	619	Aceclofenac IP+Paracetamol IP	50mg+125mg	Tablet	a Aceclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
118	620	Paracetamol IP+Mefenamic Acid IP	325mg+250mg	Uncoated Tablets	c
119	632	Paracetamol IP+Mefenamic Acid IP	125mg+50mg	Uncoated Tablets	c for peadiatric use.
120	636	Paracetamol IP+Mefenamic Acid IP	325mg+500mg	Tablets	c
121	643	Diclofenac Sodium IP+Paracetamol IP+Benzyl Alcohol IP	25mg+75mg+1 %w/v	Injection	a There is no scientific rationale for this FDC.Dosage of ingredients are subtherapeutic.

122	648	Thiocolchicoside IP+Diclofenac SodiumIP (As enteric coated tablet)+Paracetamol IP	4mg/8mg+50mg +325mg	Hard Gelatin Capsules	d
123	650	Thiocolchicoside IP+Diclofenac Sodium IP (As enteric coated tablet)+Paracetamol IP	4mg/8mg+50mg +325mg	Hard Gelatin Capsules	d
124	659	Diclofenac Sodium IP+Chlorzoxazone USP	50mg+500mg	Uncoated tablets	c Already approved by DCGI
125	660	Trypsin-Chymotrypsin+Aceclofenac IP+Paracetamol IP	50,000 Armour unts of enzymatic activity+100mg+ 500mg	Film Coated Tablets	d
126	664	Diclofenac Sodium IP+Chlorzoxazone USP	50mg+250mg	Film Coated Tablets	a Dose of chlorzoxazone is subtherapeutic
127	667	Camylofin Dihydrochloride+Mefenamic Acid IP	50mg+250mg	Film Coated Tablets	d
128	680	Diclofenac Sodium IP+ParacetamolIP+Benzyl ALCOHOL ip	25mg+75mg+1 %w/v	Small Volume Parenterals (Ampoules)	a There is no scientific rationale for this FDC.Dosage of ingredients are subtherapeutic.
129	685	Ampicillin Sodium IP+Cloxacillin Sodium IP	250mg/500mg+ 250mg/500mg	Dry powder for injection	c
130	689	Levofloxacin Hemihydrate IP+Ornidazole IP	62.5mg+125mg per 5ml	Oral suspension	sub-judice
131	694	Levofloxacin Hemihydrate eq. to Levofloxacin +Ornidazole	250mg+500mg	Tablets	Sub-Judice
132	705	clindamycin phosphate+ clotrimazole+ tinidazole	100mg+ 100 mg+ 100 mg	Soft gelatin capsule	c if vaginal delivary system.
133	718	Amoxicillin+Potassium Clavulanate Diluted	400mg/200mg/2 50mg+57mg/28. 5mg/62.5mg	Dry Syrup	c Except Amoxycilin 250 mg + Clavulanic acid 62.5 mg

134	719	Procaine Penicillin IP+Penicillin G Sodium IP+Steptomycin Sulphate IP eq. to Streptomycin base	1,500,000 units (1.5g)+500,000 units (300mg)+2.5mg	Dry Powder Injection	a, There is no adequate scientific data to justify the rationality of this FDC Though individual drugs may be efficacious seperately in a few conditions . However there is no rational for combining them in FDC form.
135	722	Levofloxacin Hemihydrate IP+Ornidazole IP	100mg+200mg	Oral suspension	Sub-judice
136	739	Procaine penicillin + benzyl penicillin sodium	1.5g + 300 mg	dry powder injection	c
137	772	amoxycillin + Potassium clavulanic acid	250 mg/500 mg/875 mg/200 mg+ 125 mg/125 mg/125 mg/28.5 mg	tablets	c Except Amoxycilin 200 mg + Clavulanic acid 28.5 mg for which data needs to be generated as recommended by earlier committee on 06.03.2014.(Regarding amoxicillin 200 mg + Clavulanic acid 28.5mg Tablet/dispersible tablet, committee observed that original data needs to be generated on their own formulation of the firms in respect of Bioavailability, Acceptability/ palatability, in pediatric population. Accordingly, protocol shall be submitted within 3 months and data shall be generated within next one and half year.)
138	773	procaine penicillin+ penicillin G sodium+	800 mg+ 120 mg	sry powder injection	c
139	776	levofloxacin hemihydrate+ ornidazole	250 mg/250 mg+ 125 mg/125 mg	film coated tablet/syrup	sub-judice
140	777	ampicillin sodium+ cloxacillinsodium	250 mg+ 250 mg	injection	c
141	792	Procaine Penicillin+Penicillin G Sodium IP	600,000 units (600mg)+400,000 units (240mg)	Dry Powder Injection	c
142	813	levofloxacin + ornidazole	250 mg+ 500 mg	tablets	sub-judice
143	816	Procaine Penicillin+Penicillin G Sodium IP	3000, 000 units (3.0gm) + 2000, 000 units (1.2gm)	Dry Powder Injection	c
144	830	Azithromycin IP+Adapalene	2%w/w + 1%w/w	gel	a As per standard treatment guidelines topical azithromycin is not recommended. No scientific evidence is to support its topical use. Further topical misuse of azithromycin will lead to resistance development
145	847	Flavoxate HCL+Ofloxacin	200mg+200mg	Tablet	a, Flavoxate may cause urinary retension.This will further worsen UTI.There is also pharmacokinetin incompatibility
146	851	Procain Penicillin+Benzyl Penicillin sodium	1.5g+300mg	Dry Powder Injection	c
147	854	Cephalexin Monohydrate IP+Serratiopeptidase	1.5gm+10mg	Powder	a Irrationale combination without any scientific evidence.
148	875	Procaine Penicillin+Penicillin G Sodium	300mg+120mg	Dry powder injections	c
149	884	Clotrimazole IP+Tinidazole IP+Povidone Iodine IP+Lactic Acid Bacillus	200mg+500mg +200mg+150 millon spores	Uncoated Tablets	c If vaginal tablets
150	899	Levofloxacin Hemihydrate IP+Ornidazole IP	250mg+500mg	Film Coated Tablets	sub-judice

151	902	Flavoxate HCl BP+Ofloxacin IP	200mg+200mg	Film Coated Tablets	a, Flavoxate may cause urinary retension.This will further worsen UTI.There is also pharmacokinetin incompatibility.
152	907	Cefixime IP eq. to anhydrous Cefixime+Acetyl Cysteine USP	200mg+300mg	Film Coated Tablets	a There is no justification for combining an antibiotic with mucolytic agent.
153	912	Clotrimazole IP+Tinidazole IP+Lactic Acidbacillus	200mg+500mg +150 million spores	Uncoated Tablets	c if vaginal tablets
154	935	Flavoxate HCl BP+Ofloxacin IP	200+200mg	Uncoated Tablets	a There are chances of misuse.Flavoxate may cause retention of urine in elder which will further worsen UTI . Also there is pharmacokinetic incompatibility.
155	948	Flavoxate HCl BP+Ofloxacin IP	200mg+200mg	Film Coated Tablets	a, Flavoxate may cause urinary retension.This will further worsen UTI.There is also pharmacokinetin incompatibility.
156	956	Amoxicillin Trihydrate+Dicloxacillin Sodium+Lactobacillus	250mg+250mg +60 million spores	Hard gelatin capsules	a, Committee opined that : (a) Since, 2006 the scenario of antimicrobial resistance pattern has changed significantly, majority of isolates of Staph. aureus have become resistance to the amoxicillin &cloxacillin including dicloxacillin (b) Better efficacious antibiotic andare now available and used for staph. aureus infections. In light of these, the rationality of combination in current scenario is questionable
157	974	Clindamycin Phosphate USP+Niacinamide IP+Tretinin USP	1.0%w/w + 4.0%w/w + 0.025%w/w	Gel	c
158	995	Clotrimazole+Tinidazole+Povidone Iodine	200mg+600mg +200mg	Vaginal Tablets	c
159	998	Clindamycin+Nicotinamide	1.0%w/w+4.0% w/w	Gel	c
160	1031	Metronidazole+Furazolidone IP	100mg+30mg	Suspension	c
161	1065	Furazolidone IP+Metronidazole IP	100mg+200mg	uncoated tablet	c

162	1089	Povidone Iodine IP+Metronidazole IP+Aloe Vera	5%w/w + 1.0%w/w + 1.5%w/w	Ointment	a Irrationale combination ingredients have different therapeutic indication
163	1076	Clindamycin Phosphate BP eq. to Clindamycin+Nicotinamide IP	1% w/w + 4% w/w	Gel	c
164	1079	Amoxycillin Trihydrate IP eq. to Amoxycillin+Cloxacillin Sodium IP eq. to Cloxacillin + Probenecid IP	250mg+250mg +250mg	Film Coated Tablet	c
165	1086	Flavoxate Hydrochloride BP+Ofloxacin IP	200mg+200mg	Film Coated Tablets	a, Flavoxate may cause urinary retension.This will further worsen UTI.There is also pharmacokinetin incompatibility.
166	1089	Norfloxacin IP+Tinidazole (With Betacyclodextrin) IP	1.0% w/w + 0.5% w/w	Eye Ointment	a The Committee obeserved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
167	1092	Erythromycin Stearate IP eq. to Erythromycin+Lactic Acid Bacillus IH	500mg+60 Million spores	Uncoated Tablets	a, The lactic acid bacillus dose is suboptimal
168	1121	Cefixime IP(as trihydrate) eq. to anhydrous Cefixime, Streptococcocus faecalis T-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus (Lactobacillus sporogenes)	200mg, 60 Million+4 Million+2Million +100 Million	Capsules	c
169	1123	Cefpodoxime Proxetil IP eq. to Cefpodoxime, Streptococcus faecalis T-110 JPC+Clostridium butyricum TO-A JPC+Bacillus mesentericus TO-A JPC+Lactic acid Bacillus	200mg, 60 Million+4 Million+2 Million+100 Million	Capsules	c
170	1128	Outer sachet 1.0 g contains (Cefixime IP (as trihydrate) eq. to anhydrous Cefixime), Inner Pre & Probiotics Sachet 0.5g Contains (Streptococcus faecalis TO-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus (Lactobacillus sporogenes)	50mg, 30 Million+2 Million+1 Million+50 Million	Sachet in sachet	c
171	1129	Outer sachet 1.0 g contains (Cefixime IP (as trihydrate) eq. to anhydrous Cefixime), Inner Pre & Probiotics Sachet 0.5g Contains (Streptococcus faecalis TO-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus (Lactobacillus sporogenes)	100mg+30 Million+2 Million+1 Million+50 Million	Sachet in sachet	c
172	1130	Outer sachet 1.25g contains (Cefpodoxime proxetil IP eq. to Cefpodoxime),Inner Pre & Probiotics Sachet 0.5g Contains (Streptococcus faecalis TO-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus (Lactobacillus sporogenes)	100mg,30 Million+2 Million+1 Million+50 Million	Sachet in sachet	c
173	1131	HPMC capsules contains (Cefpodoxime proxetil IP eq. to Cefpodoxime)+Inner HPMC Capsules Contains (Streptococcus faecalis TO-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus (Lactobacillus sporogenes)	200mg, 60 Million+4 Million+2 Million+100 Million	Capsules	c

174	1132	Levofloxacin Hemihydrate IP eq. to Levofloxacin+Ornidazole IP	250mg+500mg +250mg+20mg	Film Coated Tablets	Sub-judice
175	1134	Sterile Collagen Periodontal Chip with Chlorhexidine Gluconate IP	2.5mg	Chip	c
176	1135	Sterile Collagen with Tetracycline Hydrochloride IP	2.0mg	Chip	c
177	1142	Diethylcarbamazine Citrate IP+Cetirizine Hcl IP	150mg+5mg	Film Coated Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only.The dose titration of ingredients is not practical in this FDC.
178	1143	Diethylcarbamazine Citrate IP+Cetirizine Hcl IP	300mg+10mg	Film Coated Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only.The dose titration of ingredients is not practical in this FDC.
179	1148	Levofloxacin Hemihydrate IP eq. to Levofloxacin+Ornidazole IP	250mg+500mg	Film Coated Tablets	Sub-judice
180	1149	Povidone Iodine IP+Ornidazole IP+Dexpanthenol USP	5% w/w + 1% w/w + 5% w/w	Ointment	a irrationale combination.The role of dexpanthenol is not scientifically justified.
181	1150	Outer sachet (1 gm) Cefixime IP (As Trihydrate) eq. to anhydrous cefixime & Inner Probiotics sachet (0.5 gm)Streptococcus Faecalis T-110JPC+Clostridium butyricum TO-A+Basillus mesentricus TO-A JPC+Lactic Acid bacillus	50mg , 30 Million+2 Million+1 Million+50 Million	Powder	c
182	1151	Outer sachet (1.25 gm) Cefpodoxime proxil IP (As Trihydrate) eq. to anhydrous Cefpodoxime & Inner Probiotics sachet (0.5 gm)Streptococcus Faecalis T-110JPC+Clostridium butyricum TO-A+Basillus mesentricus TO-A JPC+Lactic Acid bacillus	50mg, 30 Million+2 Million+1 Million+50 Million	Powder	c
183	1152	Outer sachet (1 gm) Cefixime IP (As Trihydrate) eq. to anhydrous cefixime & Inner Probiotics sachet (0.5 gm)Streptococcus Faecalis T-110JPC+Clostridium butyricum TO-A+Basillus mesentricus TO-A JPC+Lactic Acid bacillus	100mg , 30 Million+2 Million+1 Million+50 Million	Powder	c
184	1153	Outer sachet (1.25 gm) Cefpodoxime proxil IP (As Trihydrate) eq. to anhydrous Cefpodoxime & Inner Probiotics sachet (0.5 gm)Streptococcus Faecalis T-110JPC+Clostridium butyricum TO-A+Basillus mesentricus TO-A JPC+Lactic Acid bacillus	100mg , 30 Million+2 Million+1 Million+50 Million	Powder	c
185	1156	Aloes IP+Povidone Iodine (0.5% w/w available Iodine) IP+Metronidazole IP	1.5% w/w + 5%+1% w/w	Ointment	a All the three ingredients have different therapeutic indications. The FDC is not scientifically rationale.
186	1163	FDC list for obtaining permission of New Drugs within 18 Months	Nil	Nil	No information
187	1164	Propranolol Hcl IP+Clonazepam IP	10mg/10mg/20 mg/20mg+0.25 mg/0.5mg/0.25 mg/0.5mg	Tablet	d

188	1167	Rosuvastatin+Clopidogrel	10mg/5mg+75mg	Capsules	c recommended only for post coronary interventation and acute coronary syndrome.
189	1171	Atorvastatin+Clopidogrel	20mg/10mg+75 mg	Capsules	c similar type of FDC containing different types of calcium channel blockers with ARBs have already been approved by DCGI
190	1181	propranolol hydrochloride + clonazepam	20.0 mg/20.0 mg+ 0.25 mg/0.5 mg	Tablet	d
191	1182	propranolol hydrochloride + etizolam	20mg/20 mg/40 mg+ 0.25 mg/0.5 mg/ 0.5 mg	tablet	a There is no rationale for combining beta blocker with an benzodiazepine analogue.
192	1189	Cilnidipine+Telmisartan IP	10mg+40mg	film coated tablets	c similar type of FDC containing different types of calcium channel blockers with ARBs have already been approved by DCGI
193	1191	Metoprolol+Cilnidipine	50mg+10mg	Tablets	c similar type of FDC containing different types of calcium channel blockers with beta blockers have already been approved by DCGI
194	1192	Cilnidipine+Metoprolol Succinate	10mg+50mg	Tablets	c similar type of FDC containing different types of calcium channel blockers with beta blockers have already been approved by DCGI
195	1193	Telmisartan+Cilnidipine	40mg+10mg	Tablets	c similar type of FDC containing different types of calcium channel blockers with ARBs have already been approved by DCGI
196	1201	Rosuvastatin+Clopidogrel	5mg/10mg/20mg+75mg	Capsules	c recommended only for post coronary interventation and acute coronary syndrome.
197	1203	Atorvastatin+Clopidogrel	10mg/20mg+75 mg/75mg	Capsules	c recommended only for post coronary interventation and acute coronary syndrome.
198	1209	Rosuvastatin+Aspirin+Clopidogrel	10mg+75mg+75mg	Hard Gelatin Capsule	c recommended only for post coronary interventation and acute coronary syndrome.
199	1217	rosuvastatin calcium + clopidogrel bi sulphate	5/10 mg+ 75 mg	capsule	c recommended only for post coronary interventation and acute coronary syndrome.
200	1218	atrovastatin calcium+ clopidogeral bisulphate	10 mg+ 75 mg	hard gelatin caspule	c recommended only for post coronary interventation and acute coronary syndrome.
201	1228	Cilnidipine+Telmisartan IP	10mg+40mg	Tablets	c similar type of FDC containing different types of calcium channel blockers with ARBs have already been approved by DCGI
202	1233	Atorvastatin calcium+Clopidogrel Bisulphate	10/20mg+75 mg	Capsule	c recommended only for post coronary interventation and acute coronary syndrome.
203	1241	Cilnidipine+ Telmisartan	10mg+40mg	Tablets	c similar type of FDC containing different types of calcium channel blockers with ARBs have already been approved by DCGI
204	1242	Cilnidipine+Telmisartan+Chlorthalidone	10mg+40mg+6.25mg	Tablets	c similar type of FDC containing different types of calcium channel blockers with ARBs and diuretics have already been approved by DCGI
205	1245	cilnidipine + olmesaratan medoximil	10mg+ 20 mg	film coated tablet	c similar type of FDC containing different types of calcium channel blockers with ARBs have already been approved by DCGI
206	1247	Cilnidipine+telmisartan+Chlorthalidone	10mg+40mg+6.25mg	Tablet	c similar type of FDC containing different types of calcium channel blockers with ARBs and diuretics have already been approved by DCGI
207	1261	Rosuvastatin Calcium IP+Clopidogrel Bisulphate IP	5mg/10mg+75mg/75mg	Hard Gelatin Capsules	c recommended only for post coronary interventation and acute coronary syndrome.

208	1263	Fenofibrate + atorvastatin calcium + ezetimbine	160 mg+ 10 mg+ 10 mg	tablet	c For the treatment of combined hyperlipidemia in patients with normal hepatic and renal function
209	1265	Cilnidipine+Metoprolol Succinate	10mg+25mg/50 mg	Tablets	c similar type of FDC containing different types of calcium channel blockers with beta blockers have already been approved by DCGI
210	1266	Atorvastatin Calcium+Ramipril & Clopidogrel	10mg+5mg&75 mg	Combikit	c For secondary prevention of coronoryheart disease/stroke in patients where use of such combination is appropriate
211	1275	Rosuvastatin Calcium IP+Clopidogrel Bisulphate IP	5mg/10mg+75m g	Tablets	c recommended only for post coronary interventation and acute coronary syndrome.
212	1283	Atorvastatin Calcium eq. to Atorvastatin+Clopidogrel Bisulphate eq. to Clopidogrel	10mg+75mg	Capsules	c recommended only for post coronary interventation and acute coronary syndrome.
213	1285	Cilnidipine+Chlorthalidone IP	10mg/10mg+6.2 5mg/12.5mg	Film Coated Tablets	c similar type of FDC containing different types of calcium channel blockers with diuretics have already been approved by DCGI
214	1289	Trimetazidine HCl IP+Metoprolol Succinate USP	35mg/35mg+ 25mg/50mg	Uncoated bilayered tablets	c If trimetazidine is in SR form. FDC is indicated for coronary artery disease
215	1294	Rosuvastatin Calcium IP+Clopidogrel Bisulphate IP	10mg+150mg	Hard Geletin Capsules	c recommended only for post coronary interventation and acute coronary syndrome
216	1296	Pitavastatin Calcium+Choline Fenofibrate	2mg+135mg	Hard Geletin Capsules	c For the treatment of combined hyperlipidemia in patients with normal hepatic and renal function
217	1299	Trimetazidine HCl IP+Metoprolol Succinate USP	35mg/35mg+25 mg/50mg	Uncoated Tablets	c If trimetazidine is in SR form. FDC is indicated for coronary artery disease
218	1300	Cilnidipine+Ramipril	5mg/10mg+2.5 mg/5mg	Capsules	c similar type of FDC containing different types of calcium channel blockers with ACE inhibitor have already been approved by DCGI
219	1303	Cilnidipine+Telmisartan	10mg+40mg	Film coated bilayered tablets	c similar type of FDC containing different types of calcium channel blockers with ARBs have already been approved by DCGI
220	1309	Rosuvastatin Calcium IP+Aspirin IP+Clopidogrel Bisulphate IP	5mg/10mg/20m g+75mg/75mg/7 5mg+75mg/75m g/75mg	Hard gelatin capsules	c recommended only for post coronary interventation and acute coronary syndrome
221	1315	Telmisartan+Cilnidipine+chlorthalidone	40mg+10mg+1 2.5mg	Tablets	c similar type of FDC containing different types of calcium channel blockers with ARBs and diuretics have already been approved by DCGI
222	1321	Nebivolol HCl+Cilnidipine	2.5mg/5.0mg+1 0mg/10mg	Tablets	c similar type of FDC containing different types of calcium channel blockers with beta blockers have already been approved by DCGI
223	1322	Telmisartan+cilnidipine	40mg/80mg+10 mg/10mg	Tablets	c similar type of FDC containing different types of calcium channel blockers with ARBs have already been approved by DCGI
224	1334	Atorvastatin+Clopidrogrel	10mg/20mg+75 mg/75mg	Capsulee	c similar type of FDC containing different types of calcium channel blockers with ARBs have already been approved by DCGI
225	1337	Atorastatin Calcium IP eq. to Atorastatin+Clopidogrel Bisulphate IP eq. to Clopidogrel	10mg+75mg	Hard GelatinCaps ule	c similar type of FDC containing different types of calcium channel blockers with ARBs have already been approved by DCGI

226	1338	Atorvastatin Calcium IP eq. to Atorvastatin+Ramipril IP & Aspirin IP	10mg+5mg & 75mg	Combikit (Hard Gelatin Capsule/Enteric Coated Tablet)	subjudice
227	1342	Atorvastatin+Fenofibrate+Ezitimibe	10mg+200mg+10mg	Film Coated Tablets	c For the treatment of combined hyperlipidemia in patients with normal hepatic and renal function
228	1343	Chlorthalidone IP+Metoprolol Succinate USP eq. to Metoprolol tartrate (in extended release form)	12.5mg+47.5mg eq. to 50 mg	Film coated bilayered tablets	c
229	1346	Clopidogrel Bisulfate IP eq. to Clopidogrel+Aspirin IP(As enteric coated granules)	75mg+162.5mg	Film Coated tablets	c
230	1349	Rosuvastatin Calcium IP eq. to Rosuvastatin+Clopidogrel Bisulphate IP eq. to Clopidogrel	10mg+75mg	Hard Gelatin Capsules	c recommended only for post coronary interventation and acute coronary syndrome.
231	1350	Rosuvastatin Calcium IP eq. to Rosuvastatin+Clopidogrel Bisulphate IP eq. to Clopidogrel	5mg+75mg	Hard Gelatin Capsules	c recommended only for post coronary interventation and acute coronary syndrome.
232	1351	Rosuvastatin Calcium IP eq. to Rosuvastatin+Clopidogrel Bisulphate IP eq. to Clopidogrel	5mg+75mg	Hard Gelatin Capsules	c recommended only for post coronary interventation and acute coronary syndrome.
233	1352	Rosuvastatin Calcium IP eq. to Rosuvastatin+Clopidogrel Bisulphate IP eq. to Clopidogrel	10mg+75mg	Hard Gelatin Capsules	c recommended only for post coronary interventation and acute coronary syndrome.
234	1356	Atorvastatin calcium IP eq. to Atorvastatin(as film coated tablets)+Clopidogrel Bisulphate IP eq. to Clopidogrel	10mg/20mg+75mg	Hard gerlatin Capsules	c recommended only for post coronary interventation and acute coronary syndrome.
235	1381	Diethyl Carbamazine Citrate IP+Chlorpheniramine Maleate IP	250mg+4mg	Uncoated Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
236	1383	Risperidone BP+Trihexyphenidyl HCl IP	2mg+2mg	film coated tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
237	1400	Risperidone+Trihexyphenidyal	2mg+2mg	Tablet	c Indicated for patients on risperidon with extra pyramidal side effects.
238	1405	Risperidone BP+Trihexyphenidyl HCL IP	3mg+2mg	Film Coated Tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
239	1411	Risperidone+ tri Hexy-phenidyl hydrochloride	2 mg+ 2 mg	tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
240	1412	zolpidem tartrate+ melatonin	5 mg/10 mg+ 3 mg	tablets	d
241	1418	Risperidone IP+Trihexychenidyl HCl IP	4mg+2mg	Film Coated Tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
242	1431	Risperidone BP+Trihexyphenidyl HCL IP	2mg/3mg/4mg+2mg/2mg/2mg	Film Coated Tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
243	1433	cyproheptadine hydrochloride+ trichicline citrate+ sorbitol	2 mg+ 275 mg+ 2 gm	suspension/oral liquid	c
244	1438	Doxylamine Succinate USP+Pyridoxine HCl IP	10mg+10mg	Tablets	c
245	1440	piracetam + Ginkgo biloba extracts	400 mg+ 60 mg	film coated tablet	a Inadequate scientific data for this FDC.
246	1441	piracetam + Ginkgo biloba extracts + vinpocetin	800 mg+ 60 mg+ 5 mg	film coated tablet	a There is no scientific rationale for this FDC.
247	1444	risperidone + trihexyphenidyl HCL	2 mg/3 mg/4mg+ 2 mg	film coated tablet	c Indicated for patients on risperidon with extra pyramidal side effects.

248	1445	Doxylamine succinate+Pyridoxin HCL+Folic acid	10mg+10mg+2.5mg	Enteric Coated Tablets	c
249	1448	Diethyl Cabamazine citrate+Cetrizine dihydrochloride	150mg+5mg	Film coated Tablet	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
250	1450	Diethyl Carbamazine citrate+Cetrizine dihydrochloride	300mg+10mg	Tablet	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
251	1458	Doxylamine Succinate + Pyridoxine HCl + Folic Acid	10mg/20mg+20mg+5mg	Tablets	c
252	1460	Doxylamine Succinate+Pyridoxine HCl	10mg/20mg+10mg/20mg	Tablets	c
253	1461	Diethyl Carbamazine Citrate + Cetrizine HCl	150mg/300mg+5mg/10mg	Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
254	1463	Pyridoxine HCl IP+Doxylamine Succinate USP	10mg+10mg	Enteric Coated Tablets	c
255	1465	Doxylamine Succinate USP + Pyridoxal-5-Phosphate + L-Methylfolate Calcium	10mg+10mg+1mg	Tablets	c
256	1469	Doxylamine Succinate BP+Pyridoxine HCl IP	10mg/20mg+10mg/20mg	Enteric Coated Tablets	c
257	1470	Doxylamine Succinate+Pyridoxine HCl+Folic Acid IP	10mg+10mg+2.5mg	Enteric Coated Tablets	c
258	1471	Doxylamine Succinate+Pyridoxal-5-Phosphate+L-Methyl Folate Calcium	10mg+10mg+1mg	Film Coated Tablets	c
259	1472	Doxylamine Succinate USP + Pyridoxine HCl IP + Folic Acid IP	10mg+10mg+2.5mg	Enteric Coated Tablets	c
260	1475	Doxylamine Succinate USP + Pyridoxine HCl IP + Folic Acid IP	10mg+10mg+2.5mg	Enteric Coated Tablets	c
261	1476	Doxylamine Succinate USP + Pyridoxine HCl IP	10mg+10mg	Enteric Coated Tablets	c
262	1483	Doxylamine IP+Pyridoxine IP+Folic Acid IP	10mg+10mg+2.5mg	Enteric Coated Tablets	c
263	1484	Doxylamine Succinate USP+Pyridoxine HCl IP	10mg+10mg	Enteric Coated Tablets	c
264	1485	Divalproex Sodium + Levetiracetam	150mg/300mg+250mg/500mg	Film Coated Tablets	a FDC in the treatment of epilepsy has no therapeutic role .Treatment of epilepsy is always started with a single drug. Before introducing the second drug , the dose of first drug need to be achieved to the maximum/tolerated level. With this FDC, titration of individual drug is not possible.

265	1487	Divalproex Sodium + Oxcarbazepine IP	250mg+150mg	Film Coated Tablets	a FDC in the treatment of epilepsy has no therapeutic role .Treatment of epilepsy is always started with a single drug. Before introducing the second drug , the dose of first drug need to be achieved to the maximum/tolerated level. With this FDC, titration of individual drug is not possible.
266	1492	Risperidone+Trihexyphenidyl	3mg/4mg+2mg/2mg	Mouth-Disolving Tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
267	1496	Doxylamine Succinate USP+Pyridoxine HCl IP+Folic Acid IP	10mg+10mg+2.5mg	Enteric Coated Tablets	c
268	1498	Risperidone+Benzhexol HCl	2mg/3mg/4mg+2mg	Tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
269	1501	Diethyl Carbamazine+Cetirizine	150mg/300mg+5mg/10mg	Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
270	1502	Divalproex Sodium+Leveticetam	200mg+500mg	Suspension	a FDC in the treatment of epilepsy has no therapeutic role .Treatment of epilepsy is always started with a single drug. Before introducing the second drug , the dose of first drug need to be achieved to the maximum/tolerated level. With this FDC, titration of individual drug is not possible.
271	1503	Piracetam+Ginkgo Biloba+Vinpocetin	800mg+80mg+5mg	Tablets	a There is no scientific rationale for this FDC.
272	1505	Doxylamine Succinate+Pyridoxine HCl+Folic Acid	10mg+10mg+2.5mg	Film Coated Tablets	c
273	1507	Diethylcarbamazine Citrate IP+Levocetirizine HCl IP	150mg+2.5mg	Film Coated tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
274	1508	Doxylamine Succinate+Vitamin B6 IP	10mg+10mg	Enteric Coated Tablets	c
275	1518	Pyridoxine HCl IP+Doxylamine Succinate USP	20mg+20mg	Enteric Coated Tablets	c
276	1524	Risperidone+Trihyxyphenidyl HCl	2mg/3mg+2mg	Tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
277	1533	Nicergoline BP+Vinpocetine BP	5mg+5mg	Film Coated Tablets	a There is no scientific rationale for this FDC.
278	1535	Risperidone BP+Trihexiphenidyl HCl IP	2mg+2mg	Film Coated Tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
279	1540	Doxylamine Succianate USP+Pyridoxine Hcl IP+Folic Acid IP	20mg/10mg+20mg/10mg+5mg/2.5mg	Tablet	c
280	1545	Pregabalin SR+Aceclofenac SR	75mg/150mg+200mg	Tablets	Already categorize as c

281	1551	Doxylamine Succinate+Pyridoxine HCl+Folic Acid	10mg+10mg+2.5mg	Film Coated Tablets	c
282	1555	Doxylamine Succinate USP+Pyridoxine HCl+Folic Acid	10mg+10mg+2.5mg	Enteric Coated Tablets	c
283	1557	Diethylcarbamazine Citrate IP+Chlorpheniramine Maleate IP	250mg+4mg	Film Coated Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only.The dose titration of ingredients is not practical in this FDC.
284	1558	Diethylcarbamazine Citrate IP+Chlorpheniramine Maleate IP	100mg+2mg	Film Coated Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only.The dose titration of ingredients is not practical in this FDC.
285	1574	Zolpidem Tartrate IP+Melatonin	10mg+3mg	Film Coated Tablets	d
286	1575	Zolpidem Tartrate IP+Melatonin	5mg+3mg	Film Coated Tablets	d
287	1580	Risperidone BP+Trihexyphenidyl Hydrochloride IP	3mg/4mg+2mg	Film coated tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
288	1581	Risperidone BP+Trihexyphenidyl Hydrochloride IP	2mg/4mg+2mg	Film coated tablets	c Indicated for patients on risperidon with extra pyramidal side effects.
289	1599	Glimepiride+Metformin HCl SR	3mg/4mg/3mg/4mg+500mg/500mg/1000mg/1000mg	Tablets	c
290	1694	Ursodeoxycholic Acid+Metformin HCl SR	150mg+500mg	Bilayered tablet	a
291	1695	Glimepiride+Metformin HCl	3mg/4mg+500mg/500mg	Tablets	c
292	1703	Glimepiride IP+Metformin HCl IP	3mg/4mg/3mg/4mg+500mg/500mg/1000mg/1000mg	Film coated bilayered tablets	c
293	1717	Glimepiride IP+Pioglitazone Hydrochloride IP eq. to Pioglitazone+Metformin Hydrochloride IP (in sustained release form)	1mg/2mg+7.5mg/15mg+500mg/1000mg	Uncoated bilayered tablets	a Already categorize as "a" earlier
294	1730	Metformin Hydrochloride IP (sustainded release)+Pioglitazone Hydrochloride IP eq. to Pioglitazone+Glimepride IP	1000mg+15mg+2mg	Uncoated bilayered tablets	a Already categorize as "a " earlier.
295	1745	Clotrimazole IP+Beclomethasone Dipropionate IP+Lignocaine HCl IP	1% w/v + 0.5% w/v + 0.025% w/v +2% w/v	Ear Drops	c Indicated for itching and pain, not for the dicharging ear.
296	1771	Naphazoline HCl+Sodium Carboxymethylcellulose+Menthol+Camphor +Stabilized Oxychlorocomplex	0.1%w/v+0.5% w/v+0.005%w/v +0.01%w/v+0.005%w/v	Nasal Spray	a There is no scientific rationale for this FDC.
297	1774	Naphazoline HCl+Azelastine HCl+Sodium Carboxy Methyl Cellulose+Menthol+Camphor+Stabilized oxychloro complex	0.1%w/v+0.05% w/v+0.5%w/v+0.005%w/v+0.01 %w/v+0.005%w/v	Drops	a There is no scientific rationale for this FDC.
298	1776	naphazoline HCL IP+Chlorpheniramine Maleate IP+Zinc Sulphate IP+Hydroxypropylmethycellulose IP+Benzalkonium Chloride IP	0.56mg+0.10mg +1.20mg+2.00 mg+0.0001 per ml	Ear Drops	a There is no scientific rationale for this FDC.

299	1781	Ofloxacin IP+Beclomethasone Dipropionate IP+Lignocaine HCl IP	0.3%w/v + 0.025%w/v + 1%w/v / 2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Lignocaine use in discharging ear is not required.
300	1782	Beclomethasone Dipropionate IP+Neomycin Sulphate IP+Clotrimazole IP+Lignocaine HCl IP	0.025%w/v + 0.5%w/v + 1%w/v + 2%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required.
301	1787	Beclomethasone Dipropionate IP+Neomycin Sulphate IP+Clotrimazole IP+Lignocaine HCl IP	0.025%w/v + 0.5%w/v + 1.0%w/v + 2.0%w/v	Ear Drops	a, Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required.
302	1788	Naphazoline HCl BP+Hydroxyl Propyl Methyl Cellulose IP+Boric Acid IP+Borax BP+Menthol IP+Camphor IP 66+ BKC IP	0.1%w/v + 0.2%w/v + 3.0%w/v + 0.05%w/v + 0.0025%w/v + 0.0025%w/v + 0.02%w/v	Ear Drops	a There is no scientific rationale for this FDC.
303	1800	Calcitonin (Salmon) BP+Benzalkonium Chloride IP	200 IU / 220 IU+0.01%w/v	Nasal Spray	c
304	1824	Streptococcus faecalis T-110 JPC+Clostridium Butyricum TO-A+Bacillus Mesentericus TO-A+Bacillus Coagulans	60 Million+4 Million+2 Million+100 Million	Lozenges	c
305	1825	Ofloxacin+Racecadotril	200mg/50mg+100mg/15mg	tablet/oral suspension	c only in case of tablet dosage form and not for suspension/dispersible tablet dosage form as there are chances of misuse in peadiatric population.
306	1826	Magladrate IP+Domperidone	480mg+10mg per 10ml	Oral suspension	d
307	1828	13.8108g Sachet (Macrogol 3350 13.125 g+Sodium Bicarbonate 178.5 mg+Sodium Chloride 350.7 mg+Pottasium Chloride 46.6 mg+Acesulfame K+Lime & Lemon Flavour)	Nil	Powder for Oral Solution	c, if used only for bowel preperation before colonoscopy examination.

308	1829	Sachet A 111.896g (Macrogol 3350 :100gm+Sodium Sulphate 7.5 gm+Sodium Chloride 2.891 gm+Pottasium Chloride 1.015 gm), Sachet B 10.60 gm (Ascorbic acid 4.7 gm + Sod. Ascorbate 5.90 gm)		Powder for Oral Solution	c, If used only for bowel preparation before colonoscopy examination.
309	1831	Rabeprazole +Domperidone	20mg+10mg	Enteric Coated Tablets	c
310	1838	Tricholine citate + sorbitol solution non crystallising IP	10 mg+ 7.15 mg	Liquid	c
311	1840	Cyproheptadine HCL IP+Tricholine Citrate	1.5mg+55mg	Syrup base	c
312	1843	Rabeprazole Sodium IP+Domperidone IP	20mg+10mg	Enteric coated tablets	c
313	1849	Dimethicone IP+Domperidone Maleate eq. to Domperidone+Dicyclomine HCL IP	40mg+5mg+10 mg	Liquid Suspension	c
314	1860	Laftutidine IR+Domperidone ER	10mg+30mg	Tablets	c
315	1868	Rabeprazole Sodium EC+Clindinium Bromide+Dicyclomine HCL+Chlordiazepoxide	10mg+2.5mg+10mg+5mg	Capsules	a There is no therepeutic justification for this FDC.
316	1869	Lafutudine+Domperidone	10mg+10mg/20 mg	Capsules	c If only domperidone 20 mg is in this FDC in SR form and domperidone 10 mg is in IR form in the
317	1872	Cyproheptadine HCl+Tricholine Citrate+Sorbitol Solution	2mg+275mg+3 gm	Syrup	c
318	1873	Chlordiazepoxide IP+Clidinium Bromide USP+Dicyclomine HCL	5mg+2.5mg+20 mg	Hard Gelatin Capsule	c
319	1882	Simethicone Emulsion USP eq. to Simethicone USP+Dil Oil BP+Fennel oil USP+	40mg+0.005ml+ 0.0007ml	Oral Drops	d
320	1884	Ursodeoxycholic Acid BP+Silymarin	150mg/300mg+ 70mg/140mg	Tablets	a
321	1892	Simethicone emulsion + fennel oil +Dil oil	40 mg+ 0.007 ml+ 0.005 ml	drop suspension	d
322	1895	cyproheptadine hydrochloride + tricholine Citrate	2 mg+ 275 mg	syrup	c
323	1898	Cyproheptadine HCl IP+Tricloline Citrate + Sorbitol 70% Solution IP	2.0mg+275.0mg +2gm	Oral Liquid	c
324	1903	Silymarine+Tricholine Citrate+Sorbitol	70mg+210mg+ 1gm	Oral Liquid	c
325	1904	Cyproheptadine HCl IP eq. to anhydrous Cyproheptadine HCl+Tricholine Citrate+Sorbitol (70%) IP	2mg+275mg+2 gm	Oral Liquid	c
326	1905	Omeprazole Magnesium USP eq. to Omeprazole+Domperidone	20mg+15mg	Tablets	a 1. omeprazole is not in EC form 2 Domperidone dose is not appropriate
327	1907	Rabeprazole sodium+ domperidone	20 mg+ 10 mg	tablets	c
328	1910	S- adenocyl methionine+ metadoxine+ ursodeoxycholic acid + chloine bi tratrtae+ silymarin+ L-ornithine L- aspartate+ inositol+ taurine	50 mg+250 mg+ 50 mg+ 200 mcg+ 30 mg + 70 mg+ 75 mg+ 8 mg + 50 mg	enteric coated tablet	a There is no therapeutic justification for this FDC.
329	1913	Cyproheptadine HCL + Tricholine Citrate	2mg+0.275gm	Syrup	c

330	1920	Ilaprazole+Domperidone IP	10mg+30mg	Hard Gelatin Capsules	c If only domperidone in this FDC is in SR form.
331	1922	Ursodeoxycholic Acid BP+Silymarin	150mg/300mg+ 70mg/140mg	Film coated tablets	a
332	1923	Ursodeoxycholic Acid BP+Silymarin	300mg+140mg	Tablets	a
333	1924	Diastase IP+Cardamom Oil+Caraway Oil BP+Cinammon Oil BP	20mg+400µg+400µg+200µg+	Oral Liquid	d
334	1925	Rabeprazole Sodium IP+Ondansetron HCl IP	20mg+4mg/2mg	Hard Gelatin Capsules	c
335	1931	Cyperoheptadine HCL+Tricholine citrate+Sorbitol solution70%	2mg+275mg+2 gm	Syrup	c
336	1937	cyproheptadine HCL+ trichloline citrate+ sorbitol	2 mg+ 275 mg+2 gm 70 %	syrup	c
337	1942	Ilaprazole + domperidone	10 mg+ 30 mg	capsules	c If only domperidone in this FDC is in SR form.
338	1946	Troxerutin+ calcium dobesilate monohydrate+ lignocaine hydrochloride + hydrocortisone acetate+ zinc oxide + phenylephrine hydrochloride	2% w/w + .25% w/w+ 3 % w/w + .25 % w/w + 5% w/w+ .1 % w/w	cream	c
339	1953	Domperidone BP+lafutidine	20mg/10mg +10mg	Hard Gelatin Capsules	c If only domperidone 20 mg is in this FDC in SR form and domperidone 10 mg is in IR form in the
340	1960	aluminium hydroxide+ magnesium hydroxide +simethicon + oxethazaine	300 mg+ 150 mg+ 125 mg+ 10 mg	gel	c
341	1967	Lafutidine+Domperidone BP	10mg+30mg	Hard Gelatin Capsules	c If only domperidone in this FDC is in SR form.
342	1969	Rabeprazole Sodium IP+Domperidone IP	20mg+10mg	Enteric Coated Tablets	c
343	1970	cyproheptadine HCL + tricholine citrate	1 mg+ 95 mg	oral liquid	c
344	1971	cyproheptadine HCL+ dried yeast	2 mg+ 250 mg	oral solid	c
345	1976	Omeprazole magnesium+Domperidone	10mg+15mg	Tablets	a 1. omeprazole is in subtherapeutic dose 2.Domperidone dose is not appropriate
346	1977	Simethicone+Dill Oil+Fennel oil	40mg+0.005ml+ 0.0007ml	Oral Liquid	d
347	1984	Silymarin+Ursodeoxycholic Acid	35mg+50mg	Suspension	a
348	1985	Silymarin+Ursodeoxycholic Acid	140mg+300mg	Tablets	a
349	1990	Cyproheptadine HCl+Tricholine Citrate+Sorbitol 70%	2.0mg+275.0mg +2.0mg	Syrup	c
350	1999	Tricholine Citrate+Cyproheptadine HCl IP	55mg+1.5mg per ml	drops	c
351	2000	Trocholine Citrate+Cyproheptadine HCl IP	0.275gm+2mg+	Oral Liquid	c
352	2004	Dried Aluminium Hydroxide IP+Magnesium Hydroxide IP+Activated Dimethicone IP	200mg+200mg +25mg	Suspension	c
353	2005	Sodium Bicarbonate BP+Dill Oil BP+Sugar+Aqua to Make	0.05gm+0.005ml+1.1gm+5.0ml	Syrup	d
354	2008	Dried Aluminium Hydroxide BP+Magnesium Hydroxide BP+Simethicone BP	300mg+150mg +40mg	Uncoated Tablets	c
355	2009	Esomeprazole Magnesium Trihydrate IP+Domperidone IP	20mg+10mg	Tablets	c
356	2010	Aceclofenac IP+Paracetamol IP+Rabeprazole Sodium IP	100mg+500mg/ 325mg+20mg	Film Coated Tablets	a Already discussed as "a"

357	2015	Dompendone IP+Magaldarate IP+Simethicone IP	5mg+400mg+50mg	Oral suspension	c
358	2018	Indomethacin IP+Omeprazole IP	75mg+20mg	Hard Geletin Capsules	a Pharmacodynamically irrational.
359	2021	Fungal Diastase IP+Caraway Oil BP+Cinnamon Oil BP+Cardamom Oil BP+Simethicone IP+Papain IP	20mg+400mcg+200mcg+400mcg+40mg+10mg	Drops	d
360	2023	Ilaprazole+Levosulpinde	10mg+75mg	Hard Geletin Capsules	c If only levosulpiride in this FDC is in SR form.
361	2024	Cyproheptadine HCl+Tricholine Citrate	2mg+275mg	Oral Solution	c
362	2025	Fungal Diastase IP+Papain IP+Niacinamide IP+Activated Dimethicone IP+Activated Charcoal IP	20mg+30mg+25mg+50mg+75mg	Sugar Coated Tablets	c
363	2026	Cyproheptadine HCl+Tricholine Citrate	2mg+500mg	Syrup	c
364	2029	Simethicone IP+Dill Oil BP+Fennel Oil	40mg+0.005ml+0.0007ml	Drops	d
365	2030	Naproxen IP+Esomeprazole Magnesium Trihydrate IP	375mg+20mg	Hard Geletin Capsules	a It is an irrationale FDC .The dosing schedule of Naproxen and pentaprazole is different.
366	2031	Ilaprazole+Domperidone IP	5mg/10mg+30mg/30mg	Hard Geletin Capsules	c If only domperidone in this FDC is in SR form.
367	2032	Dried Ammonium Hydroxide Gel IP+Magnesium Hydroxide IP+Activated Dimethicone IP	200mg+200mg+25mg	Suspension	c
368	2036	Cyproheptadine HCl+Tricholine Citrate+Sorbitol Solution	2mg+375mg+2g	Syrup	c
369	2038	Ilaprazole+Domperidone IP	10mg+30mg	Sustained release tablets	c If only domperidone in this FDC is in SR form.
370	2039	Ursodeoxycholic Acid+Silymarin	150mg/300mg+70mg/140mg	Film Coated Tablets	a
371	2040	Sucralfate+Domperidone + Simethicone	500mg+10mg+25mg	Suspension	a The oral bioavailability of domperidone is less than 20 % . Sucralfate will further affect its bioavailability.There is no scientific justification for this FDC.
372	2041	Cyproheptadine HCl+Tricholine Citrate+Sorbitol Solution	2.0mg+275mg	Oral Liquid	c
373	2045	Cyproheptadine HCl IP+Tricholine Citrate +Sorbitol Solution 70%	2mg+275mg	Oral Liquid	c
374	2048	Rabeprazole Sodium IP+Domperidone IP	20mg+10mg	Enteric Coated Tablets	c
375	2050	Rabeprazole+Ondaensteron	20mg+4mg	Tablets	c
376	2052	Sucralfate+Domperidone Maleate	500mg+5mg	Suspension	a The oral bioavailability of domperidone is less than 20 % . Sucralfate will further affect its bioavailability.There is no scientific justification for this FDC.
377	2053	Sucralfate+Pantoprazole Sodium+Zinc Gluconate+Light Magnesium Carbonate	1000mg+20mg+10mg+200mg	Powder	a There is no scientific rational for this FDC.
378	2059	Simethicone emulsion+Dill oil+Fennel oil	40mg+0.005ml+0.0007ml	Coligo drops	d
379	2060	Pancreatin+Activated Dimethicone+Fructo Oligo Saccharide	170mg+80mg+100mg	Film Coated Tablets	c Indicated for pancreatic insufficiency only
380	2069	Rabeprazole Sodium+Domperidone	20mg+10mg	Enteric Coated Tablets	c

381	2074	Ilaprazole+Domperidone IP	10mg+30mg	Hard gelatin capsules	c If only dompendone in this FDC is in SR form
383	2084	Cyproheptadine HCL + Tricholine citrate	2mg+275mg	Syrup	c
384	2086	Cyproheptadine HCL + Tricholine citrate+Sorbitol Solution (70%)	2.0mg+275mg+2.0g	Oral Liquid	c
385	2091	Ursodeoxycholic Acid+Silymarin	150mg/300mg+70mg/140mg	Film Coated tablets	a
386	2092	Cyproheptadine HCl IP+Tricholine Citrate +Sorbitol Solution 70%	2.0gmg+0.275gm+2.0gm	Syrup	c
387	2094	Cyproheptadine HCl IP+Tricholine Citrate +Sorbitol Solution 70%	2mg+0.275gm+3.575gm	Syrup	c
388	2097	Domperidone Maleate IP+lafutidine	30mg+10mg	Modified Release Tablets	c
389	2102	Cyproheptadine HCl+Tricholine Citrate+Sorbitol Solution (70%)	2mg+275mg+2gm	Syrup	c
390	2103	Rabeprazole Sodium IP+Domperidone IP	20mg+10mg	Enteric Coated Tablets	c
391	2107	Tricholine Citrate+Sorbitol Solution	0.55gm+7.15gm	Syrup	c
392	2110	Cyproheptadine HCl+Tricholine Citrate+Sorbitol (70%)	2mg+275mg+3.75mg	Oral Liquid	c
393	2112	Omeprazole Magnesium+Dicyclomine HCl	10mg+10mg	Tablets	a omeprazole is in subtherapeutic dose
394	2117	Cyproheptadine HCl+Tricholine Citrate	2mg+275mg	Oral liquid	c
395	2119	Rabeprazole+Domperidone	20mg+10mg	Tablets	c
396	2121	Rabeprazole Sodium IP+Domperidone IP	20mg+10mg	Enteric Coated Tablets	c
397	2122	Rabeprazole Sodium IP+Domperidone IP	20mg+10mg	Enteric Coated Tablets	c
398	2125	Potassium Citrate Monohydrate IP+Magnesium Citrate USP	1100mg+375mg	Oral Liquid	c
399	2128	Cyproheptadine HCl+Tricholine Citrate	2mg+275mg	Oral liquid	c
400	2129	Cyproheptadine HCl+Tricholine citrate	2mg/2mg+275mg/55mg	Liquids	c
401	2133	Tricholine Citrate+Sorbitol Solution	275mg+3.60mg	Syrup	c
402	2137	Naproxen IP+Pantoprazole IP	250mg/500mg+20mg	Hard Gelatin Capsules	a It is an irrationale FDC .The dosing schedule of Naproxen and pentaprazole is different
403	2140	Rabeprazole Sodium IP+Domperidone IP	20mg+10mg	Enteri Coate Tablets	c
404	2144	Tricholine Zcitrate+Sorbitol Solution (70%) IP	0.55g+7.15g	Oral Liquid	c
405	2148	Cyproheptadine HCl IP+Tricholine Citrate	2mg+275mg	Syrup	c
406	2149	Silymarin+Vitamin B6 IP+Vitamin B12 IP+Niacinamide IP+Folic Acid IP+Tricholine Citrate 65%	35mg+1mg+2.5mcg+22.5mg+750mcg+500mg	Oral Liquid	a There is no therapeutic justification for this FDC.
407	2150	Silymarin+Pyridoxine HCl+Cyanocobalamin+Niacinamide IP+Folic Acid IP	70mg+1.5mg+1mcg+25mg+0.3mg	Capsules	a There is no therapeutic justification for this FDC.
408	2152	Ursodeoxycholic Acid IP+Silymarin	300mg+140mg	Film Coated Tablets	a
409	2155	Cyproheptadine HCl IP+Tricholine Citrate	2.0mg+275.0mg	Syrup	c

410	2156	Cyproheptadine Hydrochloride IP+Tricholine Citrate+Thiamine Hydrochloride IP+Riboflavine IP+Pyridoxine Hydrochloride IP	2mg+250mg+1.25mg+1.25mg+0.5mg	Oral Liquid	a there is no scientific rationale for combining vitamins with cyproheptadine
411	2158	Diacerin IP+Glucosamine Hydrochloride USP+Methylsulfonyl Methane USP	50mg+750mcg+250mg	Tablet	c Already approved by DCGI
412	2163	Cyproheptadine Hydrochloride IP+Tricholine Citrate	1.5mg+55mg	Oral Liquid	c
413	2166	Sucralfate USP+Domperidone Maleate IP eq. to Domperidone+Dimethicone IP	500mg+10mg+25mg	Uncoated Tablets	a The oral bioavailability of domperidone is less than 20 % . Sucralfate and dimethicone will further affect its bioavailability.There is no scientific justification for this FDC.
414	2170	Cyproheptadine Hydrochloride IP+Tricholine Citrate+Sribitol Solution (70%) IP	2.0mg+275mg+3575mg	Syrup	c
415	2178	Omeprazole IP (As Enteric coated pellets)+Domperidone IP (As Pellets form)	10mg+15mg	Hard Gelatin Capsules	a 1.omeprazole is in subtherapeutic dose. 2.Domperidone dose is not appropriate
416	2180	Cyproheptadine HCl IP+Tricholine Citrate+Sorbitol 70%	2mg+275mg+3.575gm	Oral Liquid	c
417	2185	Ciproheptadine Hcl+Tricholine Citrate	2mg+275mg	Oral Liquid	c
418	2186	Angers' Emulsion, Bismozyme, Bismozyme Plus, Bismozyme-P, Bismozyme Drops, Balancid, Brotasin, Edzyme Drops, Edzyme, Edzyme Liquid, E.D.Gel, Ecarbazan, Emol Plus, Gasanal, Gasticure, Hewlett's Mixture With Opium, hewlett's Mixture Without Opium, Systalka-(P), Stomakare, Trisol, Trox, Salicool, Ecolin, Folifer, F.R. Tone (Iron Supplement Syrup), Neurophos, Protoplex, Protoplex-Z, Vitaross, Vitaphos, Eedee's AD Vitamin Baby Oil,	Nil	Nil	Incomplete
419	2190	Ciproheptadine HCl IP+Tricholine citrate	2mg+1275mg	Oral Liquid	c
420	2195	Dried Aluminium Hydroxide Gel IP+Magnesium Hydroxide IP+Simethicone IP	250mg+250mg+50mg	Gel	c
421	2202	Tricholine Citrate+Sorbitol Solution IP	275mg+3.75gm	Solution	c
422	2203	Dried Alumunium Hydroxide Gel IP+Magnesium Hydroxide IP+Simethicone IP	200mg+200mg+25mg	Gel	c
423	2205	Cyproheptadine HCl IP+Tricholine Citrate+Sorbitol 70%	2mg+275mg+3.575gm	Syrup	c
424	2208	Cyproheptadine HCl IP+Tricholine Citrate	1.5mg+55mg	Drops	c
425	2207	Dried Aluminium Hydroxide Gel IP+Magnesium Hydroxide IP+Simethicone IP	250mg+250mg+50mg	Gel	c
426	2208	Cyproheptadine HCl IP+Tricholine Citrate	2mg+275mg	Syrup	c
427	2211	Cyproheptadine HCl IP+Tricholine Citrate IP	2mg+275mg	Syrup	c
428	2212	Dried Aluminium Hydroxide Gel IP+Magnesium Hydroxide IP+Activated Dimethicone IP+Oxetacaine BP	250mg+250mg+50mg+10mg	Suspension	c
429	2215	Cyproheptadine HCl IP+Tricholine Citrate IP+Sorbitol Solution 70% IP	2mg+275mg+3.575mg	Oral Liquid	c
430	2216	Dried Aluminium Hydroxide Gel IP+Magnesium Hydroxide IP+Simethicone IP	300mg+50mg+25mg	Chewable Uncoated Tablet	c
431	2217	Omeprazole Magnesium+Dicyclomine HCl IP	10mg+10mg	Enteric Coated Tablets	a omeprazole is in subtherapeutic dose.
432	2219	Cyproheptadine HCL IP+Tricholine Citrate (66%)+Sorbitol Solution (70%)	2mg+275mg+2gm	Syrup	c

433	2220	Pancreatin IP+Bile Constituents+Activated Dimethicone IP	192mg+25mg+40mg	Enteric Coated Tablets	c indicated for pancreatic insufficiency only
434	2221	Loratadine USP+Pseudoephedrine HCl IP	5mg+60mg	Film Coated Tablets	c
435	2222	Cyproheptadine HCl IP+Tricholine Citrate	2mg+275mg	Syrup	c
436	2225	Rabeprazole Sodium IP EC+Domperidone IP	20mg+10mg	Enteric Coated Tablets	c
437	2226	Cyproheptadine HCL IP+Tricholine Citrate+Sorbitol base (70%)IP (Non-Crystallising)	2mg+275mg	Syrup	c
438	2229	Domperidone+Naproxen Sodium	10mg+25mg	Tablets	sub-judice
439	2231	Cyproheptadine Hydrochloride IP+Tricholine Citrate	2mg+275mg	Oral Liquid Solution	c
440	2237	Dried Aluminium Hydroxide IP+Magnesium Hydroxide IP+Oxetacaine IP+Activated Dimethicone IP	500mg+50mg+10mg+50mg	Gel	c
441	2238	Domperidone Maleate IP eq. to Domperidone+Naproxen Sodium USP	10mg+500mg	Film Coated Tablets	Sub-judice
442	2242	Rabeprazole Sodium IP eq .to Rabeprazole+Cinitrapride Hydrogen Tatrtrate eq. to Cinitrapride(as immidiate release tablet)+Cinitrapride Hydrogen Tatrtrate eq. to Cinitrapride(as sustained release tablet)	20mg+1mg+2mg	Capsules	c indicated for "the treatment of patients suffering from gastroesophageal reflux disease (GERD)".
443	2243	Ursodeoxycholic Acid BP+Silymarin	150mg/300mg+70mg/140mg	Film Coated Tablets	a
444	2245	Lafutidine+Domperidone IP (as sustained release tablet)/Domperidone IP (as film coated tablet)	10mg+20mg/10mg	Hard Gelatin Capsules	c
445	2246	Cinitapride hydrogen tartrate eq. to Cinitapride(in sustained release form)+Lafutidine	3mg+10mg	Film coated bilayered tablets	d
446	2248	Polyethylene Glycol IP+PotassiumChloride IP+Sodium Chloride IP+Sodium Bicarbonate IP+Anhydrous Sodium Sulphate BP+Activated Dimethicone	14.6gm+0.18gm+0.36gm+0.42gm+1.42gm+0.01gm	Powder (Sachet)	c for bowel preparation
447	2254	Lafutidine+Domperidone IP (10mg as immediate release & 20mg as sustained release tablet)	10mg+30mg	Hard Gelatin Capsules	c
448	2257	Domperidone Maleate IP eq. to Domperidone+Naproxen Sodium USP	10mg+250mg	Film Coated Tablets	subjudice
449	2260	Ranitidine Hydrochloride IP+Domperidone IP+Simethicone IP	150mg+10mg+5mg	Film Coated Tablets	c
450	2261	Potassium Citrate IP+Magnesium Citrate (anhydrous) BP	1100mg+375mg	Oral Solution	c
451	2262	Weak Ginge tincture BP+Aromatic Spirit Of Ammonia IP66+Peppermint Spirit BPC+Chloroform IP+Sodium Bicarbonate IP+Compound Cardamom Tr. IP66+Alcohol content	0.625 ml+0.625 ml+0.250 ml+0.019 ml+0.275g+3.000 ml+20 to 26% v/v	Liquid Orals	a There is no scientific rational for this FDC.
452	2263	Weak Ginge tincture BP+Aromatic Spirit Of Ammonia IP66+Peppermint Spirit BPC+Chloroform IP+Sodium Bicarbonate IP+Compound Cardamom Tr. IP66+Alcohol content	0.104 ml+0.104 ml+0.041 ml+0.003 ml+0.046g+0.500 ml+7.6% v/v	Liquid Orals	a There is no scientific rational for this FDC.

453	2264	Tincture Ipecacuanha IP66+Tincture Urgenia IP66+Camphorated Opium Tincture IP66+Aromatic Spirit Of Ammonia IP66+Chloroform IP+Alcohol Content	0.700 ml+0.600 ml+1.300 ml+0.700 ml+0.020 ml+40 to 45% v/v	Liquid Orals	a There is no scientific rational for this FDC.
454	2265	Sodium Citrate IP+Citric Acid Monohydrate IP Flavoured With Cardamom Oil, Caraway Oil , Cinnamon Oil, Clove Oil, Ginger Oil+Acohol content	200mg+40mg+ 9.5% v/v	Liquid Orals	a Alcohol content is very high and there are chances of abuse potential.
455	2266	Sodium Citrate IP+Citric Acid Monohydrate IP Flavoured With Cardamom Oil, Caraway Oil , Cinnamon Oil, Clove Oil, Ginger Oil+Acohol content	70mg+35mg+4 % v/v	Liquid Orals	d
456	2268	Dicyclomine Hydrochloride IP+Chlordiazepoxide IP+Clidinium Bromide USP+Rabeprazole Sodium IP (ER)	10mg+5mg+2.5 mg+10mg	Hard Gelatin retard capsules	a Irrationale FDc as it is a combination of drugs for IBS and acid peptic disease and GERD . Further dicyclomine will increase the GERD.
457	2271	Ranitine Hydrochloride eq. to Ranitidine+Dompendone IP+Simethicone IP	150mg+10mg+ 5mg	Film Coated Tablets	c
458	2273	Polyethylene Glycol IP+PotassiumChloride IP+Sodium Chloride IP+Sodium Bicarbonate IP+Anhydrous Sodium Sulphate BP+Activated Dimethicone	14.6gm+0.18gm +0.36gm+0.42g m+1.42gm+0.0 1gm	Powder	c for bowel preparation
459	2278	Simethicone IP+Dill Oil BP+Fennel Oil USP	40mg+0.005mL +0.0007mL	Solid oral	d
460	2280	Acetylcysteine+Taurine	150mg+500mg	Tablets	a, There is no adequate scientific data to justify the rationality of this FDC.
461	2282	Flavoxate HCL BP+Ofloxacin IP	200mg+200mg	Tablets	a, Flavoxate may cause urinary retension.This wil further worsen UTI.There is also pharmacokinetic incompatibility.
462	2284	Clindamycin+Clotrimazole	2%w/w+2%w/w	Vaginal Cream	c
463	2285	Flavoxate HCl+Ofloxacin	200mg+200mg	Tablets	a, Flavoxate may cause urinary retension.This will further worsen UTI.There is also pharmacokinetic incompatibility.
464	2287	Flavoxate HCL BP+Ofloxacin IP	200mg+200mg	Tablets	a There are chances of misuse.Flavoxate may cause retention of urine in elder which will further worsen UTI . Also there is pharmacokinetic incompatibiity.
465	2295	Clomifene Citrate IP+Ubidecarenone BP	25mg+50mg	Tablets	a Irrationale combination.No robust scientific data to support this combination.
466	2298	clomifene citrate+ ubidecarenone	100 mg+ 100 mg	tablets	a irrationale combination.No robust scientific data to support this combination.
467	2301	Clomifene Citrate IP+Ubidecarenone BP	25mg/50mg+50 mg	Film Coated Tablets	a irrationale combination.No robust scientific data to support this combination.
468	2304	Potassium Citrate Monohydrate IP+Magnesium Citrate USP	1100mg+375mg	Oral Liquid	c
469	2318	Clomifene Citrate IP+Ubidecarenone BP	25mg+30mg	Oral Tablet	a Irrationale combination.No robust scientific data to support this combination.
470	2319	Clomiphene Citrate IP+N-Acetylcysteine USP	50mg+600mg	Film Coated Tablets	a irrationale combination.No robust scientific data to support this combination.
471	2325	Clomifene Citrate+Ubidecarnone	50mg+50mg	Tablets	a Irrationale combination.No robust scientific data to support this combination.

472	2325	Clomifene Citrate IP+Ubidecarenone BP	50mg+50mg	Tablets	a irrationale combination.No robust scientific data to support this combination.
473	2329	clomifene + ubidecarenone	25 mg+ 50 mg	tablets	a irrationale combination.No robust scientific data to support this combination.
474	2333	24 film coated tablets(Nomegestrol Acetate BP+17-Beta Estradiol USP+L-Methylfolate Calcium) & 4 Film coated tablet(L-Methylfolate Calcium)	2.5mg+1.5mg+451mcg & 451mcg	Combi pack	c
475	2335	Dienogest+Ethinylcestradiol IP,L-Methylfolate Calcium	2mg+0.03mg,451mcg	Combipack Tablet	c
476	2337	5 tabs. Of Clomiphene Citrate Tablets IP+ 10 tabs.Estradiol Valerate Tablet	50mg, 2mg	CombiKit of film coated tablets	a irrationale combikit ,estradiol valerate is required only in selected patients following the clomiphene therapy.
477	2347	Naphazoline HCl USP+Hydroxypropylmethylcellulose IP+Chlorpheniramine Maleate IP+Zinc Sulphate IP+ Benzalkonium Chloride Solution IP (As Preservative)	0.056% w/v + 0.2% w/v + 0.12% w/v + 0.1% w/v + 0.12% w/v + 0.01% w/v	Eye drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
478	2349	Ketorolac Tromethamine IP+Fluorometholone USP	0.4% w/v + 0.1% w/v	Ophthalmic Solution	a The Committee obesrved that available data does not support the rationality of this FDC. Each ingredient requires to be given for different duration. Prolonged usage of this combination can harm the eye.
479	2353	Boric Acid +Phenylephrine IP+Naphazoline Nitrate IP+Menthol IP+Camphor IP'66'	1.0% w/v + 0.12% w/v + 0.05% w/v + 0.01% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
480	2356	Phenylepherine HCl IP+Naphazoline HCl USP+Menthol IP+Camphor IP '66'+Hydroxypropylmethylcellulose IP	0.012% w/v + 0.05% w/v + 0.005% w/v + 0.01% w/v + 0.25% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
481	2357	Naphazoline HCl USP+Methylcellulose IP+Chlorpheniramine Maleate IP+Boric Acid IP+Sodium Chloride IP+Zinc Sulphate IP+Menthol IP+Camphor IP '66'	0.1% w/v + 0.1% w/v + 0.01% w/v + 1.25% w/v + 0.05% w/v + 0.012% w/v + 0.0025% w/v + 0.0025% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
482	2358	Naphazoline Nitreate IP+Chlorphiniramine Maleate IP+Zinc Sulphate IP+ Boric Acid IP+Sodium Chloride IP	0.056% w/v + 0.01% w/v + 0.012% w/v + 1.25% w/v + 0.05% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
483	2359	Naphazoline HCL USP+Phenylepherine HCl IP+Menthol IP+Camphor IP '66'+Sodium Carboxymethylcellulose IP	0.05% w/v + 0.012% w/v + 0.005% w/v + 0.01% w/v + 0.50% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
484	2360	Naphazoline HCl USP+Chlorpheniramine Maleate IP+Methylcellulose IP	0.1% w/v + 0.01% w/v + 0.2% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
485	2361	Phenylephirine HCl IP+naphazoline HCl USP+Menthol IP+Camphor IP '66'	0.12% w/v + 0.05% w/v + 0.005% w/v + 0.01% W/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
486	2362	Naphazoline HCl USP+Hydroxypropylmethylcellulose IP+Chlorpheniramine Maleate IP+Boric	0.56% w/v + 0.2% w/v +	Eye Drops	a The Committee obesrved that available data does

487	2363	Naphazoline HCl USP+Phenylepherine HCl IP+HPMC IP+Chlorpheniramine Maleate IP+Menthol IP+Camphor IP	0.05% w/v + 0.12% W/v + 0.20%b w/v + 0.01% w/v + 0.01% w/v+0.01% w/v	Eye Drops	a The Committee obesrved that availsble data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
488	2365	Chlorpheniramine maleate IP+Sodium Chloride IP+Boric Acid IP+Tetrahydrozoline HCl+Benzalkonium Chloride	0.03%w/v+0.05 %w/v+1.25%w/v +0.01%w/v+0.0 2%w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
489	2368	Naphazoline HCl+Boric Acid+Sodium Chloride+Chlorbutol+Zinc Sulphate+Chlorpheniramine Maleate	0.056%w/v+1.2 5%w/v+0.05%w /v+0.50%w/v+0 12%w/v+0.01% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
490	2369	Chlorpheniramine+Sodium Chloride+Boric Acid+Chlorbutol+Naphazoline Nitrate+Zinc Sulphate	0.01%w/v+0.05 %w/v+1.25%w/v +0.35%w/v+0.0 56%w/v+0.012 %w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
491	2378	Naphazoline HCl USP+Chloramphenicol Maleate IP+Boric Acid IP+Sodium Chloride IP+Chlorbutol IP	0.056% w/v + 0.01% w/v + 1.25% w/v + 0.05% w/v + 0.50% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
492	2381	Naphazoline HCl USP+Hydroxy Propyl Methyl Cellulose IP+Chlorpheniramine Maleate IP+Zinc Sulphate IP+Boric Acid IP+Sodium Choride IP+Chlobutol IP	0.056% w/v + 0.25% w/v + 0.01%w/v + 1.25% w/v + 0.05% w/v + 0.05% w/v +0.35% w/v	Ophthalmic Solution	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
493	2382	Phenylepherine HCL IP+Naphazoline HCl USP+Chlorpheniramine Maleate IP+Menthol IP+Camphor IP+Benzalkonium Chloride Solution IP	0.12% w/v + 0.05% w/v + 0.1% w/v + 0.005% w/v + 0.01% w/v + 0.01% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
494	2383	Tobramycin Sulphate USP Eq to Tobramycin+Fluorometholone USP+Banzalkonium Chloride Solution IP	0.3% w/v + 0.1% w/v + 0.02% v/v	Ophthalmic Drops	c
495	2384	Naphazoline Hcl+Hydroxypropylmethycellulose+Chlorph eniramine maleate+Boric Acid+Sodium Chloride+Zinc sulphate+Menthol+Camphor	0.056%w/v+0.1 %w/v+0.01%w/v +0.25%w/v+0.5 %w/v+0.12%w/v +0.0025%w/v+0 .0025%w/v	ophthalmic	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
496	2385	Chlorpheniramine maleate+Phenylephrine HCl+antipyrine+Chlorobutol	0.2%w/v+0.12% w/v+0.1%w/v+0. 5%w/v	Ophthalmic solution	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
497	2389	Phenylephrine HCL+Naphazoline HCL+Menthol+Camphor+Benzalkonium Chloride	0.12%w/v+0.05 %w/v+0.005%w /v+0.01%w/v+0. 01%w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
498	2391	Phenylephrine HCl+Homatropine Hydrobromide+Benzalkonium chloride solution	5%w/v+1%w/v+ 0.01%w/v	Ophthalmic solution	c
499	2394	Naphazoline Hcl USP+Hydroxypropylmethycellulose+Chlorp heniramine maleate+Boric Acid	0.1% w/v + 0.1% w/v + 0.01% w/v + 1.25%w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

500	2398	chlorpheniramine maleate + naphazoline HCL+ phenyl epherine HCL+ camphor+ menthol+ benalkonium chloride solution	.10%w/v+ .05% w/v+ .12%w/v+.01% w/v + .005%w/v	eye drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
501	2408	Phenylephrine HCL+Naphazoline HCL+Menthol+camphor	0.12%w/v+0.05 %w/v+0.005%w /v+0.01%w/v	Opthalmic Drop	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
502	2410	Ketorolac tromethamine+chlorpheniramine maleate+Phenylephrine HCL+Hydroxy propylmethyl cellulose	0.5%w/v+0.02% w/v+0.12%w/v+ 0.25%w/v	Opthalmic Drop	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
503	2411	naphazoline hydrochloride+ hydroxypropylmethylcellulose + chlorpheniramine maleate + boric acid + sodium chloride + zinc sulphate + menthol + camphor	.1 w/v + .1 % w/v + .01 % w/v + 1.25 w/v + .05 % w/v + .12 % w/v + .0025% w/v + .0025 % w/v	eye drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
504	2412	Naphazoline hydrochloride+ Hydroxypropylmethylcellulose + Chlorpheniramine maleate + Boric acid + Zinc sulphate + Benzalkonium Chloride	0.1% w/v + 0.1% w/v + 0.01% w/v + 1.25%w/v + 0.1% w/v + 0.02% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
505	2413	Ketorolac tromethamine+Dexamethasone Sodium Phosphate IP+Phenylephrine HCL+Hydroxy propylmethyl cellulose	0.5%w/v + 0.05%w/v + 0.001%w/v + 0.25%w/v	Ophthalmic Solution	c indicated for short term use only
506	2417	Dexamethasone Sodium Phosphate+Chloramphenicol+Phenyl Mercuric Nitrate	0.1%w/v + 0.5%w/v + 0.001%w/v	Eye Drops	already categorized as 'c'
507	2419	boric acid + phenylephrine HCL+ naphazoline nitrate+methol + camphor IP- *%	1% w/v+ .12 % w/v + .05 % w/v + .005 % + .01% w/v	opthalmic drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
508	2421	naphazoline HCL + zinc sulphate + boric acid+ sodium chloride + chlorpheniramine maleate	.056% w/v+ .12 % w/v + 1.25 % w/v+ .05 % w/v + .01 % w/v	opthalemic drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
509	2425	Chloramphenicol+Beclomethasone Dipropionate+Clotrimazole+Lignocaine HCl	5%w/v+0.025% w/v+1%w/v+2% w/v	Drops	a. Pharmacodynamically irrelevant- 1.Each ingredients of FDC has different therapeutic indication and is at variance from the concept and purpose of FDC. 2. Combining antibiotic , antifungal, steroid in the present FDC is liable to be misuse and emergence of resistance and adverse effects. 3.Use of steroid in case of fungal infection might actually worsen the treatment as it encourages fungal growth. NO study is found supporting the combined use of an antibacterial with an antifungal ingredient. 4.Lignocaine use in discharging ear is not required.
510	2433	Phenylephrine HCl IP+Naphazoline HCL USP+Menthol IP+Camphor IP+Benzalkonium Chloride IP	0.12%w/v + 0.05%w/v + 0.005%w/v + 0.01%w/v + 0.02%w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
511	2440	Boric Acid IP+Phenylephrine HCl IP+Naphazoline Nitrate IP+Menthol IP+Camphor IP+Benzalkonium Chloride Solution IP	1.0%w/v + 0.12%w/v + 0.05%w/v + 0.005%w/v + 0.01%w/v + 0.02%w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

512	2443	Phenylephrine HCl IP+Naphazoline HCL USP+Menthol IP+Camphor IP+Hydroxyl Propyl Methyl Cellulose IP+Benzalkonium Chloride IP	0.12%w/v + 0.05%w/v + 0.005%w/v + 0.01%w/v + 0.25%w/v + 0.01%w/v	Ophthalmic Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
513	2446	Naphazoline Nitrate IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Hydroxyl Methyl Cellulose IP+Boric Acid IP+Menthol IP+Camphor IP+Benzalkonium Chloride IP	0.05%w/v + 0.01%w/v + 0.12%w/v + 0.2%w/v + 1.25%w/v + 0.005%w/v + 0.01%w/v + 0.02%w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
514	2457	Boric Acid IP+Chlorpheniramine Maleate IP+Naphazoline HCL IP+Zinc Sulphate IP+Sodium Chloride IP+Chlorbutol IP+BKC IP	1.25%w/v + 0.01%w/v + 0.56%w/v + 0.012%w/v + 0.05%w/v + 0.5%w/v + 0.005%w/v	Ophthalmic Solution	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
515	2458	Chlorpheniramine Maleate IP+Naphazoline HCL IP+Zinc Sulphate IP+Sodium Chloride IP+Hydroxyl Propyl Methyl Cellulose IP+Chlorbutol IP	1.25%w/v + 0.01%w/v + 0.56%w/v + 0.012%w/v + 0.05%w/v + 0.25%w/v + 0.5%w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
516	2459	Phenylephrine HCL IP+Naphazoline HCL IP+Menthol IP+Camphor IP+Hydroxyl Propyl Methyl Cellulose IP+BKC IP	0.12%w/v + 0.05%w/v+ 0.005%w/v + 0.01%w/v + 0.25%w/v + 0.01%w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
517	2462	Naphazoline HCl USP+Chlorpheniramine Maleate IP+Zinc Sulphate IP+Hydroxyl Methylcellulose IP+Benzalkonium Chloride IP	0.56mg+0.1mg +1.2mg+2mg+0 .0001ml	Ophthalmic Solution	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
518	2465	Naphazoline HCl USP+Chlorpheniramine Maleate IP+Zinc Sulphate IP+Hydroxyl Methylcellulose IP+Benzalkonium Chloride IP	0.056%w/v + 0.01%w/v + 0.12%w/v + 0.2%w/v + 0.0001ml	Ophthalmic Solution	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
519	2470	Phenylephrine Hcl IP+Naphazoline HCL USP+Menthol IP+Camphor IP '66 +Hydroxyl propyl methyl cellulose IP+Benzalkonium Chloride Solution IP	0.12%w/v + 0.05%w/v+ 0.005%w/v + 0.01%w/v + 0.1%w/v + 0.01%w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
520	2473	Chlorpheniramine Maleate IP+Naphazoline HCL USP+Hydroxylpropylmethylcellulose IP+Benzalkonium Chloride IP	0.01%w/v + 0.1%w/v + 0.2%w/v + 0.02%v/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
521	2478	Naphazoline HCl USP+Hydroxyl Methylcellulose IP+Boric Acid IP+Menthol IP+Camphor IP '96'	0.1%w/v + 0.2%w/v + 3.0%w/v + 0.05%w/v + 0.0025%w/v + 0.0025%w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.
522	2495	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaiphenesin IP+Menthol IP	1.25mg/1.25mg +4mg/2mg+50 mg/50mg+2.5m g/0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.

523	2498	Paracetamol IP+Chlorpheniramine maleate IP+Phenylephrine HCl IP	125mg/125mg/125mg/250mg+1mg/1mg/5mg/5mg+5mg/2.5mg per 5ml or 2mg/2mg per 5ml	Syrup/Suspension	d Similar FDC is already discussed by 10 expert Committee
524	2499	Ambroxol Hcl IP+Terbutaline Sulphate IP+Guaiphenesin IP+Menthol IP	15mg/15mg/30mg+1.25mg/1.25mg/1.25mg+50mg/50mg/100mg+1mg/0.5mg/2.5mg per 5ml	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
525	2502	Terbutaline Sulphate IP+Ambroxol HCl IP+Guaiphenesin IP	1.25mg/1.5mg & 0.25mg+15mg/15mg & 7.5mg+50mg/50mg per 5ml & 12.5mg per ml	Expectorant & Oral Drops	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
526	2512	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaiphenesin IP+Menthol IP	1.5mg+4.0mg+50mg per 5ml	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
527	2522	Paracetamol +phenylephrine-Hydrochloride + chlorpheniramine maleate + sodium citrate+ menthol	125 mg+ 2.5 mg+ 1 mg+ 60 mg+ 0.5 mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
528	2523	Phenylephrine hydrochoride + chlorpheniramine maleate + paracetamol + sodium citerate	5mg+ 1 mg+ 125 mg+ 60 mg	oral syrup	d Similar FDC is already discussed by 10 expert Committee
529	2524	Ambroxol Hydrochloride + salbutamol Sulphate+ Guaiphenesin+ mentholated flavoured syrup base	7.5 mg+ 0.5 mg+12.5 mg +q.s	Oral drops	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
530	2529	Phenylephrine hydrochoride + chlorpheniramine maleate +sodium citrate+ menthol	5mg+ 1 mg+ 60 mg+ 1 mg	oral syrup	c
531	2530	Ambroxol hydrochloride + terbutaline sulphate + guaiphenesin	10mg+ 0.5 mg + 25 mg	syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
532	2532	Paracetamol Ip+ phenylephrine Hydrochloride + chlorpheniramine maleate	250 mg+ 5 mg+ 2 mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
533	2533	paracetamol + phenylephrine hydrochloride + chlorpheniramine Maleate + caffeine	500 mg+ 10 mg+ 2 mg+ 30 mg)	tablet	a
534	2534	paracetamol + cetirizine hydrochloride + phenylephrine hydrochloride	325 mg+ 5 mg+ 5 mg/10 mg	tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
535	2535	Pareacetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+2.5mg+1mg	Oral drops	d Similar FDC is already discussed by 10 expert Committee
536	2537	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate	125mg+2.5mg+1mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
537	2538	Bromhexine HCl IP+Terbutaline Sulphate IP+Guaiphenesin IP	4mg+1.25mg+50mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
538	2540	Paracetamol IP+Phenylephrine HCL IP+Chlorpheniramine Maleate IP+Sodium Citrate IP+Menthol IP	250mg+5mg+2mg+60mg+1mg	Suspension	d Similar FDC is already discussed by 10 expert Committee

539	2541	Cetirizine HCl IP+Phenylephrine HCl IP+Paracetamol IP	5mg+5mg+325 mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
540	2544	Cetirizine HCl IP+Paracetamol IP+Phenylephrine HCl IP	1.0mg+125mg+ 2.5mg	Oral drops	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
541	2546	Terbutaline Sulphate IP+Guaiphenesin IP+Bromhexine HCl IP	1.25mg+100mg +8mg	Uncoated Tablets	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
542	2552	Bromhexine HCl IP+Dextromethorphan Hydrobromide IP+Ammonium Chloride IP	4mg+5mg+50m g	Syrup	a Contradictory pharmacodynamic effect of ingredients. Dextromethorphan is a cough supressent where as Bromhexine and Ammonium Chloride are expectorant.
543	2556	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Sodium Citrate IP+Menthol IP	125mg/125mg/1 25mg/250mg+2 mg/1mg/1mg/2 mg+5mg/2.5mg/ 5mg/2.5mg+60 mg/60mg/60mg/ 60mg	Syrup/Oral Suspension	d Similar FDC is already discussed by 10 expert Committee
544	2557	Ambroxol HCl IP+Terbutaline Sulphate IP+Guaiphenesin IP	15mg+1.5mg+5 0mg	Expactorent	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
545	2559	Paracetamol IP+Cetrizine HCl IP+Phenylephrine HCl IP+	500mg/500mg+ 5mg/5mg+10mg /5mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
546	2569	Bromhexine HCl+Terbutaline Sulphate+Guaiphenesin+Menthol	4mg+1.25mg+5 0mg+2.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
547	2571	Bromhexine HCl+Terbutaline Sulphate+Guaiphenesin	4mg+1.25mg+5 0mg+2.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
548	2574	Ambroxol HCl+Terbutalin Sulphate+Guaiphenesin	7.5mg+0.25mg +12.5mg	Drops	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
549	2576	Paracetamol+Phenylephrine HCl+Chlorpheniramine maleate	125mg+2.5mg+ 1mg	Oral Drops	d Similar FDC is already discussed by 10 expert Committee
550	2577	Paracetamol+Phenylephrine HCl+Chlorpheniramine maleate	325mg+10mg+ 4mg	Tablets	d Similar FDC is already discussed by 10 expert Committee
551	2580	Paracetamol+Phenylephrine HCl+Chlorpheniramine Maleate	125mg+5mg+1 mg	Syrup	d Similar FDC is already discussed by 10 expert Committee

552	2585	Levocetirizine HCL+ Phenylephrine HCL	2.5 mg + 10 mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
553	2589	Paracetamol IP+Phenylephrine HCL IP+Chlorpheniramine Maleate	250mg+5mg+2 mg	Liquid Oral	d Similar FDC is already discussed by 10 expert Committee
554	2590	Terbutaline Sulphate IP+Bromhexine HCL IP+Guaiphenesin IP	2.45 mg + 8 mg + 100 mg	Tablets	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
555	2594	paracetamol + phenylephrine HCL + chlorpheniramine Maleate	250 mg+ 5 mg+2 mg	Liquid suspension	d Similar FDC is already discussed by 10 expert Committee
556	2601	ambroxol hydrochloride + guaiphenesin+ terbutaline	30 mg+ 50 mg+ 1.25 mg	Expectorant	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
557	2602	paracetamol+ phenylephrineHCL+ chlorpheniramine maleate + sodium citrate +	250 mg+ 5 mg+ 2 mg+ 60 mg+	liquid oral suspension	d Similar FDC is already discussed by 10 expert Committee
558	2609	Levocetirizine Hcl+Ambroxol HCl+Phenylephrine HCl	5mg+60mg+2.5 mg	Uncoated tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration.
559	2613	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Menthol IP	250mg+5.0mg+ 2.0mg+1.0mg	suspension	d Similar FDC is already discussed by 10 expert Committee
560	2614	Ambroxol HCl IP+Guaiphenesin IP+Terbutaline Sulphate IP	7.5mg+12.5mg +0.25mg	Drops	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
561	2615	Terbutaline Sulphate IP+Bromhexine HCL IP+Guaiphenesin IP+Menthol IP	1.25mg+2mg+5 0mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
562	2619	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaiphenesin IP+Menthol IP	1.25mg+4mg+5 0mg+1mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
563	2621	Terbutaline Sulphate IP+Ambroxol HCl IP+Guaiphenesin IP	2.5mg+30mg+1 00mg	Tablets	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
564	2623	Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP+Menthol IP	10mg+4mg+24 0mg+240mg+1. 25mg	Syrup	a Use of antihistaminic with centrally acting anti tussive is not rational, moreover ammonium chloride is secretogogue and its combination with anti-tussive is irrational
565	2627	Terbutaline Sulphate IP+Bromhexine HCl IP	2.5mg/5mg/2.5 mg+4mg/8mg/4 mg	Tablets/Syru p	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
566	2629	Levocetirizine Dihydrchloride+Phenylephrine HCl IP+Paracetamol IP	5mg+10mg+50 0mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
567	2631	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP	325mg+2mg+5 mg	Tablets	d Similar FDC is already discussed by 10 expert
568	2633	Paracetamol IP+Phenylephrine HCl IP+Cetirizine Dihydrochloride IP	325mg+10mg+ 5mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.

569	2634	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaiphenesin	1.25mg+4.0mg +50mg	Oral Liquid	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
570	2635	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP+	125mg+1mg+2. 5mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
571	2636	Phenylephrine HCl IP+Ambroxol HCL IP+Guaiphenesin IP	5mg+60mg+50 mg	Film Coated Tablets	a There is no scientific rationality of FDC.Phenylephrine is decongestant where as Ambroxol HCL and Guaiphenesin IP are mucolytic , these effect are contradictory to each other.
572	2639	cetirizine + paracetamol + phenylephrine hydrochloride	5 mg + 325 mg + 5 mg	tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
573	2641	terbutaline sulphate + bromhexine hydrochloride + guaiphenesin	1.25 mg+ 4 mg+ 50 mg	expectorant	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
574	2643	paracetamol+ phenylephrine hydrochloride + chlorpheniramine maleate	250 mg/325 mg+ 5 mg+ 2 mg	suspension/uncoated tablet	d Similar FDC is already discussed by 10 expert Committee
575	2645	paracetamol + sodium Citrate+ phenylephrine hydrochloride + chlorpheniramine maleate	250 mg+ 60 mg_ 5 mg+ 2 mg	liquid orals	d Similar FDC is already discussed by 10 expert Committee
576	2649	paracetamol+ phenylephrine hydrochloride + chlorpheniramine maleate	125mg+ 2.5 mg+ 1 mg	oral drops	d Similar FDC is already discussed by 10 expert Committee
577	2651	paracetamol + chlorphenirmine maleate + phenylephrine hydrochloride	125 mg+ 1 mg+ 2.5 mg	oral drops	d Similar FDC is already discussed by 10 expert Committee
578	2656	phenylephrine+ cetirizine+ paracetamol	5 mg+5 mg+ 500 mg	uncoated tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
579	2657	terbutaline sulphate+ guaiphenesin + bromhexine hydrochloride	2.5 mg+ 100 mg+ 8 mg	uncoated tablet	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
580	2669	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Sodium Citrate IP+Menthol IP	250mg+5mg+2 mg+60mg+1mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
581	2680	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	250mg+5mg+2 mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
582	2683	Ambroxol HCl IP+Terbutaline Sulphate IP+Guaiphenesin IP	15mg+1.25mg+ 50mg	Oral Liquid	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
583	2685	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaiphenesin IP	1.25mg+4mg+5 0mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
584	2686	Terbutaline Sulphate IP+Ambroxol HCl IP+Guaiphenesin IP	1.5mg+15mg+5 0mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
585	2691	paracetamol+ chlorpheniramine maleate+ phenylephrine hcl	125 mg+ 1 mg+ 2.5 mg	drop	d Similar FDC is already discussed by 10 expert Committee
586	2692	salbutamol sulpahte+ ambroxol hydrochloride	.5 mg+ 7 .5 mg	oral syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.

587	2693	paracetamol+ chlorpheniramine maleate+ phenylephrine hcl	125 mg+ 1 mg+ 2.5 mg	drop	d Similar FDC is already discussed by 10 expert Committee
588	2694	salbutamol sulpahte+ ambroxol hydrochloride	.5 mg+ 7 .5 mg	oral syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
589	2695	cetirizine dihydrochloride + phenylephrine+ paracetamol	5 mg+ 10 mg+ 325 mg	tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
590	2699	Ambroxol HCL+ guaiphenesin+ terbutaline sulphate+ menthol	15 mg+ 50 mg+ 1.25 mg+ 1 mg	syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
591	2704	Bromhexine HCL + Terbutaline Sulphate + Guaiphenesin + Menthol	4mg + 1.25mg+ 50mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
592	2705	Bromhexine HCL IP +Terbutaline sulphate +guaiphenesin	4mg+2mg+100 mg	Oral liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
593	2706	Ambroxol HCL IP+Terbutalin sulphate+Guaiphensin+Menthol IP	15mg+1.25mg+ 50mg+1.25mg	oral liquid (syrup)	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
594	2707	Terbutaline + Bromhexine sulphate+Guaiphenesin	1.25mg+4mg+50mg	Oral Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
595	2713	Paracetamol+Chlorpheniramine Maleate+Phenylephrine HCL+Sodium Citrate	250mg+2mg+5 mg+60mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
596	2715	Cetrizine HCL+Terbutaline sulphate+Ambroxol HCL+Guaiphenesin	3.25mg+1.25mg +15mg+50mg	Syrup	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration.
597	2717	Solbutamol Sulphate+Bromhexine HCL+Guaiphensin	2mg+8mg+100 mg	Tablet	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
598	2720	Terbutaline Sulphate IP+Guaiphenesin IP+Ambroxol HCl IP	1.25mg/1.5mg+ 50mg+15mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
599	2731	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaiphenesin IP+Menthol IP	1.25mg+2mg+50mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
600	2737	Ambroxol HCl IP+Terbutaline Sulphate IP+Ammonium Chloride IP+Guaiphenesin IP+Menthol IP	30mg+1.25mg+ 100mg+50mg+ 1.5mg	Syrup	a There are already two mucolytic drugs (ambroxol and guaiphenesin) , addition of ammonium chloride as bronchial secretogogue is not required for claimed indication- Symptomatic relief from wet or productive cough with or without bronchospasm.
601	2739	Bromhexine HCl+Phenylephirine HCl	8mg/8mg+10mg /20mg	Tablets	a There is no scientific rationality of FDC.Phenylephrine is decongestant where as bromhexine is mucolytic , these effect are contradictory to each other.
602	2742	Levocetrizine HCL+Phenylephrine HCL	5mg+20mg	Uncoated bi layer Tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
603	2743	Tebutaline Sulphate+Ambroxol HCL+Guaiphenesin	2.5mg+30mg+100mg	Uncoated Tablet	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
604	2748	Terbutaline sulphate+Guaiphenesin+Bromhexine HCL+Menthol	1.25mg+50mg+ 2mg+0.5mg	Liquid Dosage form	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.

605	2750	Phenylephrine hydrochloride + Chlorpheniramine maleate + Paracetamol	5 mg+ 4 mg+ 325 mg	uncoated tablet	d Similar FDC is already discussed by 10 expert Committee
606	2758	paracetamol + phnylephrine HCL+ chlorpheniramine maletae	125 mg+ 5 mg+ 1 mg	liquid oral dose	d Similar FDC is already discussed by 10 expert Committee
607	2762	Paracetamol+Phenylephrine HCL+Chlorampheniramine Maleate	125mg+2.5mg+ 1mg	Liquid oral (Drop)	d Similar FDC is already discussed by 10 expert Committee
608	2763	Terbutaline sulphate+Guaiphenesin+Bromhexine HCL+Menthol	1.25mg+50mg+ 2mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
609	2764	Terbutaline sulphate+Ambroxol HCL+Guauphenesin+menthol	2.5mg+30mg+1 00mg+5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
610	2765	Paracetamol+Phenylephrine HCL+Chlorampheniramine Maleate	325mg+10mg+ 2mg	Tablet	d Similar FDC is already discussed by 10 expert Committee
611	2769	paracetamol+ phenylephrine HCL+ chlorpheniramine maleate	125 m +2.5 mg+ 1 mg	liquid oral dose	d Similar FDC is already discussed by 10 expert Committee
612	2770	terbutaline sulphate+ Ambroxol HCL+ guaifenesin	1.5 mg+ 15 mg+ 50 mg	liquid oral dose	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
613	2775	bromhexine hydrochloride+ salbutamol sulphate + guaiphesin + menthol	2 mg+ 1 mg+ 50 mg + 1 mg	syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
614	2776	paracetamol + phenylephrine HCL+ chlorpheniramine maleate	500 mg + 10 mg+ 2 mg	uncoated tablet	d Similar FDC is already discussed by 10 expert Committee
615	2779	phenylephrine hydrochloride+ chlorpheniramine maleate+ paracetamol	5 mg+ 2 mg+ 250 mg	suspension	d Similar FDC is already discussed by 10 expert Committee
616	2781	cetirizine dihydrochloride+ paracetamol+ phenylephrine hydrochloride	5 mg+ 500 mg+ 10 mg	uncoated tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
617	2790	Diethylcarbamazine+Levocetirizine	150mg/300mg+ 2.5mg/5mg	Film Coated Tablets	a, diethyl carbamazine is used for tropical pulmonary eosinophilia and filaria.Anti histaminics may be used only for initial phase however diethyl carbamazine has to be use for several weeks.Furthermore there is also pharmacokinetic incompatibility. Therefore this FDC is not justified.
618	2797	terbutalines sulphate + guaiphensin + brohexine hydrochloride + menthol	1.25 mg+ 50 .0 mg+ 4.0 mg+ 2.5 mg	suspension/o ral liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
619	2807	Cetirizine HCl+Phenylephrine HCl	10mg+10mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
620	2813	Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Paracetamol IP	1mg+5mg+125 mg	Syrup	d Similar FDC is already discussed by 10 expert Committee

621	2817	diethyl carbamazine citrate+ chlorpheniramine maleate	100 mg+ 2mg	uncoated tablet	a, diethyl carbamazine is used for tropical pulmonary eosinophilia and filaria.Anti histaminics may be used only for initial phase however diethyl carbamazine has to be use for several weeks. Therefore this FDC is not justified.
622	2819	paracetamol + cetirizine HCL+ phenylephrine HCL	325 mg+ 5 mg+ 5 mg	uncoated tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
623	2821	chlorpheniramine Maleate+ phenylephrine hydrochloride + paraceatmol	2 mg+ 2.5 mg+ 125mg	syrup	d Similar FDC is already discussed by 10 expert Committee
624	2824	cetirizine HCL+ phenylephrine hydrochloride	10 mg+ 10 mg	tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
625	2830	Terbutaline sulphate+Ambroxol HCL+Guauphenesin+menthol	1.25mg+20mg+ 50mg+0.5mg	syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
626	2832	Terbutaline sulphate+Bromhexine HCL+Guaiphenesin+menthol	1.25mg+4mg+5 0mg+0.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
627	2835	Terbutaline sulphate+bromhexine HCL+Guaiphenesin	1.25mg+2mg+2 5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
628	2840	Paracetamol+Phenylephrine HCL+Cetrizine HCL	325mg+5mg+5 mg	Tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength
629	2842	Cetirizine HCL+Phenylephrine HCL	5mg+20mg	Tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
630	2844	Etofylline BP+Theophylline anhydrous eq. to Theophylline IP hydrate+Montelukast IP	231mg+69mg+ 10mg	Uncoated Tablets	a irrelevant combination without any therapeutic advantage.
631	2848	Ambroxol HCl IP+Terbutaline Sulphate IP	15mg+1.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
632	2849	Ambroxol HCl IP+Terbutaline Sulphate IP+Guaiphenesin IP+Menthol IP	30mg+1.25mg+ 100mg+2.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
633	2851	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+5mg+1 mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
634	2852	Terbutaline Sulphate IP+Ambroxol HCl IP+Guaiphenesin IP+Menthol IP	1.5mg+15mg+5 0mg+0.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
635	2858	paracetamol + cetirizine hydrochloride + phenylephrine HCL	325 mg+ 5 mg+ 5 mg	tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.

636	2860	bromhexine hydrochloride + terbutaline sulphate + guaiphensin+ menthol	2 mg+ 1.25 mg + 50 mg + .5 mg	syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
637	2861	cetirizine hydrochloride + phenylephrine HCL+ paracetamol	5 mg+ 5 mg+ 500 mg	uncoated tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
638	2862	bromhexine hydrochloride + terbutaline sulphate + guaiphensin	2 mg+ 1.25 mg+ 50 mg+ .5 mg	syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
639	2865	paracetamol + cetirizine hydrochloride + phenylephrine hydrochloride	125 mg+ 2.5 mg+ 2.5 mg	suspension	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
640	2871	Phnylephrine HCl+Bromhexine HCl+Chlorpheniramine Maleate	5mg/5mg+16mg /4mg+4mg/2mg	Tablets	a there is no scientific rationality of the FDC.There is no added advantage of bromhexine.
641	2872	Ambroxol HCl+Guaifenesin+Terbutaline Sulphate+Propylene Glycol+Sorbitol 70% Solution+Sugar D+Methyl Paraben+Propyl Paraben+sodium Benzoate+Citric Acid anhydrous+Sodium Chloride+Sodium Saccharine+Essence Pineapple sweet quest+Essense mix fruit	30mg+50mg+1. 25mg+500mg+ 2000mg+2000m g+0.5mg+5mg+ 7.5mg+30mg+5 mg+5mg+5mg+ 10mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
642	2876	Phenylephrine HCl+Ambroxol HCl+Guaiphenesin	5mg+60mg+50 mg	Tablets	a There is no scientific rationality of FDC.Phenylephrine is decongestant where as Ambroxol HCL and Guaiphenesin IP are mucolytic , these effect are contradictory to each other.
643	2877	Ambroxol HCL+Terbutaline sulphate+Guaifenesin+Menthol	15mg+1.25mg+ 100mg+2.5mg	Expectorant	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
644	2879	Ambroxol HCl+Salbutamol Sulphate	15mg+1mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
645	2883	Salbutamol Sulphate+Bromhexine HCl	2mg+4mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis. Already declaredas a for higher stregth
646	2884	Chlorpheniramine Maleate+P.G Sulphonate+Ammonium Chloride+Sodium Citrate+Menthol	10mg+30mg+6 0mg+47mg+0.3 mg	Syrup	a Pharmacodynamic incompatibility .Chlorpheniramine produce dryness of cough secretion while ammonium chloride stimulate secretion, which is antagonist effect.
647	2885	Levocetirizine HCl+Phenylephrine HCl+Ambroxol HCl	5mg/2.5mg+10 mg/10mg+60mg /60mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration.
648	2886	Levocetirizine+Phenylephrine HCl	2.5mg+10mg	Syrup	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.

649	2887	Levocetirizine HCl+Phenylephrine HCl	5mg+30mg	SR tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
650	2890	Terbutaline Sulphate+Bromhexine HCl+Guaiphenesin	1.25mg+2.0mg +50.0mg	Salbunex Expectorant	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
651	2891	Ambroxol+Guaifenesin+Terbutaline Sulphate+Menthol	15.0mg+50.0mg +1.25mg+1.00 mg	Liquid oral	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
652	2892	Terbutaline Sulphate+Bromhexine HCl+Guaifenesin	1.25mg+4.0mg +50.0mg	Liquid oral	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
653	2893	Terbutaline Sulphate+Bromhexine HCl+Guaifenesin	1.25mg+4.0mg +50.0mg	Liquid oral	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
654	2895	Terbutaline Sulphate+Bromhexine HCl+Guaifenesin	1.25mg+2.0mg +50.0mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
655	2896	Paracetamol+Phenylephrine HCl+Chlorpheniramine Maleate	125mg+2.5mg+ 1.0mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
656	2897	Phenylephrine HCl+Dextromethorphan HBr+Chlorpheniramine maleate	5.00mg+15.0mg +2.0mg	Syrup	a Use of antihistaminic with centrally acting anti tussive is not rational.
657	2899	Paracetamol+Phenylephrine+Cetirizine Di Hydrochloride	125mg+5.0mg+ 2.0mg	Liquid oral	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
658	2901	Ambroxol+Guaiphenesin+Terbutaline Sulphate+Menthol	15.0mg+50.0mg +1.25mg+1.00 mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
659	2903	Dextromethorphan Hydrobromide IP+Chlorpheniramine Maleate IP+Menthol IP	10mg+4mg+0.1 mg	Syrup	a Use of antihistaminic with centrally acting anti tussive is not rational.
660	2910	Terbutaline Sulphate IP+Bromhexine HCL IP+Guaiphenesin IP+Menthol IP	2.5mg+8mg+10 0mg+5mg	Oral Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
661	2915	Phenylephrine HCl IP+Paracetamol IP+Levocetirizine HCl IP+Menthol IP	5mg+125mg+1. 25mg+1mg	Oral Liquid	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
662	2916	Guaifenesin IP+Bromhexine HCL IP+Terbutaline Sulphate IP	100mg+4mg+1. 5mg	Syrup	c
663	2930	Cetrizine HCl ip+Phenylephrine HCl IP+Paracetamol IP	2.5mg+2.5mg/5 mg+125mg/250 mg	Suspension	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
664	2931	Terbutaline Sulphate IP+Bromhexine HCl IP	2.5mg+8mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
665	2935	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Sodium Citrate IP+Menthol IP	250mg+5mg+2 mg+60mg+1mg	Suspension	d Similar FDC is already discussed by 10 expert Committee

666	2936	Ambroxol HCl IP+Salbutamol Sulphate IP+Guaifenesin IP+Ammonium Chloride IP+Menthol IP	15mg+1mg+50 mg+100g+1mg	Syrup	a There are already two mucolytic drugs (ambroxol and guaiphenesin) , addition of ammonium chloride as bronchial secretogogue is not required for claimed indication- Symptomatic relief from wet or productive cough with or without bronchospasm.
667	2938	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaifenesin IP	1.25mg+4mg+50mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
668	2942	Terbutaline Sulphate IP+Bromhexine HCL IP+Guaifenesin IP+Menthol IP	1.25mg+4mg+50mg+2.5mg	Oral Liquid	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
669	2950	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephrine HCl IP	125mg+1.0mg+2.5mg	Oral Liquid	d Similar FDC is already discussed by 10 expert Committee
670	2956	Terbutaline Sulphate+Guaifenesin+Ambroxol Hcl+Menthol	1.5mg+100mg+30mg+2.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
671	2960	Terbutaline sulphate+Guaifenesin+Bromhexine HCL+Menthol	1.25mg+50mg+2mg+0.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
672	2962	Cetirizine HCl IP+Paracetamol IP+Phenylephrine HCl IP	5mg+325mg+5 mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
673	2963	Bromhexine HCL IP+Terbutaline Sulphate IP+Guaifenesin IP+Menthol IP	4mg+1.25mg+50mg+0.5mg/2.5 mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
674	2968	Ambroxol HCl IP+Levosalbutamol Sulphate eq. to Levosalbutamol+Guaifenesin IP	15 mg + 0.5 mg + 50 mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
675	2972	Bromhexine HCl IP+Terbutaline Sulphate IP+Guaifenesin IP	4mg+1.25mg+50mg	Oral Liquid	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
676	2975	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	250mg+2.5mg+1mg	Uncoated Tablets	d Similar FDC is already discussed by 10 expert Committee
677	2976	Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Paracetamol IP+Sodium Citrate IP+Menthol IP	5mg+2mg+250 mg+60mg+1mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
678	2977	Etofylline BP+Theophylline anhydrous eq. to Theophylline IP hydrate+Salbutamol Sulphate IP	231mg+69mg+4mg	Film Coated Tablets	c
679	2979	Phenylephrine HCL IP+Paracetamol IP+Chlorpheniramine Maleate IP	2.5mg+125mg+2mg	Suspension	d Similar FDC is already discussed by 10 expert Committee

680	2985	Cetirizine HCl+Phenylephrine HCl+Paracetamoml IP	5mg+5mg+500 mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
681	2987	Terbutaline Sulphate IP+Bromhexine HCl IP+Gualphenesin IP	1.25mg+2.0mg +50.0mg	Oral Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
682	2991	Paracetamol IP+Phenylephrine IP+Chlorpheniramine Maleate IP	125mg+2.5mg+ 1mg+7.5mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
683	2992	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+2.5mg+ 1mg	Drops	d Similar FDC is already discussed by 10 expert Committee
684	2994	Cetirizine DHCl BP+Phenylephrine HCl BP+Paracetamol IP	5mg+5mg+500 mgf	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
685	3000	Terbutaline Sulphate IP+Guaifenesin IP+Bromhexine HCl IP+Menthol IP	1.25mg+50mg+ 4mg+2.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
686	3014	Terbutaline Sulphate IP+Bromhexine HCL IP+Guaifenesin IP+Menthol IP	1.25mg+2mg+5 0mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
687	3016	Paracetamol IP+Phenylephrine Hcl IP+Chlorpheniramine Maleate IP	125mg+2.5mg+ 1mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
688	3023	Terbutaline Sulphate+Bromhexine HCl+Guaifenesin IP+Menthol IP	1.25mg+4mg+5 0mg+2.5mg per 5ml	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
689	3024	Terbutaline Sulphate+Bromhexine HCl+Guaifenesin IP+Menthol IP	1.25mg+2mg+5 0mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
690	3031	Dextromethorphan Hydrobromide IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	10mg/5mg+5mg +2.0mg	Syrup	c
691	3032	Ambroxol HCl IP+Terbutaline Sulphate IP	15mg+1.25mg per5ml	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
692	3039	Terbutaline Sulphate+Ambroxol HCl IP+Guaifenesin IP+Menthol IP	1.5mg+15mg+5 0mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
693	3040	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP	125mg+5mg+2. 5mg	Suspension	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
694	3043	Cetirizine HCL IP+Phenylphrine HCl IP	5mg+10mg	Film Coated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
695	3047	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Sodium Citrate IP+Menthol IP	250mg+5mg+2 mg+80mg+1mg	Suspension	d Similar FDC is already discussed by 10 expert Committee

696	3051	Cetirizine HCl IP+Paracetamol IP+Phenylephrine HCL IP	5mg+325mg+5 mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
697	3056	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Sodium Citrate	125mg+5mg+1 mg+60mg	Oral	d Similar FDC is already discussed by 10 expert Committee
698	3057	Salbutamol Sulphate+Bromhexine HCl+Guaifenesin IP+Ammonium Chloride+Menthol IP	2 mg + 4 mg + 66 mg +100 mg + 1 mg	Syrup	a There is no added advantage of adding mucolytic along with bronchodilator and secretogogue.
699	3059	Terbutaline Sulphate+Bromhexine HCl+Guaifenesin+Menthol	1.25mg+2.0mg +50mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
700	3061	Paracetamol+Phenylephrine+ CPM	125mg+2.5mg+ 2mg	Drops	d Similar FDC is already discussed by 10 expert Committee
701	3069	Paracetamol+Phenylephrine+Cetirizine	325mg+5mg+5 mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
702	3074	Levocetirizine HCl+Phenylephrine HCl+Ambroxol HCl	5mg+5mg+50m g	Film Coated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration.
703	3075	Paracetamol+Phenylephrine HCl+Chlorpheniramine Maleate	125mg+2.5mg+ 1mg	Liquid	d Similar FDC is already discussed by 10 expert Committee
704	3080	Phenylephrine HCl+Chlorpheniramine maleate+Paracetamol	2.5mg+1mg+12 5mg	Drops	d Similar FDC is already discussed by 10 expert Committee
705	3090	Bromohexine HCl+Terbutaline Sulpahte+Guaiphenesin	4mg+1.25mg+5 0mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
706	3091	Levocetrizine DiHCl+Phenylephrine HCl	5mg+20mg	Film Coated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
707	3095	Salbutamol Sulphate+Bromhexine HCl+Guaifenesin	1mg+2mg+25m g	Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
708	3097	Cetirizine HCl IP+Phenylephrine HCl IP+Paracetamol IP	2.5mg+1.25mg +125mg	Oral Liquid	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.

709	3100	Paracetamol IP+Phenylephrine HCl IP+Levocetrizine HCl IP	325mg+2.5mg+2.5mg	Uncoated tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
710	3101	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP	325mg+5mg+5 mg	Uncoated tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
711	3107	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Sodium Citrate IP	125mg+5mg+1 mg+60mg	Oral Liquid	d Similar FDC is already discussed by 10 expert Committee
712	3110	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaiphenesin IP+Menthol IP	1.25mg+4mg+5 0mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis
713	3113	Paracetamol IP+Levocetirizine HCl IP+Ambroxol HCl IP	325mg+5mg+6 0mg	Film Coated tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
714	3116	Bromhexine HCl IP+Guaifenesin IP+Salbutamol+Menthol IP	2mg+50mg+1m g+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis
715	3117	Paracetmol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	250mg+5mg+2 mg+60mg+1mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
716	3122	Terbutaline Sulphate IP+Bromhexine Hcl IP+Guaifenesin IP	1.25mg+2.0mg +50mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis
717	3124	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaifenesin IP+Menthol IP	1.25mg+4mg+5 0mg+2.5mg per 5ml	Oral	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis
718	3126	Chlorpheniramine Maleate IP+Paracetamol IP+Phenylephrine HCl IP	1.0mg+125mg+2.5mg	Oral Liquid	d Similar FDC is already discussed by 10 expert Committee
719	3134	Levocetirizine HCl IP+Phenylephrine HCl IP+Paracetamol IP	5mg+5mg+325 mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
720	3137	Terbutaline Sulphate+Bromhexine HCl+Guaifenesin IP	2.5mg+4mg+50 mg	Soft Gelatin Capsules	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis
721	3140	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+5mg+2 mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
722	3145	Paracetamol IP+Chlorpheniramine HCl IP+Phenylephrine HCl IP	125mg+1.0mg+2.5mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
723	3149	Cetirizine HCl IP+Paracetamol IP+Phenylephrine HCl IP	5mg+325mg+5 mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.

724	3150	Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Paracetamol IP	2mg+5mg+325 mg	Uncoated Tablets	d Similar FDC is already discussed by 10 expert Committee
725	3153	Bromhexine HCl+Salbutamol Sulphate IP+Guaifenesin IP+Menthol IP	2mg+1mg+50m g+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
726	3156	Etofylline BP+Theophylline anhydrous eq. to Theophylline IP hydrate+Ambroxol HCl IP	231mg+69mg+ 75mg	Uncoated Tablets	a Combining mucolytic with bronchodilator has no added therapeutic advantage
727	3164	Levocetirizine HCl IP+Ambroxol HCl IP+Paracetamol IP	5mg+60mg+32 5mg	Film Coated tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
728	3170	Chlorpheniramine Maleate IP+Paracetamol IP+Phenylephrine HCl IP	1mg+125mg+2. 5mg	Oral Liquid	d Similar FDC is already discussed by 10 expert Committee
729	3175	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+5mg+1 mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
730	3177	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaipheresin IP+Menthol IP	1.25mg+4mg+5 0mg+2.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
731	3180	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP	325mg+5mg+5 mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
732	3183	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+5mg+1 mg	Liquids	d Similar FDC is already discussed by 10 expert Committee
733	3184	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP	125mg+2.5mg+ 2.5mg	Oral Liquid	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
734	3185	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+2.5mg+ 2mg	Oral Liquid	d Similar FDC is already discussed by 10 expert Committee
735	3189	Salbutamol Sulphate+Bromhexine HCl	2mg+4mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.Already declaredas a for higher stregth
736	3191	Cetirizine HCl+Phenylephrine HCL SR	5mg+20mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
737	3192	Terbutaline Sulphate+Guaifenesin+Bromhexine HCl	1.25mg+50mg+ 2.0mg	oral liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
738	3197	Phenylephrine HCl+Paracetamol+Levocetirizine HCl+Menthol	5mg+250mg+0. 8mg+1.25mg	Syrup	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.

739	3198	Paracetamol+Phenylephrine HCl+chlorpheniramine Maleate+Sodium Citrate+Menthol	125mg+5mg+1 mg+60mg+1mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
740	3202	Paracetamol+Phenylephrine HCl+Chlorpheniramine maleate	125mg+5mg+1 mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
741	3206	Paracetamol+Phenylephrine HCl+Cetirizine Di HCl	325mg+5mg+5 mg	Uncoated tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength.
742	3208	Ambroxol Hcl+Terbutaline Sulphate	15mg+1.25mg	Cough syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
743	3209	Paracetamol+Phenylephrine HCl+Cetirizine Di HCl	325mg+5mg+5 mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength.
744	3212	Paracetamol+Phenylephrine HCl+Chlorpheniramine maleate+Sodium Citrate	125mg+5mg+1 mg+60mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
745	3213	Cetirizine HCl+Phenylephrine HCL+Paracetamol	2.5mg+2.5mg+ 125mg	Suspension	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
746	3217	Terbutaline Sulpahte+Bromhexine HCl+Guaiphenesin+Menthol	1.25mg+2mg+5 0mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
747	3218	Ambroxol HCl+Salbutamol sulphate	30mg+2mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
748	3220	Bromhexine HCl+Terbutaline sulpahte+Guaiphenesin	8mg+2.50mg+1 00mg	Oral liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
749	3223	Paracetamol+Phenylephrine HCl+Chlorpheniramine maleate	325mg+10mg+ 2mg	Uncoated tablet	d Similar FDC is already discussed by 10 expert Committee
750	3231	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP	325mg+5mg+5 mg	Uncoated tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
751	3235	Levocetirizine Dihydrochloride IP+Phenylephrine HCl IP	5mg+10mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
752	3240	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP	325mg+5mg+5 mg	Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.

753	3243	Paracetamol IP+Phenylephrine HCl IP+Sodium Citrate IP+Chlorpheniramine Maleate IP	250mg+2.5mg+60mg+1mg	Oral Liquid	d Similar FDC is already discussed by 10 expert Committee
754	3245	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP	325mg/500mg/125mg+5mg/2.5mg+5mg/2.5mg	Uncoated tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
755	3249	Bromhexine HCL IP+Terbutaline Sulphate IP+Guaifenesin IP+Menthol IP	8mg+2.5mg+100mg+5mg	Liquids	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
756	3250	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg/125mg/2.50mg+2.5mg/2.5mg/5mg+1mg/1mg/2mg	Liquids	d Similar FDC is already discussed by 10 expert Committee
757	3253	Ambroxol HCl IP+Terbutaline Sulphate IP+Guaifenesin IP	15mg+1.25mg+50mg	Oral Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
758	3254	Terbutaline Sulpahte+Bromhexine HCl+Guaifenesin+Menthol	1.25mg+2mg+50mg+0.5mg	Oral liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
759	3260	Cetirizine HCl+Phenylephrine HCl	2.5mg+2.5mg	Oral liquid	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredient would require more frequent administration.
760	3270	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaifenesin IP+Menthol IP	1.25mg+4mg+50mg+1mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
761	3271	Bromhexine HCL IP+Guaifenesin IP+Phenylephrine HCl IP	4mg+50mg+5mg	Syrup	d
762	3272	Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Paracetamol IP	2.5mg+1.0mg+125mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
763	3274	Paracetamol IP+Phenylephrine HCl+Chlorpheniramine Maleate IP+Sodium Citrate+Menthol	125mg+5mg+1mg+60mg+0.5mg	Oral Suspension	d Similar FDC is already discussed by 10 expert Committee
764	3284	Ambroxol HCl IP+Guaifenesin IP+Terbutaline Sulphate IP	15mg+50mg+1.25mg	Oral Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
765	3285	Phenylephrine HCl IP+Cetirizine HCl IP+Paracetamol IP	10mg+5mg+325mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
766	3286	Acebropyline+Terbutaline Sulphate+Menthol	50mg+1.25mg+2.5mg	Syrup	c For peadiatric use
767	3287	Phenylephrine HCl+Cetirizine HCl (as pellets)	10 mg +5 mg	Hard gelatin capsules	a There is no scientific rationality of FDC
768	3291	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+2.5mg+1mg	Oral Liquid	d Similar FDC is already discussed by 10 expert Committee
769	3293	Terbutaline Sulphate IP+Bromhexine HCl IP	1.5mg+4.0mg	Oral Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
770	3294	Terbutaline Sulphate IP+Bromhexine HCl IP	2.5mg+8.0mg	Uncoated Tablets	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.

771	3295	Terbutaline Sulphate IP+Bromhexine HCl IP	2.5mg+8.0mg	Oral Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
772	3297	Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Paracetamol IP	2mg+2.5mg+125mg	Liquid Oral	d Similar FDC is already discussed by 10 expert Committee
773	3298	Ambroxol HCl IP+Guaifenesin IP+Terbutaline Sulphate IP	15mg+50mg+1.5mg	Liquid Oral	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
774	3301	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaifenesin IP	1.25mg+2mg+50mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
775	3303	Cetirizine HCl IP+Phenylephrine HCl IP+Paracetamol IP	2mg+2.5mg+125mg	Oral Liquid	e There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
776	3306	Ambroxol HCl IP+Guaifenesin IP+Terbutalin Sulphate IP	15mg+50mg+1.5mg	Liquid Oral	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
777	3319	Ambroxol HCl IP+Terbutaline Sulphate IP+Guaiphenesin IP+Menthol IP	15mg+1.25mg+50mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
778	3321	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+2.5mg+1mg	Liquid Oral	d Similar FDC is already discussed by 10 expert Committee
779	3322	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	125mg+2.5mg+1mg	Liquid Oral	d Similar FDC is already discussed by 10 expert Committee
780	3331	Paracetamol IP+Chlorpheniramine maleate IP	500mg+5mg/2.0mg	Uncoated Tablets	c
781	3332	Terbutaline Sulphate IP+Bromhexine HCl IP	2.5mg+8.0mg	Oral Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
782	3336	Terbutaline Sulphate IP+Ambroxol Hydrochloride IP+Guaifenesin IP+Menthol IP	1.25mg+30mg+50mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
783	3339	Chlorpheniramine maleate+Phenylephrine HCl +Paracetamol ip	2mg+2.5mg+125mg	Liquid Oral	d Similar FDC is already discussed by 10 expert Committee
784	3340	Cetrizine HCl IP+Phenylephirine HCl IP+Paracetamol IP	2mg+2.5mg+125mg	Liquid Oral	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
785	3343	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaiphenesin IP+Menthol IP	1.25mg+2mg+50mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
786	3346	Phenylephrine Hcl Ip+Chlorpheniramine Maleate IP+Paracetamol IP	2.5mg+1mg+125mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
787	3347	Paracetamol IP+Chlorpheniramine Maleate IP	125mg+1.5mg	Suspension	c for peadiatric use
788	3348	Terbutaline Sulphate IP+Ambroxol Hydrochloride IP+Guaifenesin IP	1.25mg+15mg+50mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
789	3349	Paracetamol IP+Chlorpheniramine Maleate IP	500mg+2mg	Uncoated Tablets	c

790	3352	Terbutaline Sulphate IP+Bromhexine Hydrochloride IP+Guaifenesin IP+Menthol IP	1.25mg+2mg+50mg+0.5mg	Liquid Oral	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
791	3356	Salbutamol Sulphate IP eq. to Salbutamol+Bromhexine Hydrochloride IP+Guaiphenesin IP	1mg+2mg+25mg	Oral Liquid	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
792	3361	Paracetamol IP+Phenylephrine Hydrochloride IP+Cetirizine Hydrochloride IP	500mg+5mg+5mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
793	3362	Paracetamol IP+Phenylephrine Hydrochloride IP+Chlorpheniramine Maleate IP	500mg+5mg+2mg	Uncoated Tablets	d Similar FDC is already discussed by 10 expert Committee
794	3368	Ambroxol Hydrochloride IP+Guaifenesin IP	15mg+1.50mg+50mg	Oral Liquid	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
795	3370	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Sodium Citrate IP+Menthol IP	250mg+5mg+2.0mg+60mg+1mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
796	3372	Ambroxol Hydrochloride IP+Terbutaline Sulphate IP+Guaifenesin IP+Menthol IP	15mg+1.25mg+50mg+1mg	Liquid Orals	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
797	3373	Chlorpheniramine Maleate IP+Phenylephrine Hydrochloride IP+Paracetamol IP	1mg+5mg+125mg	Liquid Orals	d Similar FDC is already discussed by 10 expert Committee
798	3374	Ambroxol Hydrochloride IP+Levosalbutamol Sulphate IP eq. to Levosalbutamol+Guaifenesin IP	15mg+0.5mg+50mg	Liquid Orals	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
799	3375	Bromhexine Hydrochloride IP+Terbutaline Sulphate IP+Guaifenesin IP	2mg+1.25mg+50mg	Liquid Orals	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
800	3380	Paracetamol IP+Cetirizine HCl IP+Phenylephrine HCl IP	325mg+5mg+5mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
801	3393	Diethyl Carbamazine Citrate IP+Cetirizine Di-Hydrocholoride IP	150mg+5mg	Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
802	3394	Paracetamol IP+Phenylephrine HCl Chlorpheniramine Maleate IP	125mg+5mg+1mg	oral suspension/s yrup	d Similar FDC is already discussed by 10 expert Committee
803	3398	Bromhexine HCl IP+Terbutaline Sulphate IP+Guaifenesin IP+Menthol IP	4mg+2.5mg+100mg+1mg	Expectorent	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
804	3400	Bromhexine HCl IP+Terbutaline Sulphate IP+Guaifenesin IP	2mg+1.25mg+25mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
805	3401	Bromhexine HCl IP+Terbutaline Sulphate IP+Guaifenesin IP+Menthol IP	2mg+1.5mg+50mg+0.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
806	3402	Bromhexine HCl IP+Terbutaline Sulphate IP+Guaifenesin IP	8mg+2.5mg+100mg	Uncoated Tablets	c

807	3407	Salbutamol Sulphate IP+Theophylline IP+Bromhexine HCl IP	2mg+100mg+8 mg	Uncoated Tablet	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
808	3408	Salbutamol Sulphate IP+Guaifenesin IP+Bromhexine HCL IP+Menthol IP	1mg+50mg+2m g+0.5mg	Oral Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
809	3412	Bromhexine HCl IP+Terbutaline Sulphate IP+Guaifenesin IP+Menthol IP	2mg+1.25mg+5 0mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
810	3413	Diethyl carbamazine citrate IP+Chlorpheniramine Maleate IP	0.12gms+3.0mg		a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
811	3414	Paracetamol IP+Chlorpheniramine Maleate IP	125mg+2mg	oral	c for peadiatric use
812	3416	Paracetamol IP+Chlorpheniramine Maleate IP+Phenyl Propanolamine HCL BP	500mg+2mg+2 5mg	Tablet	a
813	3417	Di-ethylcarbamazine Citrate IP+Chlorpheniramine Maleate IP	120mg+3mg	Syrup	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
814	3419	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaifenesin IP+Menthol IP	1.25mg+2mg+5 0mg+0.5mg	Cough Expectorant	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
815	3421	Diethyl Carbamazine Citrate IP+Chlorpheniramine Maleate IP	100mg+2.5mg	Syrup	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
816	3422	Ambroxol HCL IP+Terbutaline Sulphate IP+Guaiphenesin IP+Menthol IP	15mg+1.25mg+ 50mg+2mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
817	3423	Ambroxol HCL IP+Terbutaline Sulphate IP+Guaifenesin IP+Menthol IP	30mg+1.25mg+ 50mg+2mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
818	3425	Cetirizine Dihydrochloride IP+Phenylephirine HCl IP+Paracetamol IP	2mg+5mg+125 mg	Syrup	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
819	3426	Ambroxol HCL IP+Terbutaline Sulphate IP+Guaifenesin IP+Menthol IP	15mg+1.25mg+ 50mg+2.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
820	3428	Diethyl Carbamazine Citrate IP+Cetirizine Dihydrochloride IP	100mg+2.5mg	Syrup	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.

821	3429	Diethyl Carbamazine Citrate IP+Chlorpheniramine Maleate IP	150mg+5mg	Tablet	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
822	3430	Paracetamol IP+Chlorpheniramine Maleate IP+Phenylephirine HCl IP	125mg+1mg+5 mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
823	3431	Ambroxol HCl IP+Salbutamol Sulphate IP eq. to Salbutamol+Guaiphenesin IP+Menthol IP	30mg+1mg+50 mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
824	3435	Phenylephirine HCl IP+Chlorpheniramine Maleate IP+Paracetamol IP	5mg+2mg+1.25 mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
825	3436	Phenylephirine HCl IP+Chlorpheniramine Maleate IP+Paracetamol IP	5mg+2mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
826	3437	Ambroxol HCl IP+Terbutaline Sulphate IP+Guaifenesin IP	5mg+1.5mg+50 mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
827	3438	Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Paracetamol IP	5mg+2mg+250 mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
828	3440	Salbutamol Sulphate IP eq. to Salbutamol+bromhexine HCl IP+Guaifenesin IP	1mg+4mg+50m g	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
829	3441	Phenylephrine HCl IP+Chlorpheniramine Maleate IP+Paracetamol IP	5mg+2mg125m g	Drops	d Similar FDC is already discussed by 10 expert Committee
830	3442	Cetirizine HCl IP+Phenylephrine HCl IP+Paracetamol IP	2.5mg+5mg+32 5mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
831	3454	Terbutaline Sulphate IP+Bromhexine HCl IP+Chlorpheniramine Maleate IP	1.25mg/2.5mg+ 4mg/16mg+2mg /4mg	Uncoated Tablets	a Use of chlorpheniramine with bronchodialator has no advantage of this FDC, as chlorpheniramine will cause dryness of secretion.
832	3457	Paracetamol IP+Cetirizine HCl IP+Phenylephrine HCl IP	125mg+2.5mg+ 2.5mg	Oral Liquid Syrup	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
833	3458	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaifenesin IP	1.25mg+2mg+5 0mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
834	3461	Diethylcarbamazine Citrate+Chlorpheniramine Maleate USP	50mg+1.25mg	Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
835	3462	Diethylcarbamazine Citrate+Chlorpheniramine Maleate USP	0.25g+5mg	Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.

836	3464	Levocetirizine IP+Diethyl Carbamazine Citrate	2.5mg+150mg	Film Coated Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
837	3466	Terbutaline Sulphate IP+Bromhexine HCl IP+Guaifenesin IP+Menthol IP	2.5mg+8mg+100mg+5.0mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
838	3469	Levocetirizine IP+Diethyl Carbamazine Citrate	5mg+300mg	Film Coated Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
839	3474	Ambroxol HCl IP+Terbutaline Sulphate eq. to elemental Terbutaline+Guaifenesin IP+Menthol IP	15mg+1.25mg+50mg+1.0mg	Oral Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
840	3475	Ambroxol HCl IP+Terbutaline Sulphate eq. to elemental Terbutaline+Guaifenesin IP+Menthol IP	15mg+2.5mg+50mg+1.0mg	Oral Liquid	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
841	3485	Chlorpheniramine Maleate IP+Phenylephrine HCl IP+Paracetamol IP	4mg+5mg+500 mg	Oral Tablet	d Similar FDC is already discussed by 10 expert Committee
842	3490	Terbutaline Sulphate IP+Bromhexine Hydrochloride IP+Guaifenesin IP	2.5mg+8mg+100mg	Liquid Orals	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
843	3491	Terbutaline Sulphate IP+Bromhexine Hydrochloride IP+Guaifenesin IP+Menthol IP	0.75mg+2mg+25mg+0.5mg	Liquid Orals	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
844	3495	Terbutaline Sulphate IP+Bromhexine Hydrochloride IP+Guaiphenesin IP+Menthol IP	1.25mg+4mg+50mg+1mg	Liquid Orals	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
845	3496	Paracetamol IP+Phenylephrine Hydrochloride IP+Chlorpheniramine Maleate IP	250mg/125mg+5mg/2.5mg+2mg/1mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
846	3498	Bromhexine Hcl IP+Guaifenesin IP+Terbutaline Sulphate IP+Menthol IP	5mg+50mg+1.25mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
847	3503	Paracetamol IP+Phenylephrine Hcl IP+Cetrizine HCl IP	650mg+10mg+5mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration. Use of Paracetamol in FDCs seems un- warranted, not to speak of the strength of the Paracetamol used.
848	3505	Levocetirizine Hydrchloride IP+Phenylephrine Hydrchloride IP(in sustained release form)	5mg+30mg	Uncoated bilayered tablet	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration.
849	3525	Levocetirizine Hydrochloride IP+Phenylephrine Hydrochloride IP	2.5mg+10mg	Uncoated Tablets	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration.
850	3526	Levocetirizine dihydrochloride IP+Diethylcarbamazine Citrate IP	2.5mg+150mg	Film Coated Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
851	3531	Ammonium Chloride IP+Chlorpheniramine Maleate IP+Sodium citrate IP+menthol IP	100mg+2mg+0.5mg+0.1mg	Syrup	a Contradictory pharmacodynamic effect of ammonium chloride and Chlorpheniramine.

852	3532	Diethylcarbamazine Citrate IP+Cetrizine Hydrochloride Ip	120mg+5mg	Syrup	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
853	3533	Diethylcarbamazine Citrate IP+Cetrizine Hydrochloride Ip	300mg+10mg	Film Coated Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
854	3538	Terbutaline Sulphate IP+Guaiphenesin BP+Ambroxol Hcl IP	1.25mg+50mg+15mg	Oral Liquid	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
855	3539	Terbutaline Sulphate IP+Guaifenesin BP+Ambroxol Hcl IP+Menthol IP	1.5mg+50mg+15mg+1mg	Oral Liquid	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
856	3540	Terbutaline Sulphate IP+Guaifenesin BP+Ambroxol Hcl IP	1.5mg+50mg+15mg	Oral Liquid	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
857	3542	Paracetamol IP+Phenylephrine Hcl IP+Chlorpheniramine Maleate IP+Menthol IP	250mg+5mg+2mg+1mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
858	3543	Levocloperastine Fendizoate eq. to Levocloperastine HCl+Chlorpheniramine Maleate IP	35.4mg eq. to 20mg+4mg	Suspension	a There is no pharmacokinetic and pharmacodynamic compatibility - while Cetrizine is usually given once a day, other ingredients would require more frequent administration.
859	3544	Bromhexine Hcl IP+Guaifenesin Ip+Menthol IP+Terbutaline Sulphate IP	4mg+50mg+2.5mg+1.25mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
860	3545	Ammonium Chloride IP+Chlorpheniramine Maleate IP+Sodium Citrate IP+Menthol IP	10mg+2mg+50mg+1mg	Oral Liquid-Syrup	a Contradictory pharmacodynamic effect of ammonium chloride and Chlorpheniramine.
861	3546	Bromhexine HCl IP+Terbutaline Sulphate IP eq. to Terbutaline+Guaifenesin IP+Menthol IP	4mg+1.25mg+50mg+0.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
862	3547	Ambroxol HCl IP+Terbutaline Sulphate IP eq. to Terbutaline+Guaifenesin IP+Menthol IP	30mg+2.5mg+50mg+0.5mg	Syrup	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
863	3551	Ambroxol HCl IP+Terbutaline Sulphate IP eq. to Terbutaline	30mg+2.5mg	Uncoated Tablets	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
864	3554	Terbutaline Sulphate IP+Ambroxol HCl IP+Guaifenesin IP	1.5mg+15mg+50mg	Oral Liquid	c For symptometic relief of bronchospasm in bronchial asthma and chronic bronchitis.
865	3558	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	250mg+5mg+2mg	Liquid Orals	d Similar FDC is already discussed by 10 expert Committee
866	3559	Paracetamol IP+Phenylephrine HCl IP+Chlorpheniramine Maleate IP	325mg+10mg+4mg	Uncoated Tablets	d Similar FDC is already discussed by 10 expert Committee
867	3572	Paracetamol IP+Chlorpheniramine Maleate IP	400mg+2mg	Uncoated Tablets	c If paracetamol dose is 500 mg.
868	3573	Etofylline BP+Theophylline (Anhydrous) IP eq. to Theophylline hydrous	77mg+23mg	Uncoated Tablets	c
869	3578	Clindamycin Phosphate USP+Zinc Acetate+Methylparaben IP+ Propylparaben	1% w/w + 1% w/w + 0.2% w/w + 0.05% w/w	Cream	a Irrationale combination.
870	3587	Lornoxicam+Thicolchicoside IP+Oleum Lini+Menthol IP+Methylsalicylate IP	0.125% w/w + 0.125% w/w + 3% w/w + 5% w/w + 10% w/w	Gel	a Fdc has no scientific rationale.

871	3590	Podophllum Resin IP'66'+Benzoin IP+Aloes IP+Salylylic Acid IP+Isopropyl Alcohol IP	25% w/v + 10% w/v + 2% w/v + 5% w/v + 100% w/v	Paint	c
872	3598	Hydroquinone+Tretionoin+Fluticasone Propionate	2% w/w + 0.025% w/w + 0.05% w/w	Cream	c
873	3599	Paracetamol IP+Phenylephrine HCl IP+Cetirizine HCl IP	125mg+2.5mg+ 2.5mg	Topical Use	a it appears that dosage form is incorrect, it is irrationale FDC as o oral tablet.
874	3607	Tretinoin+Clindamycin Phosphate USP eq. to Clindamycin	0.04% w/w + 1.0% w/w	Topical Gel	c
875	3609	Podophyllum BP+Benzoin IP+Aloes IP+Isopropyl Alcohol IP	20% w/v + 10% w/v + 2% w/v +100% v/v	Paint	c
876	3611	Octyl Methoxy Cinnamate USP+Oxybenzone USP+Vitamin-E Acetate IP+Methylene Bis-Benzotriazolyl Tetramethylbutylphenol	3.0% w/w + 2.0% w/w + 0.5% w/w+4.0% w/w	Cream	d
877	3617	Povidone Iodine IP+Ornidazole IP+Dexpanthenol USP	5% w/w + 1% w/w + 5% w/w	Topical Ointment	a irrationale combination.Ingredients have different therapeutic indication
878	3619	Clindamycin Phosphate BP eq. to Clindamycin+Nicotinamide IP	1% w/w + 4% w/w	Topical Gel	c
879	3625	Povidone Iodine IP+Tinidazole	5% w/w + 2% w/w	Ointment	c
880	3629	Povidone-Iodine+Tinidazole+Sucralfate	5%w/w+1%w/w +7%w/w	Topical Powder	c Similar FDC already approved by CDSCO
881	3630	Povidone-Iodine+Tinidazole+Sucralfate	5%w/w+1%w/w +7%w/w	Ointment	c Similar FDC already approved by CDSCO
882	3633	Clindamycin+Nicotinamide	1%w/w+4%w/w	Gel	c
883	3637	Sodium Salicylate+Zinc Gluconate+Pyridoxine HCl	1.0%w/w+0.5% w/w+0.5%w/w	Liquid in shampoo base	a Use of pyridoxine is not justified.
884	3639	Octyl Methoxy Cinnamate USP (OMC)+Oxybenzole USP+Vitamin E Acetate IP+MBBT(Methylene Bis-Benzotriazolyl Tetramethylbutylphenol)	5.0%w/w+5.0% w/w+0.5%w/w+ 10%w/w	Cream	d
885	3655	Pine Bark Extract+Kojic Acid+Sodium Ascorbyl Phosphate	0.4% w/w + 2.0% w/w + 1.0%w/w	Cream	a Irrationale combination
886	3671	Hydroxyl ethyl cellulose+sodium alginate	Nil (not mentioned in license)	External gel	Incomplete Information
887	3674	clindamycin phosphate + nicotinamide	1%w/w + 4 % w/w	cream/ointment/gel/lotion	c
888	3685	lornoxicam + capsaicin 95% powder + menthol+ camphor	1mg+ .02 mg+ 70 mg+ 10 mg	liniment	a Irrationale combination without any scientific evidence.
889	3692	Povidone-Iodine IP+Metronidazole IP	5.0%w/w+1.0% w/w	Ointment	c
890	3705	Clindamycin Phosphate USP eq. to Clindamycin + Nicotinamide IP	1.0% w/w + 4.0% w/w	Gel	c
891	3709	Minoxidil + Aminexil + Absolute Alcohol	2.0%/5.0%w/v+ 1.5%1/1.05%w/v+63%v/v / 40%v/v	Topical Solution	a Irrationale combination without any scientific evidence. Aminexil is not approved drug in India.
892	3711	Povidone Iodine + ornidazole	5.0%w/w&10.0 %w/w+1.0%w/w	Ointment	c
893	3716	glucosamine hydrochloride + diacerein + menthol + camphor+ capsaicin powder	10 % w/w + 1 % w/w + 5 % w/w + 1 % w/w + .05% w/w	ointment	a Irrationale combination without any scientific evidence.

894	3717	miconazole nitrate+ fluconazole acetonide	2% w/w + .025% w/w	ointment	c if fluconazole is fluocinolone
895	3720	Clindamycin Phosphate+Nicotinamide	1.0%w/w + 4.0%w/w	Gel	c
896	3738	Povidone Iodine+ornidazole	5%w/w+1%w/w	Typical Ointment	c FDC is already approved by CDSCO
897	3739	Hydroquinone + Tretinoin + Mometasone Furoate	2%w/w+0.025% w/w+0.1%w/w	Cream	c
898	3743	Diaveridine HCl + Sulphaquinoxaline Sodium	3.3gm+18.7gm	Powder	veterinary
899	3751	Povidone-Iodine + Tinidazole + Sucralfate	5%w/w+1%w/w +7%w/w	Ointment	c Similar FDC already approved by CDSCO
900	3753	Hydroquinone + Oxybenzone + Octinoxate	4.0%w/w+3.0% w/w+5.0%w/w	Cream	c
901	3766	Hydroquinone+Oxybenzone+Octinoxate	2.0%w/w+2.5% w/w+9.0%w/w	Cream	c
902	3769	Clindamycin Phosphate + Nicotinamide	1.0%w/w+4.0% w/w	Cream	c
903	3771	Silver Sulphadiazine + Chlorhexidine Gluconate Solution + Allantoin + Aloe Vera Gel + Vitamin E Acetate	1%w/w+0.2%w/ w+0.1%w/w+15 %w/w+0.2%w/w	Cream	a Irrationale combination. Addition of Allantoin + Aloe Vera Gel + Vitamin E Acetate , in the present formulation for treatment of burn wound has no therapeutic merit
904	3773	Chloroxylenol+Terpinol+Alcohol Absolute (Denatured)	4.80%w/v+9.0% v/v+13.1%v/v	Gel	a Irrationale combination without any scientific evidence.
905	3785	Povidone Iodine+Sucralfate USP+Tinidazole IP	5.0%w/w + 7.0%w/w + 1.0%w/w	Powder	c Similar FDC already approved by CDSCO
906	3787	Povidone Iodine IP+Sucralfate USP+Tinidazole IP	0.5%w/w + 7.0%w/w + 1.0%w/w	Ointment	c Similar FDC already approved by CDSCO
907	3798	Clindamycin Phosphate IP+Nicotinamide IP	1.0%w/w + 4.0%w/w	Gel	c
908	3799	Hydroquinone USP+Octyl Methoxycinnamate USP+Oxybenzone USP	2.0%w/w + 5.0%w/w + 3.0%w/w	Cream	c
909	3806	Hydroquinone USP+Tretinoin USP+Mementasone Furoate	2%w/w + 0.025%w/w + 0.1%w/w	Cream for external use	c
910	3813	Povidone Iodine IP+metronidazole IP+Aloe vera	5.00%w/w + 1.00%w/w + 1.50%w/w	Ointment	a Irrationale combination.Ingredients have different therapeutic indication
911	3840	Hydroquinone USP+Octyl Methoxycinnamate USP+Oxybenzone USP	2.0%w/w + 5.0%w/w + 3.0%w/w	Cream	c
912	3849	Hydroquinone USP+Tretinoin USP+Fluocinolone Acetonide IP	4.0%w/w + 0.05%w/w + 0.01%w/w	Cream	c
913	3855	Calamine+Aloe+Light Liquid Paraffin	8%w/w + 10%w/w + 10%w/w	Lotin	c
914	3858	Clindamycin Phosphate BP eq. to Clindamycin+Nicotinamide IP	1.0%w/w + 4.0%w/w	Gel	c
915	3860	Clindamycin Phosphate BP eq. to Clindamycin+Nicotinamide IP	1%w/w + 4%w/w	Gel	c
916	3862	Minoxidil+Aminexil	5.0%w/v + 1.5%w/v	Topical Solution	a Irrationale combination without any scientific evidence.Aminexil is not approved drug in india
917	3868	White Soft Paraffin IP+Light Liquid Paraffin IP+Aloe Vera Gel	3%w/v + 3%w/v + 10%w/v	Lotion	c
918	3878	Clindamycin Phosphate BP+Nicotinamide IP	1%w/w + 4%w/w	Gel	c

919	3879	Ketoconazole IP+Zinc Pyrithione+D-Panthenol IP+Tea Tree Oil BP+Aloes IP	2%w/v + 1%w/v + 0.25%w/v + 0.5%w/v + 5%w/v	Lotion	a Irrationale combination without any scientific evidence.
920	3885	Calamine 10% + Aloes 10% +Allantoin	10% + 10% + 0.5%	Lotion	a Irrationale combination due to different indications of ingredients
921	3886	Ketoconazole+Aloes+ZPTO	2% + 10% + 1%	Solution	a Irrationale combination without any scientific evidence.
922	3889	Dichlorometaxylenol BP+Terpineol BP	2.0%w/v + 2.0%w/v	Antiseptic Liquid	a Irrationale combination without any scientific evidence.
923	3891	Hydroquinone USP+Hydrocortisone Acetate IP+Tretinoin USP	2%w/w + 1%w/w + 0.025%w/w	Ointment	c
924	3899	Povidone Iodine+Tinidazole+Sucralfate	5%w/w+1%w/w +7%w/w	Ointment	c Similar FDC already approved by CDSCO
925	3900	Tetracycline HCl+Colistin Sulphate	14%w/w+1%w/w	Powder	a Irrational combination.
926	3904	Povidone Iodine+Tinidazole	5%+1%	Ointment	a irrationale combination.Ingredients have different therapeutic indication
928	3906	Kojic Acid + Arbutin+ Octinoxate + Vitamin E +Mulberry	2%+1.5%+7.5% +1%	Cream	a Irrationale combination without any scientific evidence.
929	3914	Chloroxylenol+Terpineol+Alcohol	4.8%w/v+9.0% w/v+13.1%w/v	Antiseptic Liquid	a Irrationale combination without any scientific evidence.
930	3916	Minoxidil+Azelaic Acid+ saw palmetto	10%w/v+5%w/v +3%v/v	Topical Solution	a Irrationale combination without any scientific evidence. Saw palmetto is not approved drug in
931	3926	Calcium Dobesilate monohydrate+Hydrocortisone Acetate+Lignocaine Hydrochloride+Zinc	0.5%w/w+0.25 %w/w+3.0%w/w +5.0%w/w	Cream	c
932	3928	Sulfaquinoxaline+Diaveridine HCl+Vitamin K	37.4gm+6.6gm +2000mcg	Powder	a Therapeutic value of this FDC not proven.
933	3931	Clindamycin+Nicotinamide	nil (formal application not received)	Gel	c if strength is 1%+4%
934	3932	Aloes+Vitamin E Acetate	10%w/v+ 0.5%w/v	Lotion	c
935	3933	Minoxidil IP+Azelaic Acid +saw palmetto	3.0%w/v + 1.5%w/v + 1.5%w/v	Topical Solution	a Irrationale combination without any scientific evidence. Saw palmetto is not approved drug in
936	3934	Clindamycin Phosphate BP+Nicotinamide IP	1%w/w + 4%w/w	Gel	c
937	3948	Calcitriol IP+Clobetasol Propionate BP	3mcg+0.5mg	Ointment	c indication to be limited for psoriasis.
938	3949	Minoxidil IP+Aminexil+Alcohol 95% v/v eq to absolute Alcohol	2.0%w/v/5%/4% + 1.5%w/v/1.5%.1.5% + 63%v/v/40%/40%	Topical Solution	a Irrationale combination without any scientific evidence.Aminexil is not approved drug in India.
939	3951	Calcium Dobesilate monohydrate+Hydrocortisone Acetate+Lignocaine Hydrochloride+Zinc	0.25%w/w + 0.25%w/w + 3%w/w + 5.0%w/w	Cream	c
940	3958	Clindamycin Phosphate USP+Nicotinamide IP+Allantoin BP	1.0%w/w + 4.0%w/w + 0.5%w/w	Gel	d

941	3976	Troxerutin Calcium Dobesilate Monohydrate BP (Eq. to Anhydrous Calcium Dobesilate IP+Lignocaine HCl IP+Hydrocortisone Acetate IP+Zinc Oxide IP+Phenylephrine HCl IP	2.0%w/w + 0.25%w/w + 3.0%w/w + 0.25%w/w + 5.0%w/w + 0.1%w/w	Cream	c
942	3977	Calcium Dobesilate monohydrate+Lignocaine Hydrochloride+Hydrocortisone Acetate+Zinc	0.25%w/w + 3.0%w/w + 0.25%w/w + 5.0%w/w	Ointment	c
943	3985	Heparin Sodium IP+Benzyl Nicotinate+Sorbic Acid IP	50 IU+2mg+1.97mg	Ointment	a Irrationale combination without any scientific evidence.
944	3991	Hydroquinone USP+Tretinoin USP+Fluocinolone Acetonide IP+Methyl Paraben IP+Propyl Paraben IP	2.0%w/w + 0.05%w/w + 0.01%w/w + 0.2%w/w + 0.02%w/w	Cream	c
945	4003	Sildenafil Citrate IP+Papaverine+L-Arginine IP	1%w/w + 15%w/w + 0.5%w/w	Cream	a irrationale combination.Ingredients have different therapeutic indication
946	4012	Azelaic Acid+Tea Tree oil+Salicylic Acid+Allantoin+Zinc Oxide+Aloe Vera+Jojoba oil+Vitamin-E+Soap noodles	2.5%w/w+ 0.5%w/w+ 0.5%w/w+ 0.2%w/w+ 0.5%w/w+ 0.5%w/w+ 1.0%w/w+ 0.2%w/w+ 100%w/w	External	a Already categorise as "a".
947	4024	Clindamycin Phosphate USP+Nicotinamide IP	1.00%w/w + 4.00%w/w	Gel	c
948	4028	Tetracaine+Lidocaine	70mg+70mg	Cream	c
949	4032	Hydroquinone USP+Tretinoin USP+Mometasone Furoate IP	2.0%w/w + 0.025%w/w + 0.1%w/w	Cream	c
950	4033	Salicylic Acid IP+Aloe Vera+Allantoin IP+D-Panthenol IP	2%w/v + 5%w/v + 0.1%w/v + 0.2%w/v	Cream	a Irrationale combination.
951	4039	Menthol+Lignocaine HCl+Aloe Vera gel+clotrimazole+Diphenhydramine HCl	1%w/w+0.5%w/w+0.5%w/w+1.0%w/w+2%w/w	Topical Gel	a Irrationale combination without any scientific evidence.Ingredients are used separately for different clinical condition.
952	4049	Hydroquinone USP+Octyl Methoxycinnamate USP+Oxybenzone USP	2.0%w/w + 5.0%w/w + 3.0%w/w	Cream	c
953	4064	Mephenesin+Methyl Nicotinate BP+Capsicum Oleoresin USP	10%w/w + 1%w/w + 0.05%w/w	Ointment	a Irrationale combination without any scientific evidence.Ingredients are used separately for different clinical condition.
954	4067	Menthol IP+Aloe Vera Gel+Insert Solvent & Propellant Deodorised LPG q.s. to (Butane, Isobutane, Propane)	19% w/w + 01.00% w/w + 100%	Topical Pain Relief Spray	a Irrationale combination without any scientific evidence.
955	4068	Chloroxylenol IP+Turpinol BP	00.24%w/w + 00.50%w/w	Disinfectant Spray	a Irrationale combination without any scientific evidence.
956	4074	Vitamin E Acetate IP in Aloe Vera cream base	0.5%w/w	Cream	c
957	4087	Chloroxylenol IP+Terpineol BP+Alcohol (Denatured)	4.8%w/v + 9%w/v + 13.1%v/v	External Liquid	a Irrationale combination without any scientific evidence.
958	4090	Chloroxylenol BP+Terpineol BP+Alcohol (Denatured)	4.8%w/v + 9%w/v + 13.1%v/v	Topical Liquid	a Irrationale combination without any scientific evidence.

959	4094	Dichloroxylenol B.P.C+Terpineol BP+Phenol IP+Alcohol (Denatured)	1%w/v + 1%w/v + 0.25%w/v + 1%w/v	Cream	a Irrationale combination without any scientific evidence.
960	4097	Dichlorometaxylenol B.P.C+Terpineol BP+Alcohol (Denatured)	2%w/v + 2%w/v + 2%w/v	Topical Liquid	a Irrationale combination without any scientific evidence.
961	4102	Troxerutin+Calcium Dobesilate BP eq. to Anhydrous Calcium Dobesilate+Lignocaine HCL IP+Hydrocortisone Acetate IP+Zinc Oxide IP+Phenylephrine HCl IP	2% w/w + 3%w/w + 0.25%w/w + 5%w/w + 0.1%w/w	Cream	c
962	4108	Calamine IP+Diphenhydramine Hydrochloride IP+Aloevera Juice+Camphor BP+Glycerin IP	8% w/v + 1% w/v + 5% w/v + 6.25% w/v	Topical Lotion	a Irrationale combination.
963	4111	Dichlorometaxylenol BPC+Terpineol BPC	1.5% w/v + 5% w/v	Nil	a Irrationale combination without any scientific evidence.
964	4112	Dichloroxylenol BPC+Terpineol BPC+Phenol IP	1% + 1% + 0.25%	Nil	a Irrationale combination without any scientific evidence.
965	4114	Euphorbia Prostrata Extract (Containing0.315mg to 0.825mg total flavonoids calculated as Apigenin-7-glucoside and 1.26 to 4.40 mg total phenolics calculated as gallic acid)+Lidocaine BP	10mg+30mg	Cream	a Irrationale combination without any scientific evidence.
966	4115	Hydroquinone USP + Tretinoin BP + Mometasone Furoate IP	2% w/w + 0.025 w/w + 0.1% w/w	External Preparation cream	c
967	4117	Glimepiride IP+Metformin HCl IP (In extended released form)	3mg/4mg+500mg	Bilayered modified released tablets	c
968	4118	Glimepiride IP+Metformin HCl IP (In extended released form)	3mg/4mg+500mg	Bilayered modified released tablets	c
969	4120	Chlorphenesin IP'85+Zinc Oxide IP+Starch IP	1% w/w + 1.6%w/w + 11% w/w	Powders	a Irrationale combination without any scientific evidence.
970	4134	Clindamycin Phosphate BP eq. to Clindamycin+Nicotinamide IP	1%w/w+4% w/w	Gel	c
971	4137	Cyproheptadine Hydrochloride IP+Tricholine Citrate	1.5mg+55mg	Liquid Oral Preperation	c
972	4138	Cyproheptadine HCl+Tricholine Citrate+Sorbitol Solution (70%) (Non-Crystalling) IP	2mg+275mg+2gm	Liquid Oral Preperation	c

973	4139	Cyproheptadine Hydrochloride IP+Dried Yeast IP'85	2mg+100mg	Hard Gelatin Capsules	c
974	4140	Octinoxate USP+Avobenzone USP+Oxybenzone USP+Octocrylene USP+Zinc Oxide IP	7.5%w/w+2.0% w/w+3.0% w/w+3.0%w/w+2.0% w/w	Gel	d
975	4141	Calamine IP+Aloe Vera Gel+Light Liquid Paraffin IP	8.0%w/w+10.0%w/w+10.0%w/w	Lotion	c
976	4153	Chlorpheniramine Maleate IP+Phenylephrine Hydrochloride IP+Paracetamol IP+Menthol IP	1.5mg+2.5mg+125mg+1mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
977	4156	Chlorphniramine Maleate IP+Phenylephrine Hydrochloride IP+Paracetamol IP	4mg+5mg+325mg	Uncoated Tablets	d Similar FDC is already discussed by 10 expert Committee
978	4157	Diastase IP (1:1200)+Pepsin IP (1:3000)+Simethicon Emulsion USP eqvt. To Simethicone	33.33mg+5mg+40mg	Drops	d
979	4158	Miconazole USP+Tinidazole USP	2.0% w/v + 2.0% w/v	lotion	a Irrationale combination without any scientific evidence.Ingredients are used separately for different clinical condition
980	4163	Ornidazole IP+Miconazole IP	2%w/v + 2%w/v	Cream	a irrationale combination.Both have different therapeutic indication
981	4165	Ornidazole IP+Miconazole IP	2500mg+100mg	Uncoated tablets	a, this combination is not scientifically justify and will lead to antimicrobial resistance
982	4173	Paracetamol IP+Phenyephrine hydrochloride IP+Chlorpheniramine Maleate IP	125mg+2.5mg+1mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
983	4185	Terbutaline sulphate IP+Bromohexine HCL+Guaifenesin IP	1.25mg+4mg+50mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
984	4186	Terbutaline sulphate IP+Bromohexine HCL+Guaifenesin IP	2.5mg+8mg+100mg	Uncoated Tablets	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
985	4193	Tricholine citrate + sorbitol solution (70%)IP (Non-crystallising)	0.55gm+7.15gm	Liquid	c
986	4194	Atenolol IP+chlorthalidone IP	25mg/50mg/100mg+12.5mg/12.5mg/25mg	Uncoated Tablets	c
987	4205	Ambroxol Hydrochloride IP+Salbutamol Sulphate IP equivalent to Salbutamol+Guaifenesin IP	15mg+2mg+100mg	Uncoated Tablets	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
988	4209	Pepsin (1:3000) IP+Fungal Diastase (1:1200) IP(derived from Aspergilus oryzae)+Sodium Tauroglycocholate Docusate Sodium IP	10mg+50mg+60mg	Hard Gelatin Capsules	c
989	4218	Camylofin dihydrochloride+Nimesulide BP	50mg+100mg	Film Coated Tablets	d
990	4219	Glucosamine sulphate(added as glucosamine sulphate sodium chloride)+Chondroitin Sulphate (added as chondroitin sulphate sodium)	500mg+400mg	Film Coated Tablets	a, There is no scietnific evidence favoring this combination
991	4220	Terbutaline Sulphate IP+Bromhexine Hydrochloride IP+Guaiphenesin IP	1.25mg+4m+50mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
992	4227	Camylofin dihydrochloride+Paracetamol IP	25mg+300mg	Film Coated Tablets	a Subtherapeutic dose of Paracetamol

993	4229	Hydroquinone USP+Tretinoin BP+Allantoin BP	2.00%w/w 0.025% w/w+1.00% w/w	Cream	a Irrationale combination without any scientific evidence.
994	4230	Bromhexine Hydrochloride IP+Phenylephrine Hydrochloride IP+Chlorpheniramine Maleate IP	4mg+5mg+2mg	Syrup	d
995	4233	Simethicone emulsion USP equivalent to Simethicone IP+Dill Oil BP+Fennel Oil USP Simethicone IP+Dill Oil BP+Fennel Oil USP	40mg+0.005ml+ 0.0007ml	Drops	d
996	4253	Paracetamol IP+Phenyephrine hydrochloride IP+Chlorpheniramine maleate IP	250mg+2.5mg+ 2mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
997	4259	Minoxidil IP+Aminexil+Alcohol 95%v/v eqvt. To absolute alcohol	5%w/v + 1.5%w/v + 40%v/v		a Irrationale combination without any scientific evidence.Aminexil is not approved drug in india.
998	4260	Chlorpheniramine Maleate IP+Paracetamol IP+Phenyephrine hydrochloride IP	2mg+250mg+5 mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
999	4266	Enalapril maleate IP+Hydrochlorthiazide IP	10mg+25mg	Uncoated Tablets	c
1000	4268	Camylofin dihydrochloride+Paracetamol IP	12.5mg+125mg	Syrup	d
1001	4272	Diethyl carbamzine citrate IP+Chlorpheniramine maleate IP	100mg+200mg	Tablets	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
1002	4285	Calcium gluconogalactogluconate+calcium lactobionate UAP+cholecalciferol IP	1.18gm+0.26gm +100 IU	Syrup	c
1003	4297	Ambroxol hydrochloride IP+Guaifenesin IP+Terbutaline IP	30mg+100mg+ 2.5mg	Uncoated Tablets	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
1004	4298	Dried alumminium hydroxide gel IP(Added as paste)+Magnesium hydroxide IP(Added as paste)+Simethicone emulsion USP eqvt to simethicone+Oxetacaine BP	300mg+150mg +125mg+10mg	Suspension	c
1005	4318	Phenylephrine HCL IP+ Bromhexine HCL IP	5mg+4mg	Suspension	a There is no scientific rationality of FDC.Phenylephrine is decongestant where as bromhexine is mucolytic , these effect are contradictory to each other.
1006	4321	Phenylephrine hydrochloride+ Bromhexine Hydrochloride	10mg+8mg	Uncoated Tablets	a There is no scientific rationality of FDC.Phenylephrine is decongestant where as bromhexine is mucolytic , these effect are contradictory to each other.
1007	4325	Doxylamine Succinate USP+Pyridoxine Hcl IP+Folic AcidIP	10mg/20mg+10 mg/20mg+2.5m g/5mg	Enteric Coated Tablets	c
1008	4330	Chlorpheniramine maleate IP+Paracetamol IP+Phenylepherine Hydrochloride IP	2mg+250mg+5 mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
1009	4331	Cyproheptadine Hydrochloride IP+Tricholine Citrate+Sorbitol IP	2mg+275mg+3. 575gm	Syrup	c
1010	4334	Terbutaline Sulphate IP+Guaiphensin IP+Bromhexine Hydrochloride IP+Menthol IP	125mg+50mg+ 2mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.

1011	4337	Terbutaline Sulphate IP+Bromhexie Hydrochloride IP+Guaifensin IP+Menthol IP	1.25mg+2mg+50mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
1012	4343	Aceclofenac IP+Paracetamol IP	50mg+125mg	Suspension	a Acaclofenac is not recommended paediatric population . Dosage of paracetamol and Aceclofenac are subtherapeutic for adult population. Hence FDC is irrationale
1013	4347	Terbutaline Sulphate IP+Bromhexine HCl IP	1.5mg+4mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
1014	4349	Propyphenazone IP+Paracetamol IP+Caffeine Tablets	150mg+250mg +50mg	Uncoated Tablets	a
1015	4350	Camylofine Dihydrochloride+Diclofenac Potassium Each Film Coated Tablets Contains Camylofin Dihydrochloride ..... 50 mg Colour: Tartrazine, Brilliant Blue & Black Iron Oxide IP	50mg + 50 mg	Film Coated Tablets	d
1016	4351	Camylofine Dihydrochloride+Diclofenac Sodium+Benzyl Alcohol IP	25mg+25mg+2.0%w/v	Injection	d
1017	4352	Methocarbamol USP+Diclofenac Potassium+Paracetamol Tablet	500mg+50mg+325mg	Film Coated Tablets	a Individual drug is available separately. Mismatch in duration of treatment
1018	4355	Diethyl Carbamazine Citrate IP+Chlorpheniramine Maleate IP	50mg+1mg	Syrup	a There is no scientific rationality of FDC.Diethyl carbamazine citrate is prescribed for long term and Chlorpheniramine Maleate/Cetrizine is prescribed for allergic reactions during initial period only .The dose titration of ingredients is not practical in this FDC.
1019	4356	Diastase IP(1:1200) 50 mg(Fungal Diastase Derived from Aspergillus Oryzae+Pepsin IP (1:300)	50mg+10mg	Syrup	c
1020	4362	Hydroquinone USP+Octyl Methoxycinnamate+Oxybenzone USP	2.0% w/w + 5.0% w/w + 30.% w/w	Cream	a Irrationale combination .Mismatch between hydroquinone (once a day) and others ingredients(3-4 times during day time).
1021	4368	Paracetamol IP+Phenylephrine Hcl IP+Chlorpheniramine Maleate IP	125mg+5mg+1mg	Syrup	d Similar FDC is already discussed by 10 expert Committee
1022	4369	Minoxidil IP+Aminexil+Alcohol alcohol	2.0% w/v + 1.50% w/v + 63% v/v	Topical Solution	a Irrationale combination without any scientific evidence.Aminexil is not approved drug in India.
1023	4370	Calamine IP+Aloe Vera Gel+Light Liquid Paraffin IP	8.0%w/w+ 10.0%w/w+10.0 %w/w	Topical Lotion	c
1024	4371	Calcium Dobesilate Monohydrate BP eq. to Anhydrous Calcium Dobesilate+Lignocaine HCl IP eq. to Anhydrous Lignocaine+Hydrocortisone Acetate IP+Zinc (as Zinc Oxide IP)	0.25% w/w + 3% w/w + 0.25% w/w + 5% w/w	Topical cream	c
1025	4372	Albendazole IP+Ivermectin BP	400mg+12mg	Uncoated Dispersible Tablets	c When the body weight is 65-84 kg.
1026	4374	Calamine IP+Aloe Vera Gel+Light Liquid Paraffin IP	8.0%w/w+ 10.0%w/w+10.0 %w/w	Topical Lotion	c
1027	4379	Cyproheptadine HCl IP+Tricholine Citrate	1.5mg+55mg	Liquid	c
1028	4380	Aluminium Hydroxide Paste eq. to Dried Aluminium Hydroxide Gel IP+Magnesium Hydroxide IP eq. to Magnesium Hydroxide IP+Simethicone IP	225mg+200mg +50mg	Liquid Oral Suspension	c
1029	4381	Clindamycin Phosphate BP eq. to Clindamycin+Nicotinamide IP	1.0% w/w + 4.0% w/w	Gel	c

1030	4382	Evening Primerose Oil Bp+Cod liver Oil BP	500mg+300mg	Soft gelatin Capsules	a, There is no adequate scientific data to justify the rationality of this FDC.Though individual drugs may be efficacious seperately in a few conditions However there is no rational for combining them in FDC form.
1031	4391	Refined Sunflower oil BP+Sodium Pyrrolidone Carboxylic Acid Solution eq. to Sodium Parrolidone Carboxylic Acid+Sodium Lactate Solution USP eq. to Sodium Lactate+Sodium Chloride IP+Preservatives Sodium Methylparaben IP+Sodium Propylparaben IP	10% w/w + 2.5% w/w + 2.0% w/w + 0.5% w/w + 010% w/w + 0.08% w/w	Cream	a Irrationale combination. Several ingredients without any therapeutic justification
1032	4401	Cardamom IP+Caraway IP+Cinnamon IP+Chamomile IPC+Sorbitol 70% Solution IP+Alcohol IP	0.0031gm+0.0031gm+0.0063gm+0.058gm+0.8gm+8.3% v/v	Liquid (syrup)	a The high alcohol content in this formulation is not justified and can be misused.
1033	4412	Camylofine Dihydrochloride+Paracetamol IP	50mg+325mg	Film Coated Tablets	d
1034	4415	Ambroxol HCl IP+Guaifenesin IP+Terbutaline Sulphate IP	30mg+100mg+1.25mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
1035	4421	Phenylephrine Hcl ip+Paracetamol IP+Chlorpheniramine Maleate IP	2.5mg+125mg+2mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
1036	4427	Rabeprazole Sodium IP+Domperidone IP	20mg+10mg	Enteric coated tablets	c
1037	4430	Dried Aluminium hydroxide Gel IP+Magnesium Trisilicate IP+Simethicone IP	250mg+25mg+25mg	Oral Liquid	c
1038	4434	Tricholine citrate +Sorbitol solution (70%)IP (Non-crystallising)	550mg+7.15g	Syrup	c
1039	4442	Tricholine Citrate IP+Sorbitol Solution 70% IP	550mg+7.15gm	Syrup	c
1040	4449	Doxylamine Succinate USP+Pyridoxine Hcl IP	10mg+10mg	Enteric Coated Tablets	c
1041	4451	TerbutalineSulphate IP+Cholinetheophylline BP+Ambroxol Hcl IP	1.25mg+50mg+15mg	Syrup	c
1042	4452	Ketoconazole+Shale Oil sulfonate (Ichtyol Pale)+D-Panthenol BP+Aloevera	2.00% w/v + 0.2% w/v + 1.0% w/v	Shampoo	a Irrationale combination without any scientific evidence.
1043	4454	Terbutaline Sulphate+Ambroxol Hcl IP+Guaiphenesin+Menthol	1.25mg+20mg+50mg+0.5mg	Syrup	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
1044	4458	Cyproheptadine Hydrochloride IP+Tricholine Citrate IP	2.0mg+275mg	Syrup	c
1045	4459	Ambroxol Hcl IP+Salbutamol Sulphate IP eq. to Salbutamol+Guaifenesin IP	15mg+2mg+100mg	Uncoated Tablets	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
1046	4460	Cefpodoxime Proxetil USP eq .to cefpodoxime+Dicloxacillin Sodium BP eq. to Dicloxacillin+Lactic Acid Bacillus	200mg+500mg+90 Million Spores	Film Coated Tablets	a, Committee opined that : (a) Since, 2006 the scenario of antimicrobial resistance pattern has changed significantly, majority of isolates of Staph. aureus have become resistance to the amoxicillin &cloxacillin including dicloxacillin (b) Better efficacious antibiotic andare now available and used for staph. aureus infections. In light of these, the rationality of combination in current scenario is questionable

1047	4461	Methocarbamol USP+Diclofenac Sodium IP+Benzyl Alcohol IP (As Preservative)	300mg+50mg	Injection	a Individual drug is available separately. Mismatch in duration of treatment
1048	4463	Terbutaline Sulhate IP+Bromhexine Hcl IP+Guaiphenesin IP+Menthol IP	1.25mg+2mg+5 0mg+2mg	Liquid Orals	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
1049	4483	Simethicone IP+Dill Oil BP+Fennel Oil USP	40mg+0.005 ml+.0007 ml	Liquid Orals	d
1050	4490	Zinc Sulphate IP+Boric Acid IP+Naphazoline Hcl BP+Sodium Chloride IP+Phenyl ethyl alcohol USP	0.1% w/v + 1.8% w/v + 0.2% w/v + 0.85% w/v + 0.5% w/v	Eye Drops	a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational
1051	4507	Dill Oil BP+Fennel Oil USP-NF+Simethicone Emulsion USP (30%) eq. to Simethicone USP	0.025ml+0.0035 ml+40mg	Oral Drops	d
1052	4508	Calcium Carbonate IP+Magnesium Hydroxide IP+Magnesium Trisilicate IP+Simethicone Emulsion USP (30%)	400mg+120mg +50mg+83mg	Oral Liquid	a, There is no adequate scientific data to justify the rationality of this FDC.Though individual drugs may be efficacious seperately in a few conditions . However there is no rational for combining them in FDC form. Unnecessary over use of magnesium and others minerals in long term may lead to serious cardiovascular and renal complications.
1053	4528	Zeaxanthin+Lutein+Omega 3 fatty acid providing+Ecosapentaenoic acid+Docosapentaenoic acid	1mg+5mg500m g+325mg+175 mg	Soft Gelatin Capsules	c
1054	4548	Glucosamine sulphate 2KCL USP+Chondroitin Sulphate	750mg++600m g	Film Coated Tablets	a, There is no scietnific evidence favoring this combination
1055	4566	Lactic acid bacillus+Folic Acid IP+Vitamin B12 (Gelatinised) eq. to elemental Vitamin B12 IP	120 Milion+1.5mg+ 15mcg	Dispersible Tablets	c
1056	4568	Lactic acid bacillus+Folic Acid IP+Vitamin B12 (Gelatinised) eq. to elemental Vitamin B12 IP	120 Million spores+1.5mg+ 15mcg	Capsules	c
1057	4594	Paracetamol IP+PhenylephrineHcl IP+Chlorpheniramine Maleate IP	125mg+2.5mg+ 1mg	Suspension	d Similar FDC is already discussed by 10 expert Committee
1058	4601	Ambroxol Hc IP+Terbutaline Sulphate IP+Guaifenesin IP	15mg+1.5mg+5 0mg	Oral Liquid Preparation	c For symptomatic relief of bronchospasm in bronchial asthma and chronic bronchitis.
1059	4631	Amylase+Protease+Glucoamylase+Pectinase+Alpha Galactosidase+Lactase+Beta-Gluconase+Cellulase+Lipase CR+Bromelain+Xylanase+Hemicellulase+Malt diastase+Invertase+Papain IP	20000 DU+50000 HUT+45 AGU+50 endo-PGU+225 GalU+1000 ALU+30 BGU+1000 CU+1000 FIP+125000 FCCPU+600 XU+400 HCU+200 DPO+203 SU+16000 FCCPU	Hard gelatin capsules	a There is no scientific rationale for this combination for combining hetero group of ingredients.
1060	4634	Levocloperastine Fendizoate eq. to Levocloperastine HCl+Chlorpheniramine maleate IP	35.4mg eq. to 20mg+4mg	Suspension	c
1061	4636	Glimepiride IP+Voglibose	1mg/2mg+0.2m g/0.3mg	Uncoated Tablets	c
1062	4637	Glimepiride IP+Voglibose	1mg/2mg+0.2m g/0.3mg	Uncoated Tablets	c
1063	4678	Folic Acid IP+Pottasium Iodine IP Eq. to Elemental Iodine	5mg+200mcg	Tablets	a, There is no scietific rationale of this FDC.

1064	4685	Metadoxine+Silymarin (70%)+L-Ornithine L-Aspartaten+Pyridoxine HCl +Folic Acid ip	500mg+140mg +150mg+3mg+ 1.5mg	Soft Gelatin Capsules	a There is no scientific rationale for this FDC.
1065	4697	Metadoxine+Silymarin (70%)+L-Ornithine L-Aspartaten+Pyridoxine HCl +Folic Acid IP	250mg+70mg+ 75mg+3mg+1m g	Film Coated Tablets	a There is no scientific rationale for this FDC.
1066	4704	Doxylamine Succinate + Pyridoxine Hydrichloride (vit B6)+ folic acid	20mg/10mg+ 20mg/10mg + 5mg/2.5 mg	Tablet	c
1067	4715	silymarin+ Thiamine Mononitrate+ Riboflavin+ Pyridoxine HCL+ Niacinamide + calcium pantothenate+ Vitamin B12+ exipient	70 mg+ 5 mg+ 5 mg+ 1.5 mg+ 25 mg+ 7.5 mg+ 5 mcg+q.s	Capsules	a There is no therapeutic justification for this FDC.
1068	4724	Ginkgo biloba + methylcobalamin	40 mg+ 750 mcg	capsule	a There is no role of Methycobalamin in the proposed FDC for the treatment of cerebral insufficiency, vertigo, tinnitus, hearing loss.
1069	4742	Metadoxine+Silymarin (70%)+L-Ornithine L-Aspartate+Folic Acid IP+Pyridoxine HCl	250mg/500mg+ 70mg/140mg+7 5mg/150mg+1m g/2mg+3mg/6m g	Tablets	a There is no scientific rationale for this FDC.
1070	4744	Benfotiamine+Silymarin+Ornithine L-Asparate+Selenite+Folic Acid+Pyridoxine HCl	25mg+140mg+ 150mg+50mcg+ 1mg+3mg	Tablets	a There is no definite evidence of efficacy of this drug combination as hepatoprotective drug
1071	4745	Antimony Potassium Tartrate USP+Dried Ferrous Sulphate IP	2.0g+1.26g	ORAL Solid dosage form	a, There is no adequate scientific data to justify the rationality of this FDC.
1072	4781	Aloe IP+Vitamin E Acetate IP	4% + 0.50% w/w	Soap	a The dosage form is irrationale.
1073	4782	Folic Acid+Doxylamine+Pyridoxine HCl	2.5mg+10mg+1 0mg	Tablets	c
1074	4790	Calamine IP+Diphenhydramine HCL IP+Aloe Vera Juice+Glycerine IP+Camphor BP	8% w/v + 1% w/v + 5% w/v + 6.25% w/v + 0.1% w/v	Lotion	a Irrationale combination.
1075	4803	Glucosamine Sulphate Potassium Chloride USP+Methyl Sulphonyl methane USP+Calcium carbonate IP+Vitamin E IP+Manganese	750mg+250mg +250mg+25mg +4.5mg+20mg	Tablets	a There is no scientific rationale.
1076	4804	Saccharomyces boulardi+Yeast+Lactic Acid Bacillus+Zinc Lactate eq. to elemental Zinc	2.5 billion+125mg+ 150 million spores+7.5mg	Oral Powder	c
1077	4806	Lactobacillus Acidophilus+Lactobacillus Rhamnosus+Bifidobacterium longum+ & Bifidobacterium Infantis+Saccharomyces Boulardii+Zinc Sulphate Monohydrate IP eq. to elemental Zinc+Fructo Oligo Saccharides	550 million+400milli on+100million+ 100million+50m illion+10mg+10 0mg	Oral Powder	c
1078	4807	Adenosine triphosphate diphosphate JPC+Magnesium Orotate	50mg+250mg	Hard Gelatin Capsules	a, There is no adequate scientific data to justify the rationality of this FDC.
1079	4835	Calcitrol+Calcium Citrate+Magnesium oxide+Zinc Sulphate	0.25mcg/0.25m cg+500mg/500 mg+40mg/50mg +20mg/7.5mg	Capsules	c
1080	4861	Glucosamine Sulphate Potassium+Methyl Sulphate Sodium+Sulphonyl Methane+Chondroitin Sulphate Sodium+Calcium Carbonate+Vitamin D3+Sodium Borate+Cupric Oxide+Colloidal Silicon Dioxide+Manganese Chloride	750mg+200mg +200mg+200m g+200mg+150 mcg+0.7mg+2m g+2.5mg	Tablets	a There is no scientific rationale.

1081	4863	Glucosamine Sulpahte+Chondroitin Sulphate+Methyl Sulfonyl Methane+Vitamin D3+Vitamin E+Vitamin C+Selenium+Elemental Zinc+Elemental Manganese+Elemental Chromium+Elemental Copper+Elemental Boron	750mg+100mg +250mg+200IU +12.5mg+30mg +70mcg+4mg+3 mg+50mcg+0.5 mg+0.5mg	Tablets	a There is no scientific rationale
1082	4865	Trypsin + Chymotrypsin in the ratio of approximately 6:1	1,00,000 AU	Tablets	c
1083	4870	Trypsin : Chymotrypsin	1L AU+2L AU	Tablets	c
1084	4882	cyproheptadine HCL+ thiamine HCL+ Riboflavine + pyridoxine HCL+ Niacinamide	2mg+1mg+ 1mg+ 0.5 mg+ 10 mg	syrup	a there is no scientific rationale for combining vitamins with cyproheptadine
1085	4883	Diacerein + Glucosamine sulphate potassium chloride + methyl sulfonyl methane	50 mg+ 750 mg + 250 mg	tablets	c Already approved by DCGI
1086	4884	glucosamine sulphate + methyl sufonyl methane + manganese sulphate + Vit E acetate+ calcium Carbonate	500 mg+ 200 mg+ 10 mg+ 16 mg+ 200mg	tablets	a There is no scientific rationale.
1087	4972	100000 armour units of enzymatic activity supplied by a purified cocentrate which has specific trypsin + chymotrypsin activity in ratio of approx 6:1	100000Armour unit	film coated tablet	d
1088	4979	metadoxine + silymarin+ L- ornithineL-asartate + folic acid+ pyridoxine HCL	250 mg/500mg+ 70 mg/140 mg+ 75 mg/ 150 mg+ 1 mg/2 mg+ 3 mg/6 mg	film coated tablet	a There is no scientific rationale for this FDC.
1089	5013	Doxylamine Succinate USP+Pyridoxine HCl IP+Folic Acid IP	10mg+10mg+2. 5mg	Oral Tablets	c
1090	5024	Sodium Acid Phosphate+Cyanocobalamin	200mg/ml+500 mcg	injection	c
1091	5033	L- arginine+ magnesium citrate	1.5 mg+ 200 mg	granules	c
1092	5043	Fungal Diastase + Lactic acid bacillus	20mg+150X10(6)	capsule	c
1093	5053	Doxylamine Succinate USP+Pyridoxine HCl IP	10mg+10mg	Tablets	c
1094	5079	Epigallocatechin Gallate +Chromium Polynicotinate	100mg+200mcg	Hard Gelatin Capsules	a There is no scientific justification for this FDC.
1095	5100	Alpha Galactosidase+Lipase Enzyme+Alpha Amylase+Protease Enzyme+Lactase USP	150mg+3mg+5 0mg+25mg+7m g	Hard Gelatin Capsules	d
1096	5160	calcium maleate + vitamin D3 + magnesium hydroxide	1200 mg+ 200 IU + 25 mg	uncoated chewable tablet	c
1097	5165	benfotiamine + silymarin+ L-ornithine L-aspartate+ sodium selenite + folic acid+ pyridoxine hydrochloride	25 mg+ 140 mg+ 150 mg+ 50 mcg+ 1 mg+ 3 mg	film coated tablet	a There is no definite evidence of efficacy of this drug combination as hepatoprotective drug
1098	5186	Diacerin+Glucosamine Sulphate Potassium Chloride+Methyl Sulfonyl Methane	50mg+750mg+ 250mg	Film Coated Tablets	a There is no scientific evidence of this FDC. The dose of Glucosamine is subtherapeutic.
1099	5193	Metadoxine+Silymarine+L-ornithine L-Aspartate+Pyridoxine HCl IP+Folic Acid IP	500mg+140mg +50mg+3mg+1. 5mg	Tablets	a There is no scientific rationale for this FDC.
1100	5195	Procaine Penicillin+Penicillin G Sodium IP+Stetomycin Sulphate IP	3,000,000 units + 10,00,000 units + 5gm	Dry Powder Injection	a, There is no adequate scientific data to justify the rationality of this FDC. Though individual drugs may be efficacious seperately in a few conditions . However there is no rational for combining them in FDC form.

1101	5240	Diastase IP (Fungal Diastase derived from aspergillus oryzae digests not less than 60gms of coocked strach) + Papine IP	33.33mg/75mg+ 10mg/620mg	Syrup	c
1102	5252	Lactobacillus Acidphilus+Lactobacillus Plantarum+Lactobacillus casei+Lactobacillus rhamnosus+Bifidobacterium breve+Bifidobacterium longum+Bifidobacterium infantis+Streptococcus thermophilus+Saccharomyces Boulardii+Fructooligosaccarides+Elemental Zinc	0.35 billion cfu+0.30 billion cfu+0.30 billion cfu+0.30 billion cfu+0.30 billion cfu+0.3 billion cfu+0.3 billion cfu+0.3 billion cfu+0.05 billion cfu+2.5 billion+100mg+ 10mg	Powder sachet	c
1103	5253	Lactobacillus reuteri UBLRu-87+Lactobacillus rhamnosus UBLR-58+Bifidobacterium longum UBBL-64+Bifidobacterium bifidum UBBB-55+Bifidobacterium infantis UBBI-01+Bacillus coagulans Unique IS2+Saccharomyces boulardii Unique 28+Streptococcus thermophilus UBST-50+Fructooligosaccarides+Elemental Zinc+Lactitol	0.10 billion cfu+0.20 billion cfu+0.06 billion cfu+0.10 billion cfu+0.10 billion cfu+0.20 billion cfu+0.14 billion cfu+0.10 billion cfu+20mg+10mg	Powder sachet	c
1104	5259	Polyethylene Glycol Ip+Sodium Chloride IP+Potassium Chloride+Sodium Bicarbonate IP+Anhydrous Sodium Sulphate BP	118.0gm+2.93gm+1.484gm+3.370gm+11.360gm	Electrolytes for Oral Solution	c, Only for bowel preparation before colonoscopy
1105	5305	lactobacillus acidophilus+ lactobacillus rhamnosus+ bifidobacterium bifidum+bifidobacterium longum+ saccharomyces boulardii+ streptococcus thermophilus+ fructooligosaccarides + inulin + zinc sulphate + fungul amylase	.50 billion CFU+ .50 billion CFU+ .50 billion CFU + .50 billion CFU + .25 billion CFU + .25 billion CFU+100mg+ 100mg+ 10 mg+ 50 mg	diaflora sachet	c
1106	5326	Glucosamine sulfate potassium chloride+MSM+sodium borate+copper sulphate pentahydrate+manganese sulphate+vitamin D3	750mg+200mg +0.5mg+0.5mg +3mg+200IU	Tablet	a There is no scientific rationale.
1107	5335	Sodium Sulphate BP+Potassium Sulphate BP+Magnesium Sulphate IP	17.50gm+3.13gm+1.60gm	Capsules	c
1108	5340	Fungal diastase + Pepsin + Sorbitol IP	12.5mg+7.5mg +250mg	Syrup	c
1109	5345	DL alpha tocopheryl acetate + sodium selenite	50 mg+ 1.5 mg/ml	injection	c
1110	5351	Diastase+Cardamom oil+Caraway oil+Cinnamon oil	40mg+500mg+ 500µg+250µg	Oral Liquid	d
1111	5355	Sodium Acid Phosphate+Methylcobalamin	400mg+1000mcg	Injection	c

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1112	5372	Sodium Chloride+Potassium Chloride+Calcium Chloride+Magnesium Chloride+Sodium Citrate+Sodium Acetate	0.640%w/v+0.075%w/v+0.048%w/v+0.030%w/v+0.170%w/v+0.390%w/v	Salt solution	c
1113	5389	Trypsin-Chymotrypsinin the ratio of approximately 6:1	1,00,000 AU	Enteric Coated Tablets	c
1114	5404	Gamma Linolenic Acid +Methylcobalamin JP	120mg+500mcg	Soft Gelatin Capsules	a, There is no adequate scientific data to justify the rationality of this FDC.Though individual drugs may be efficacious seperately in a few conditions . However there is no rational for combining them in FDC form
1115	5405	Glucosamine sulphate potassium chloride+Cetyl Myristoleate 20%	750mg+102.5mg	Film Coated Tablets	subjudice
1116	5414	Trypsin-Chymotrypsin	2,00,000 Armour units	Oral Solid Tablets	c
1117	5425	Glucosamine sulphate potassium chloride+Calcium Carbonate IP+Methyl Sulphonyl Methane+Vitamin D3 IP	750mg+250mg+200mg+125 IU	Film Coated Tablets	a There is no scientific rationale.
1118	5431	Glucosamine Sulphate IP+Vitamin E Acetate BP+Calcium Pantothenate IP+Vitamin D3 IP	500mg+8mg+50mg+400 IU	Film Coated Tablets	a There is no scientific rationale.
1119	5440	Potassium Citrate Monohydrate+Magnesium Citrate USP+Vitamin B6 IP	1100mg+375mg+20mg	Oral Liquid	a, There is no scietific rationale of this FDC.
1120	5480	Potassium Citrate IP+Magnesium Citrate USP+Pyridoxine HCL IP	1100mg+375mg+20mg	Liquid	a, There is no scietific rationale of this FDC.
1121	5486	Diastase IP+Pepsin IP+Compound Cardamom Tincture BP+Strong Ginger Tincture BP	50mg+12.5mg+0.375ml+0.0125 ml	Syrup	d
1122	5491	Fungal Diastase IP+cinnamon oil + Cardamom oil + carraway oil	40 mg +250 mcg 500 mcg +500 mcg	Liquid Oral	d
1123	5508	Diastase IP+Papain IP+Activated Charcoal IP	100mg+60mg+75mg	Film Coated Tablets	d
1124	5514	Doxycycline HCl IP+Omidazole IP+ Bromelain +Lactobacillus Rhamnosus GR-1+ Lactobacillus Reuteri RC-14	100mg+500mg+80mg+500 million CFU + 500 million CFU	Film Coated Tablets +Hard Gelatin Capsules	a There is no scientific rational for the combination. There is no published study in support of this combination.
1125	5526	Ginkgo Biloba Extract USP+Alpha Lipoic Acid IP+Methylcobalamin JP+Pyridoxine HCl IP	60mg+100mg+0.75mg+1.5mg	Hard Gelatin Capsules	a There is no role of Methycobalamin, ALA and Pyridoxine in the proposed FDC for the indications suggested by the firm
1126	5540	Trypsin & Chymotrypsin	1,00,000 Armour units / 2,00,000 Armour Units	Enteric Coated Tablets	c
1127	5584	Ketoconazole+Aloe Vera+Vitamin A Acetate	2%w/w+10%w/w+0.05%w/w	Drops	a Irrationale combination without any scientific evidence
1128	5614	Calcium Gluconate+Calcium Lactobionate	50mg+87.5mg/9mg	Injection	c
1129	5640	Pepsin IP+Papain IP+Fungal Diastase (1:800) IP+Lipase (Fungal) + Cellulase	25mg+50mg+50mg+12.5mg+1.5mg	Oral capsules	c
1130	5641	Fungal Diastase (1:2000) IP+Cinnamon Oil BP+Caraway Oil BP+Cardamon Oil BP	40mg+250mcg+500mcg+500mcg	Oral Liquid	d
1131	5646	Pancreatin (Lipase USP+Protase USP+Amylase USP)	25000 units+62500units+74700units	Capsules	c Indicated for pancreatic insufficiency only
1132	5665	L-Arginine IP+Acetylcysteine BP+Calcium Carbonate IP+Lactobacillus Acidophilus NLT	200mg+100mg+2.5mg+2 billion cfu	Capsules	a There is no scientific rationale for this FDC

1133	5674	Glucosamine Sulphate Potassium Chloride IP+625mg of Calcium Carbonate from an organic source (oyester shell) eq. to elemental Calcium+Vitamin D3 IP	750mg+250mg +125 IU	Film Coated tablets	a There is no scientific rationale.
1134	5687	Diastase IP (Fungal 1:800, Derived From Aspergillus Oryzae)+Papain IP+Cinamon Oil BP+Caraway Oil BP+Cardamom Oil BP	50mg+50mg+0.2mg+0.4mg+0.4mg	Oral Liquid	d
1135	5692	Trypsin & Chymotrypsin	100,000 AU	Enteric Coated Tablets	c
1136	5694	Ginseng Extract+Dried Extract Of Ginkgo Biloba	50mg+ 60 mg	Hard gelatin capsules	a Inadequate scientific data for this FDC.
1137	5696	L-Glutamine USP+Astaxanthin+Vitamin C IP+Zinc Sulphate IP eq. to Elemental Zinc+Copper Sulphate IP eq. to elemental Copper+Selenium Selenomethionine eq. to elemental Selenium+Carbohydrate	10gm+4mg+250mg+10mg+1mg+100mcg+3.9gm	Powder	c
1138	5707	Dried ferrous Sulphate IP eq. to Ferrous Iron+Folic Acid IP	100mg eq. to 30mg+0.5mg	Enteric Coated Tablets	c
1139	5741	Diastase+Pepsin+Compond cardamom+Strong ginger	50mg+12.5mg+0.0375ml+0.0125ml	Syrup	d
1140	5747	Cetyl Myristoleate+Glucosamine Sulpahte Potassium+Metyl Solfonyl methane	102.5mg+500mg+200mg	Tablets	a There is no scientific evidence of this FDC. The dose of Glucosamine is subtherapeutic.
1141	5771	Trypsin & Chymotrypsin	1,00,000 AU	Tablets	c
1142	5775	Doxylamine Succinate+Pyridoxine HCl+Folic Acid	20mg/10mg+20mg/10mg+5mg/2.5mg	Enteric Coated tablet	c
1143	5822	Pancreatin IP+Ox bile Extract+Ginger Oleoresin+Activated Charcoal IP	170mg+50mg+2mg+50mg	Enteric-sugar coated tablet	c Indicated for pancreatic insufficiency only
1144	5850	Potassium Citrate IP+Magnesium Citrate USP	100mg+375mg	Solution	c
1145	5870	Saccharomyces boulardii+Lactic Acid Bacillus+Folic Acid IP+Vitamin B12 IP	250 million spores+60 million spores+1.5mg+15mcg	Dispersible tablets	c
1146	5871	Lactobacillus Acidophilus+Lactobacillus Rhamnosus+Lactobacillus Paracasei+Lactobacillus Sporogenes+Bifidobacterium Longum+Sacchromyces Boulardii+Fructo OligosachharidesBoulardii+Fructoboulardii+Bifidobacterium Bifidus+Bifidobacterium longum+Inulin+Fructo Oligosaccharise	300 million cells+300 million cells+300 million cells+1000 million cells+300 million cellss+300 million cells+100mg+200mg	Oral Capsule	c
1147	5872	Saccharomyces boulardii+Lactic Acid Bacillus+Folic Acid IP+Vitamin B12 IP	250 million cells+120 million Spores+1.5mg+15mcg	oral Capsules	c
1148	5877	Diastase (1:1200) IP (Fungal Diastase derived from aspergillus oryzae digests not less than 60gms of coocked strach) + Pepsin (1:3000) IP(Digest not less than 30gm of coagulated egg albumin)	50mg+10mg	Tablet	c
1149	5885	Glucosamine Sulphate Potassium Chloride USP+Cetyl Myristoleate 20% +Methylsulfonylmethane USP	500mg+102.5mg+200mg	Tablets	a There is no scientific rationale.

1150	5893	Diastase (1:2000) IP(derived from aspergillus oryzae)+Cardamom Oil BP+Cinnmom Oil BP+Caraway Oil BP	40mg+500mcg+250mcg+500mcg	Syrup	d
1151	5897	Dried Ferrous Sulphate IP eq. to elemental ferrous Iron+Folic Acid IP	45mg+400mcg	Enteric Coated tablets	c
1152	5910	Tricholine Citrate+Sorbitol (70%) Solution in a potable base	275mg+3.575gm	Oral Liquid	c
1153	5913	Fungal Diastase (1:1200) IP (derived from aspergillus Oryzae)+Cinnamon Oil BP+Caraway Oil BP+Cardamom Oil BP	50mg+125mcg+250mcg+250mcg	Oral Liquid	d
1154	5923	Tricholine Citrate+Sorbitol Solution (70%) (Non-Crystallsing) IP	550mg+7.150gm	Oral Liquid	c
1155	5934	Lactobacillus Sporogenes+Diastase (1:8000) IP+Papain IP+Simethicone IP+Vitamin B12 IP+L-Lysine Monohydrochloride USP+Vitamin B6 IP+Niacinamide IP+Folic Acid IP	$40*10^6$+25mg+20mg+40mg+1mcg+5mg+0.5mg+15mg+75mcg	Suspension	c
1156	5951	Tricholine Citrate+Andrographis IP 66 eq. to Andrographolides+Sorbitol Solution 70% (Non Crystalizing)	250mg+250mcg	Oral Liquid	c
1157	5952	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	d
1158	5957	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	Oral Liquid	d
1159	5959	Bismuth Amonium Citrate BP+Papain IP	50mg+10mg	Oral Liquid	a there is no scientific rationale for this FDC.
1160	5967	Duoazyme (Fungal Diastase IP (1:2000)+Cinnamon Oil BP+Caraway Oil BP+Cardamom Oil BP)	40mg+250mcg+500mcg+500mcg	Solution	d
1161	5968	Fungal Diastase IP (1:2000) IP+Cinnamon Oil BP+Caraway Oil BP+Cadamom Oil BP	40mg+250µg+500µg+500µg	Oral Liquid	d
1162	5970	Fungal Diastase (1:800) IP+Dill Oil BP+Caraway Oil BP+Anise Oil BP	20mg+2mg+2mg+2mg	Oral Liquid	d
1163	5972	Diagest (Fungal Diastase (1:800) IP+Papain IP+Caradamom Oil BP+Caraway Oil BP+Cinnamon Oil BP+Anise Oil BP+Dill Oil BP+Ajowan Oil IP)	40mg+60mg+0.5mg+0.5mg+0.5mg+7.5mg+7.5mg+10mg	Oral Liquid	d
1164	5974	Fungal Diastase (1:800) IP+Papain IP+Nux Vomica Tincture IP+Cardamom Tincture BP+Casein Hydrolysed+Alcohol IP	5mg+0.25mg+0.00125ml+0.0075ml+22.5mg+5%w/v	Oral Liquid	a There is no scientific justification for this FDC.
1165	5975	Fungal Diastase (1:800) IP+Papain IP+Nux Vomica Tincture IP+Cardamom Tincture BP+Casein Hydrolysed+Alcohol IP)	50mg+2.5mg+0.0125ml+0.075ml+225mg+5%v/v	Oral Liquid	a There is no scientific justification for this FDC.
1166	5979	Diastase (1:2000) IP+Cinnamon Oil BP+Caraway Oil BP+Cardamom Oil BP	40mg+250mcg+500mcg+500mcg	Oral Liquid	d
1167	5980	Diastase (1:2000) IP+Cinnamon Oil BP+Caraway Oil BP+Cardamom Oil BP	20mg+0.2mg+0.4mg+0.4mg	Drops	d
1168	5992	Pepsin (1:3000) IP+Papain IP+Sodium Citrate IP+Citric Acid IP+Cinnamon Oil BP	5mg+6mg+40mg+8mg+0.0024ml	Drops	d

1169	6005	Ashoka Liquid extract IP+Sodium Benzoate IP+Alcohol	72mg+0.2% + 20%v/v	Nil	it is not an FDC
1170	6012	Aluminium Hydroxide IP+Magnesium Hydroxide IP+Simethicone IP	250mg+250mg +50mg	SuspensionS	c
1171	6020	Proteolysed Liver+Peptone+Iron and Ammonium Citrate IP eq. to elemental Iron+Folic Acid Ip	200mg+200mg +53.40mg eq. to 11.48mg+0.17m g	Oral Liquid	c
1172	6026	Fungal Diastase IP (1:1800)+Caraway Oil BP+Cinnamon Oil BP+Cardamom Oil BP+Papain IP	20mg+400mcg2 00mcg+400mcg +40mg+10mg	Oral Liquid	d
1173	6034	Diastase IP(1:120)+Pepsin IP(1:3000)+Dill Oil BP+Caraway Oil BP+Anise Oil BP	50mg+10mg+1 mg+1mg+1mg	Syrup	d
1174	6039	Fungal Diastase (1:800) IP+Papain IP+Activated Charcoal IP	100mg+60mg+ 75mg	Sugar Coated Tablets	c
1175	6046	Euphorbia Prostrate extract+Lidocaine BP	10mg+30mg	Cream	a Irrationale combination without any scientific evidence
1176	6047	Euphorbia Prostrate extract+Calcium Dobesilate BP	100mg+500mg	Film Coated Tablets	c
1177	6048	Potassium Citrate IP+Magnesium Citrate USP	1100mg+375mg	Oral Solution	c
1178	6066	Taurine USP+Acetylcysteine USP	500mg+150mg	Oral Tablet	a. There is no adequate scientific data to justify the rationality of this FDC.Though individual drugs may be efficacious seperately in a few conditions. However there is no rational for combining them in FDC form.
1179	6082	Glucosamine Sulfate Sodium Chloride USP+Manganese (as Manganese Sulphate BP)+Boron (as Sodium Borate BP)+Zinc (as Zinc Sulfate Monohydrate USP)+Copper (as Coppre Sulphate BP)	750mcg+3mg+0 .5mg+3mg+0.5 mg	Film Coated Tablets	a There is no scientific rationale.
1180	6085	Pack in pack sachet contains (WHO ORS Pack 4.1g (Sodium Chloride IP+Sodium Citrate IP+Potassium Chloride IP+Dextrose Anhydrous IP), Pre & Probiotics pack 0.5g Contains (Streptococcus faecalis TO-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus (Lactobacillus sporogenes)	(0.52gm+0.58g m+0.3gm+2.7g m),(7.5 Million+0.5 Million+0.25 Million+20 Million)	Powder	c
1181	6086	HPMC capsules contains(L-Ornithine L-Aspartate),Inner HPMC capsules contains(Streptococcus faecalis T-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus(Lactobacillus sporogenes)	150mg, 30 Million+2 Million+1 Million+ 50 Million	Capsules	c
1182	6090	HPMC Capsules contains (Cefixime IP (as trihydrate) eq. to anhydrous Cefixime),Inner HPMC Capsules Contains (Streptococcus faecalis TO-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus (Lactobacillus sporogenes)	200mg,60 Million+4 Million+2 Million+100 Million		c

1183	6091	Pack in pack sachet :Outer sachet 1.25g contains (Cefpodoxime proxetil IP eq. to Cefpodoxime), Inner Pre & Probiotics Sachet 0.5g Contains (Streptococcus faecalis TO-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus (Lactobacillus sporogenes)	50mg, 30 Million+2 Million+1 Million+50 Million	Sachet in sachet	c
1184	6092	Outer sachet 1.0g contains(L-Glutamine JPC+Zinc Sulphate Monohydrate IP eq. to elemental Zinc,Inner Pre & Probiotics Sachet 0.5g contains(Streptococcus faecalis TO-110 JPC+Clostridium butyricum TO-A+Bacillus mesentericus TO-A JPC+Lactic Acid Bacillus (Lactobacillus sporogenes)	50mg+7mg , 30 Million+2 Million+1Million +50 Million	Powder	c
1185	6105	Taurine USP+N-Acetylcysteine USP	500mg+150mg	Film Coated Tablets	a, There is no adequate scientific data to justify the rationality of this FDC.Though individual drugs may be efficacious seperately in a few conditions . However there is no rational for combining them in FDC form.
1186	6136	Euphorbia Prostrata Extract (Containing 3.15 mg to 8.25mg total flavonoids calculated as Apigenin-7- glucoside and 12.6 to 44.0 mg total phenolics calculated as gallic acid)+Calcium Dobesilate Monohydrate BP	100mg+500mg	Film Coated Tablets	c
1187	6142	Sodium Citrate IP+Citric Acid Monohydrate IP syrup base Flavoured With Cardamom Oil, Cinnamon Oil, Ginger Oil	60mg+30mg	Oral Liquid-Syrup	d
1188	6147	Water soluble Azulene (Sodium Azulene Sulfonate) JPC+L-Glutamine JPC	2.01mg+663.030mg	Granules	d
1189	6150	Ipriflavone+Calcium carbonate 1.0gm from organic source (Oyester shell) eq. to elemental calcium+Cholecalciferol IP	300mg+400mg +200 IU	Film Coated Tablets	c
1190	6154	WHO ORS Pack (4.0 gm) Sodium Chloride IP+Sodium Citrate IP+Potassium Chloride IP+Dextrose Anhydrous IP & Pre Probiotics Pack (0.5gm) Streptococcus Faecalis T-110 JPC+Clostridium butyricum TO-A+Basilus mesentricus TO-A JPC+Lactic Acid bacillus	0.52gm+0.58gm +0.3gm+2.7gm & 7.5 Million+0.5 Million+0.25 Million+20 Million	Powder	c
1191	6165	L-Ornithine L-Aspartate & inner HPMC capsule (Streptococcus Faecalis T-110 JPC+Clostridium butyricum TO-A+Bacillus mesentricus TO-A JPC+Lactic Acid Bacillus)	150mg+30 Million+2 Million+1 Million+ 50 Million	capsules	c
1192	6177	Aspergillus Oryzae+Lactic Acid Bacillus	20mg+150 Million spores	Hard Gelatin Capsules	c
1193	6190	Chlorpheniramine Maleate IP+Ammonium Chloride IP+Sodium Citrate IP	4mg+120mg+50mg	Expectorant	a Pharmacodynamic incompatibility .Chlorpheniramine produce dryness of cough secretion while ammonium chloride stimulate secretion, which is antagonist effect
1194	6205	Doxylamine+Pyridoxine HCl+Folic Acid	10mg/20mg+100mg/200mg+2.5mg/5mg	Oral	c
1195	6221	Miconazole nitrate IP- 2% w/w+ Clobetasone Butyrate BP-0.05% w/w- cream		Cream	c

1196	6223	Part-A.Rifampicin IP-450mg+Isoniazid IP-300mg+Ethambutol HCl IP-800mg tablet, Part B Ethambutol HCL IP-1500mg-tablets			c if part B of the combikit contains pyrazinamid 1500 mg intead of etambutol as given in this combikit.
1197	6224	Miconazole nitrate IP- 2.00% w/w + Gentamicin Sulphate IP eq. to Gentamicin-0.2% w/w+Fluocinolone Acetonide IP-0.01% w/w+Zinc Sulphate IP-2.50% w/w-cream		Cream	a Irrationale combination without any scientific evidence.Ingredients are used separately for different clinical condition.
1198	6225	Capsaicin USP-0.025% w/w+Diclofenac Pottasium BP-1%w/w+Methylsalicylate IP-5%w/w+Menthol IP-5% w/w+Benzyl Alcohol IP-1% w/w (as a preservative)-gel			c
1199	6226	Ampicillin Trihydrate IP eq to Ampicillin-250 mg+Cloxacillin Sodium IP-250 mg eq to Cloxacillin+Saccharomyces boulardii-40 millions spores-hard gelatin capsule			c
1200	6227	Each 10 ml contains:Aminophylline IP-100mg+Ammonium chloride IP-100 mg+Sodium citrate IP-50 mg-liquid		oral	a There are safer alternative available.
1201	6228	each 5 ml contains: dried aluminium hydroxide Gel IP-400 mg (added as paste)+magnesium hydroxide IP-400 mg(added as paste)+ Simethicone IP- 50 mg-suspension			c
1202	6229	Lactobacillus Acidophilus1.5 billion-+Lactobacillus rhamnosus-1.5 billion+Bifidobacterium longum-1.25 billion+Bifidobacterium bifidum-1.5 billion+Saccharomyces boulardii-0.10 billion+Fructo Oligo Saccharides-100 mg-hard gelatin capsule			c
1203	6231	Lidocaine USP-07.50 mg+Prilocaine USP-02.50 mg-spray			c
1204	6232	Each ml contains:Fungal Diastase(1:1200)-20.000 mg+Cinammon Oil IP-0.200 mg+Caraway Oil -0.400 mg-syrup			d

1205	6235	Sucralfate USP-1 g+ Domperidone BP-7.5 mg-suspension			a The oral bioavailability of domperidone is less than 20 % . Sucralfate will further affect its bioavailability.There is no scientific justification for this FDC.
1206	6236	Gamma Benzene Hexachloride IP-1.0 g + Benzocaine IP-3.0 g +Oil base to 100 ml-Liquid (external preparation)		Liquid topical	a Irrationale combination without any scientific evidence.
1207	6237	Camylofin Dihydrochloride-50 mg+Diclofenac potassium IP-50 mg-film coated tablet			d
1208	6239	Salbutamol Sulphate BP eq. to Salbutamol-100 mcg+ Ipratropium Bromide BP-20 mcg Excipients:- Ethanol BP-1.0 % w/w-metered Dose Inhalations			c
1209	6240	Paracetamol IP-600 mg+Caffeine anhydrous IP-50 mg-tablets			c
1210	6241	Ofloxacin IP-0.3% w/v+Dexamethasone Sodium Phosphate IP-0.1% w/v+Hydroxy Propylmethyl cellulose IP-0.25%w/w+Benzalkonium Chloride Solution IP0.02%v/v-eye/ear drops			c
1211	6244	Calcium Citrate Malate equivalent to lemental calcium-500 mg + Cholecalciferol IP-400 IU-Granules			c
1212	6246	Sulphacetamide Sodium IP-15% w/v + Zinc Sulphate IP-0.1% w/v + Chlorpheniramine Maleate IP-0.01% w/v + Boric acid IP-1.9% w/v + Sodium Chloride IP-0.1% w/v + Chlorbutol IP- 0.5 % w/v-Eye Drop			a The Committee obesrved that available data does not support the rationality of this FDC. Hence, the Committee considered this FDC as irrational.

1213	6247	rabeprazole sodium IP-20 mg (as enteric coated tablet) + cinitrapride hydrgen tartrate eq. to Cinitapride (as sustained release tablet)-3 mg-hard gelatin capsule			c Re-examined and recommended for "the treatmen of patients suffering from gastroesophageal reflux disease (GERD)"
1214	6248	L-Methyl Calsium eq to L-Methyl folate-700 mcg+Methylcobalamin-750 mcg+Docosahexaaenoic acid-200 mg(derived from omega 3 fatty acids)-capsule			c
1215	6250	Sodium pico sulfate BP-10 mg+Heavy Magnesium Oxide IP-3.5 gm+Anhydrous Citric acid IP-12.0 gm-Oral powder			a, There is no adequate scientific data to justify the rationality of this FDC.Though individual drugs may be efficacious seperately in a few conditions . However there is no rational for combining them in FDC form.
1216	6252	Diclofenac Sodium IP-37.5 mg + Thiocolchicoside IP-2 mg+ (as preservative) Benzyl Alcohol IP- 4% w/v-injection			a There is no scientific rationale for this FDC.Dosage of ingredients are subtherapeutic.
1217	6254	L-Methyl folate Calsium eq to L-Methyl folate-700 mcg+Methylcobalamin-750 mcg+Docosahexaaencic acid-200 mg(derived from omega 3 fatty acids)-capsule			c
1218	6256	Paracetamol IP-250 mg+phenylepherine HCl IP-2.5 mg+chlorpheniramine maleate IP-2 mg-suspension			d Similar FDC is already discussed by 10 expert Committee
1219	6257	Ofloxacin USP-0.3% w/v +Dexamethasone sodium Phosphate IP-0.05% w/v+Hydroxy propyl methyl cellulose IP-0.25% w/v+(preservative) Benzalconium chloride solution IP-0.02% w/v-EYE/EAR DROPS			c
1220	6258	betacarotene 15%-20 mg (Naturallymixed carotenoid) eq. to Vitamin A 5000 IU + zinc sulphate monohydarte USP-27.5 mg+ selenium dioxide (as selenious USP)-200 mcg + Manganese BP (as manganese sulphate monohydrate BP)-2 mg+ Copper (copper sulphate pentahydrate BP)-1 mg-capsules			a, This FDC of multi ingredients have no scientific relevance as under 1. Some drugs are in therapeutic dose (vitamin A) and others are in prophylactic dose.Therefore the main indication is for vitamin A deficiency and , 2.addition of many ingredients i.e. Selenium Dioxide ,Managanese, and Copper in FDC form has no scientific support and evidence for above mentioned indication.

1221	6262	Gamma Benzene Hexachloride IP-1.0 g + Benzocaine IP-3.0 g +Oil base to 100 ml-Liquid (external preparation)			a Irrationale combination without any scientific evidence.
1222	6263	Metformin HCl (ER) IP-500 mg+Gliclazide (MR) ip-60 mg+Voglibose-0.2 mg-uncoated bilayered tablet			a This FDC was discussed earlier by previous Committee on 27.06.14 as under- The firm could not present any scientific data with respect to this FDC. The dosing of voglibose is incompatible with the dosing schedule of metformin ER and gliclazide SR. Hence the committee did not recommend.
1223	6265	Pancreatine USP(CONTAINING 15,000 usp UNITS OF Amylase activity 4000 USP units of Lipase activity 15,000 USP units of Protease)+Sodium Tauroglycocholate BPC 54-65 mg with sugar coating containing essential carminative oils-tablet			c Indicated for pancreatic insufficiency only
1224	6266	Diclofenac diethylamine BP-1.16% w/w equ. To+ Diclofenac Sodium-1.0% w/w + methyl salicylate IP-10.0 %w/w + menthol IP-5.0 5 w/w+ capsasin USP-0.025% w/w+ methyl paraben IP-0.20 % w/w+ propyl paraben IP-0.02% w/w-Cream			c
1225	6268	Tylosin Tartrate IP-63%w/w+Bromhexine HCl IP-3% w/w-powder			Veterinary product
1226	6271	Coccalkyl dimethylbenzyl ammonium chloride (50%)-20%+Glutaraldehyde (50%)-30%-WATER SOULBLE FOAMING DISINFECTANT			c
1227	6272	Diclofenac Sodium IP-32.10 mg+Menthol IP-0.5% w/w topical solution			c
1228	6273	Sodium pico sulfate BP-10 mg+Heavy Magnesium Oxide IP-3.5 gm+Anhydrous Citric acid IP-12.0 gm-Oral powder			a Magnesium oxide in the present dosage will produce systemic adverse effects.

1229	6274	Benzethonium Chloride USP-0.20+Lidocaine USP-3.00-Burn relief spray			c
1230	6275	Ferrous Ascorbate IP eq. to elemental Iron-100 mg+Folic Acid IP-1500 mcg+Zinc Sulphate Monohydrate USP -61.8 mg (eq. to elemental Zinc 22.5mg)-tablet			c
1231	6282	paradichlorobenzene-2%w/v+ chlorbutol IP-5% w/v + turpentile Oil IP88-15% w/v + lignocaine USP-2% w/v- per 5ml & 10ml ear drops			c
1232	6284	Paracetamol IP 450mg+Bromhexine HCl IP 8mg+GuaiphenesinIP 50mg+Chlorpheniramine Maleate IP 2mg+Phenylephrine HCl IP 5mg tablets			a There is no pharmacodynamic relevance of adding so many ingredients which does not have any added therapeutic advantage.
1233	6285	Ferric Hydroxide in complex with Sucrose eq. to Elemental Iron 20mgLiquid Injection			c
1234	6287	1, 6 Dihydroxy 2, 5-Dioxyhexane (Chemically bound Formaldehyde) 11.2g+Glutaraldehyde 5.0g+Benzalkonium Chloride (as BKC Solution IP) 5.0g+Alkyl Urea Derivative 3.0g per 100g liquid		topical liquid	c
1235	6288	Trithioparamethoxyphenyl Propene 12.5mg+Chlorpheniramine Maleate IP 3.0mg sugar coated tablets		sugar coated tablets	a Therapeutic value of this FDC not proven.
1236	6289	Lactobacillus Acidphilus+Lactobacillus Rhamnosus Lactic Acid bacillus) total Lactobacillus 0.625 bcfu+(Bifidobacterium Bifidum+Bifidobacterium longum) Total Bifidobacterium 0.600 bcfu+Sacchromyces boulardii 0.025 bcfu Total Count 1.25 Billion cfu+Fructooligosaccharise 50mg per 1gm sachet			c
1237	6291	Povidone Iodine IP 5%w/v+Tinidazole IP 1%w/v+Zinc Sulphate IP 1%w/v solution			a irrationale combination.Both have different therapeutic indication
1238	6293	Probiotic -2.5 billion cells (Lactobacillus Acidphilus 300 million cells+Lactobacillus Rhamnosus 300 million cells+Lactobacillus Paracasei 300 milion cells+Lactobacillus Sporogenes 1000 million cells+Bifidobacterium Longum 300 million cells+Sacchromyces Boulardii 300 million cells) Prebiotic- Inulin 100mg++Fructo OligosachharidesBoulardii 200mg capsules			c
1239	6294	Lacithin USP 125mg +Silymarin 35mg per 5ml Syrup			d
1240	6295	Momentasone Furoate USP 0.1%w/w+Salicylic Acid IP 6.5%w/w Ointment			c
1241	6296	Pancreatin capsule amylase 20000+lipase 25000 +protease 1000			c Indicated for pancreatic insufficiency only
1242	6297	Ferrous sulphate 200mg eq to 60 mg iron + Folic acid 0.5 mg enteric coated tablet			c
1243	6298	Each 10 ml contains ; pepsin(1:3000)10mg(digest not less than30gm of cogulated egg) +Distase-(1:2000) 50 mg syrup			c

1244	6299	Dried aluminium Hydroxide gel 250 mg+Magnesium trisilicate 250 mg+ Activated poly dimethylsiloxane 50 mg chewable tablet			c
1245	6300	Ferrous glycine sulphate eq to iron 100 mg+Folic acid 0.5 mg +Zinc sulphate 61.8 mg tablet			c
1246	6301	Acetyl Cysteine BP 200mg +Ambroxol HCl IP 30mg Film Coated Tablets	200mg+30mg	tablets	d Similar recommendation by an earlier Experts Committee on 23.04.14 .
1247	6304	Iron Hydroxide polymaltose complex eq to iron 50 mg + Folic acid 0.5 mg per 15 ml			c
1248	6305	Dried aluminium Hydroxide gel 200 mg+Magnesium hydroxide 200 mg+ Activated dimethicone 25 mg per 5 ml suspension			c
1249	6307	Octinoxate USP +Avobenzone USP+Oxybenzone USP+Processed Zinc Oxide topical gel	7.5 %w/w+ 2%w/w+ 3%w/w+ 6%w/w	Gel	d
1250	6308	Diastase fungal conc. Eq to fungal (1:800) 75 mg+Papain 60 mg per 5 ml syrup			c
1251	6309	Chlorpheniramine Maleate 3mg IP+Ammonium chloride 130 mg+Sodium Citrate IP 65 mg+Menthol IP 0.5 mg per 5 ml oral liquid			a Pharmacodynamic incompatibility Chlorpheniramine produce dryness of cough secretion while ammonium chloride stimulate secretion, which is antagonist effect
1252	6310	Ferric ammonium citrate IP-160 mg Eq. to elemental iron-32.8 mg+ folic acid IP-1 mg+ cyanocobalamin IP-5 mcg+ sorbitol solution (70%) Non Crystelizing IP-1.5 gm-Liquid syrup			c
1253	6314	folic acid IP-5 mg Docosahexaenoic acid (DHA)-200mg			c
1254	6316	Glucosamine sulfate potassium chloride USP-410 mg Chondroitin Sulphate-100 mg			a, There is no scietnific evidence favoring this combination
1255	6319	Dried Ferrous Sulphate eq to elemental iron 30mg(SR) +Folic Acid 250 mcg capsule			c
1256	6320	Dried Ferrous Sulphate 150 mg(SR) +Folic Acid 0.5 mg capsule			c
1257	6321	Dried Ferrous Sulphate IP 335 mg eq to elemental iron 100mg +Folic Acid 0.5 mg enteric coated capsule			c
1258	6322	Tramadol HCL+ paracetamol + dicyclomine HCL	37.5 mg+ 500 mg+ 20 mg	Tablet	d paracetamol dose should be 325 mg
1259	6323	Tramadol HCL+ paracetamol + dicyclomine HCL	37.5 mg/50 mg+ 325/325 mg mg+ 20/10 mg	capsule	d
1260	6324	Miconazole nitrate 2%w/w+Flucinclone acetonide 0.025%/0.01 w/w	2%w/w + 0.025%/0.01 w/w	ointment	c
1261	6325	Clobetasol propionate 0.05%w/w+Miconazole nitrate 2%+Gentamycin sulphate 0.2% Zinc oxide 0.1 %		cream	c Committee recommended that FDC shall not be used continously for more than one week without re-evaluation by the physician.
1262	6326	Beclomethasone Dipropionate 0.025%+Neomycin sulphate 0.1%+Clotrimazole1%		cream	c
1263	6327	Mometasone furoate 0.1%+ Salicylic acid 6.5% ointment			c
1264	6328	Mometasone furoate 0.1%+ Salicylic acid 3.5% ointment			c
1265	6329	Dried aluminium hydroxide gel 400mg as paste + Magnesium hydroxide 400 mg as paste + simethicone 50 mg			c

Minutes of the Meeting of Expert Committee held on 17.08.2015 to review proposals and advice Drugs Controller General (India) in 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)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard - Member
3. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi - Member
4. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
5. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
6. Dr. Sanjeev Sinha, Addl. Prof. (Medicine), AIIMS, New Delhi – Member
7. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi - Member

Dr. G. N. Singh, Drugs Controller General (India) welcomed the members of Expert Committee. He thanked all the members of the Committee for their remarkable efforts in categorization of various FDCs, applications of which were received by CDSCO for proving safety and efficacy under 18 month policy decision.

The Committee was apprised that based on the recommendations of the Committee, CDSCO has communicated all the firms regarding approval or otherwise in respect of the FDCs falling under category 'a', 'c' and 'd'. Committee was also apprised that 30 days timeline has been given to the companies for submitting their reply in respect of the FDCs falling under category 'a'. Further 4 months timeline has been assigned for submitting CT protocol in respect of FDCs falling under category 'd' which would be evaluated in consultation with SECs.

During the meeting, following issues including issues raised by IDMA in their representation were place before the Committee for deliberation:-

1. To provide 6 months time for submitting reply to the showcause notices issued.
2. To provide reasons for declaring certain FDCs as Irrational.
3. To give an opportunity to present their case for the FDCs declared irrational.
4. Not to insist for clinical trials, when product has already been consumed over years.
5. Not to reject FDCs on the ground that their availability leads to abuse potential.

6. Evaluators must be appropriately empowered with regulatory realties such that their assessment is scientific but balanced with current prescription practices.

   - FDCs combining ingredients, which are similar to DCG(I) approved formulations like vitamins preparations, Topical preparations etc. may be labeled as rational.
   - FDCs if seemingly doubtful, may be rationalized in view of they definitely not combining any obviously irrelevant blend of ingredients.
   - Not being available in any overseas market should not be a guiding criterion to determine the suitability of FDC being categorized as rational.
   - Additionally, a combination of drugs not being recommended by any worldwide scientific body, or a medical association need not form the basis of judging rationality of the FDC.
   - For antimicrobial combinations the same should be considered permitting if: (a) a particular pathogen that needs to be eliminated has a known incidence of frequent resistance; (b) a disease gas reported incidence of Multidrug Resistant (MDR) pathogens prevalent. Permitting the use of combination for such situations would, contrary to prevailing worries, eliminate the bacteria more assuredly and, in fact, avoid making them resistant. The examples of antimicrobial combinations for tuberculosis, HIV, campylobacter infections, etc. are all widely known and for such diseases it is a norm to combine antibacterial with the very same motive in mind.

7. To discuss the information required from the companies in respect of FDCs which have been categorized under category 'b'.

8. To discuss various modalities to be followed for further examination of applications falling under category 'a' after receipt of reply to showcause notices from the firms.

9. To finalize the recommendations in respect of certain FDCs as certain discrepancies have been observed among the recommendations. List of such FDCs is attached herewith for discussion and further finalization.

10. To decide any other issues of relevance for early disposal of proposals of such FDCs

Committee went through the representations and opined to decide on the basis of rationality, safety and efficacy and also shown its willingness to consider the methods or criteria proposed by the IDMA while ensuring the safety of patients.

Secondly, as regard to the extension of time for submitting reply to the various showcause notices issued by CDSCO, Committee opined that further time for reply is justifiable and may be given based on representation. However, Committee opined that instead of giving six months, a further period of 3 months may be given for submission of reply to the showcause notices issued as the sufficient opportunity is needed to submit proper scientific data.

Committee was apprised that Ministry while approving the report of the Committee has suggested to seek information from industry in respect of FDCs categorized under category 'b' and to place the same before the Committee in which other experts will be associated on as required basis. Committee after detailed deliberation suggested that asking further information from the industry at this point of time for these FDCs is not required, as such as it will not serve any additional purpose. As suggested by the Ministry, Committee opined that subject experts can be invited to the meetings of Committee for detailed deliberation and further categorization of these FDCs. It was decided that the meetings can take place as per therapeutic category, if required and 2 subject experts of that therapeutic area can be invited to deliberate. The subject experts will be from the list of experts already available in Subject Expert Committees, Technical Committees or other committees, any other suitable experts from Govt. institutes as proposed by the Chairman, FDC Committee.

As it will take time to receive reply, collate and compilation of FDCs falling under category 'a' for which showcause notices have been issued by CDSCO, Committee desired that further meetings shall be conducted with subject experts with respect to FDCs falling under category 'b' so that these FDCs can be categorized appropriately. Committee opined that FDCs falling under "Medicine" therapeutic area can be discussed during next meeting and two subject experts can be invited to participate in the meeting.

As regard to the various discrepancies observed among the recommendations with respect to certain FDCs, these FDCs were examined again by the Committee and accordingly final recommendations made by the Committee are annexed herewith as **Annexure A.** Committee opined that CDSCO can issue letters with respect to these FDCs accordingly.

The meeting ended with the vote of thanks to the chair.

(Dr. C. L. Kaul) **(Dr. R.K. Khar)** **(Dr. Bikash Medhi)**

(Dr. C.D. Tripathi) **(Prof. Sanjay Singh)** **(Dr. Sanjeev Sinha)**

(Prof. Chandrakant Kokate)

Annexure 4

List of FDCs where discrepancy observed among recommendations.

S.No	Name of FDC	Final Recommendations by Expert committee
1	Beclomethasone + Clotrimazole + Neomycin	a, Pharmacodynamically irrelevent
2	Calcium Orotate 740 mg + Zinc Sulphate 7.5 mg + Folic acid 50 mcg+ Cyanocobalamin 0.5 mcg tablet	a, Due to subtherapeutic dose of Vit-B12
3	Propanolol + Clonazepam	b
4	Aluminium + Magnesium + Simethicone suspension per 10ml	Already discussed by the earlier Committee
5	Paracetamol + Phenylephrine + Caffeine	a, Pharmacodynamically irrelevent
6	Drotaverine +Clidinium + Chlordiazepoxide	Already discussed by the earlier Committee
7	Levocetirizine + Phenylephrine + Ambroxol + Paracetamol	a, Pharmacodynamically irrelevent
8	Alginine Acid + Sodium Bicarbonate + Aluminium Hydroxide + Magnesium Hydroxide tablet.	Already discussed by the earlier Committee
9	Cetrimide 0.5gm + Thymol 5mg + Acriflavine 0.12gm cream	Already discussed by the earlier Committee
10	Taurine + Acetylcysteine tablet	b
11	Paracetamol + Dicyclomine	c, If PCM dose is 500 mg
12	Beclomethasone + Gentamicin + Clotrimazole	a, Pharmacodynamically irrelevent
13	Dextromethorphan + Chlorpheniramine + Phenylephrine	c
14	Aceclofenac + Paracetamol + Serratiopeptidase	Subjudice
15	Atorvastatin + Metformin	Already discussed by the earlier Committee
16	Naproxen + Domperidone	Subjudice
17	Paracetamol + Phenylephrine + Chlorpheniramine + Caffeine	a, Pharmacodynamically irrelevent
18	Flunirizine + Paracetamol + Domperidone	a, PK and PD irrelevant
19	Benfothiamine + Metformin	Already discussed by the earlier Committee
20	Silymarin + Urosochlorodoxy acid	b
21	Tapentadol + Paracetamol	Already discussed by the earlier Committee
22	Dextromethorpahn + Chlorpheniramine	c
23	Paracetamol 650mg + Diclofenac 50mg	c, If PCM dose is 325 mg
24	Chloramphenicol + Dexamethasone eye drop	c
25	Aceclofenac + Paracetamol + Trypsin + Chymo trypsin	d
26	Diphenhydramine + Ammichloride + Sodium Citrate + Terpine Hydrate + Menthol syrup/suspension	a, Pharmacodynamically irrelevent
27	Beclomethasone + Miconazole + Neomycin	a, Pharmacodynamically irrelevent

28	Calcium Citrate 1000mg + Elemental Magnesium 100mg (as magnesium hydrate) + Elemental Zinc 4mg (as zinc Sulphate) +vitamin D3 200 IU	b
29	Paracetamol + Chlorpheniramine	b
30	Amlodipine + Hydrochlorothiazide + Losartan	d
31	Mometasone + Hydroquinone + Tretinoin cream	c
32	Beclomethasone + Gentamicin + Miconazole	a, Pharmacodynamically irrelevent
33	Lornoxical +Paracetamol + Tramadol	Already discussed by the earlier Committee
34	Chlorpheniramine Maleate IP 3 mg+Ammonium Chloride IP 130 mg+Sodium Citrate IP65 mg+Menthol IP 0.6 mg oral liquid	a, there is a potential of misuse in peadiatric population
35	Lactic acid bacillus 180 million +Folic acid 1500mcg +cyanocobalamin 15mcg tablet	b

Minutes of the Meeting of Expert Committee held on 23.09.15 and 24.9.2015 to review proposals and advice Drugs Controller General (India) in 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)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard - Member
3. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi - Member
4. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
5. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
6. Dr. Sanjeev Sinha, Prof. (Medicine), AIIMS, New Delhi – Member
7. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
8. Dr. Tungvir Singh, Prof., Department of Medicine LLRM Medical College, Meerut
9. Dr. Subhash Giri, Prof., Department of Medicine, UCMS, New Delhi

Prof. Kokate was not present on 24th Sept. and Dr. Sanjeev Sinha was not present on 23rd Sept. during the meeting.

Dr. G. N. Singh, Drugs Controller General (India) welcomed the members of Expert Committee for its meeting being held to advise DCG(I) in 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).

The Committee was apprised that the issue is related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term "New Drug" in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India) that had been raised in many fora from time to time.

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1.10.2012, without the permission of DCG(I), it was decided and submitted by the Ministry of Health and Family Welfare to the Parliament Standing Committee that the DCG(I) would direct all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. Accordingly, DCG (I) vide letter dated 15.01.2013 requested all the State Drug Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs within 18 months.

In view of above, a large number of applications were received by CDSCO. In order to examine such a huge number of applications in a timely manner, Ministry of Health & Family Welfare vide order No. X11035/53/2014-DQC dated: 16.09.2014 constituted a Committee under the chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka. As directed by the Ministry, following actions have been initiated by CDSCO:-

1. For FDCs which are considered as Irrational by the Committee were categorized under category 'a' and accordingly showcause notices have been issued to the concerned manufacturers.
2. For FDCs which require further deliberation with subject experts were categorized under category 'b' and action for such deliberation is under process.
3. For FDCs which are considered as rational by the Committee were categorized under category 'c' and accordingly approval letters have been issued to the concerned manufacturers.
4. For FDCs which require further generation of data were categorized under category'd' and accordingly letters asking the firms to submit Phase IV trial protocol have been issued to the concerned manufacturers.

The members were apprised that FDCs to be discussed in the meeting have already been examined. However in these cases, Committee considered it necessary for further deliberation with subject experts to further categorize these FDCs into category 'a', category 'c' or category 'd' based on the rationality, safety and efficacy of these FDCs. Committee was also requested to deliberate on additional FDCs which were left previously inadvertently. Chairman advised that these FDCS can be discussed in current as well as subsequent meetings.

The detailed therapeutic category-wise agenda containing FDCs related to Vitamins, Antimicrobial as well as Medicine category were placed before the Expert Committee. The Expert Committee adopted the blinding procedure for evaluation of the FDCs. The Committee also signed the Conflict of Interest. The Committee discussed in detail and made their recommendations. The Committee tentatively discussed in detail and categorized approximately 400 FDCs during the meeting. However these FDCs alongwith other remaining FDCs will be discussed and reviewed again in the next meeting for further finalization.

The chairman of the Committee desired that one more meeting may be conducted on 16th and 17th October 2015 to further discuss and finalize these FDCs belonging to aforesaid category. He also informed that he may not be present during the next meeting , however the outcome of the meeting will be reviewed by him during subsequent meeting.

The meeting ended with the vote of thanks to the chair.

(Dr. G. L. Kaul) (Dr. R.K. Khar) (Dr. Bikash Medhi)

(Dr. C.D. Tripathi) (Prof. Sanjay Singh) (Dr. Sanjeev Sinha)

(Dr. Tungvir Singh) (Dr. Subhash Giri)

(Prof. Chandrakant Kokate)

Minutes of the Meeting of Expert Committee held on 5.10.2015 to review proposals and advice Drugs Controller General (India) in 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)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard - Member
3. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi - Member
4. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
5. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
6. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
7. Dr. Tungvir Singh, Prof., Department of Medicine LLRM Medical College, Meerut

Dr. Sanjeev Sinha and Dr. Subhash Giri were not present during the meeting due to their prior commitments.

The Chairman welcomed the members of Expert Committee as well as subject experts for meeting being organized to advise DCG(I) in 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).

The minutes of the meeting held on 16th and 17th October 2015 were approved by the Committee.

All the FDCs under category "b" related to Vitamins, Antimicrobial as well as Medicine therapeutic categories as discussed so far with the subject experts were reviewed thoroughly and recommendations were also mentioned against each FDC. The Committee also reviewed approximately 100 other FDCs and gave its recommendations.

The Committee also opined that it would be worthwhile to add the clear cut indications of specific individual formulations to further examine them on their merits. This shall enable the quick decision.

The Committee was apprised that the FDC of Hydrochlorothiazide+ Ramipril + Losartan was inadvertently discussed in its earlier meetings. The Committee noted that the FDC is covered under 294 category and is sub-judice. The Committee recommended that any letter i.e. approval or otherwise if issued by CDSCO for this particular FDC, may be withdrawn.

The Expert Committee adopted the blinding procedure for evaluation of the FDCs. The Committee members also signed the no Conflict of Interest. The Chairman of the Committee desired that next meeting may be kept for 2 days for discussing the proposals belonging to FDCs under 'Pulmonary' category and two subject experts may be invited for participating in the meeting.

The Chairman opined that the FDCs of vitamins category require further examination and in-depth deliberations before taking the final decision.

The meeting ended with a vote of thanks to the chair.

(Dr. C. L. Kaul) (Dr. R.K. Khar) (Dr. Bikash Medhi)

(Dr. C.D. Tripathi) (Prof. Sanjay Singh) (Dr. Tungvir Singh)

(Prof. Chandrakant Kokate)

Minutes of the Meeting of Expert Committee held on 16.10.15 and 17.10.2015 to review proposals and advice Drugs Controller General (India) in 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)

Members present:

1. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard - Member
2. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi - Member
3. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
4. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
5. Dr. Sanjeev Sinha, Prof. (Medicine), AIIMS, New Delhi – Member
6. Dr. Tungvir Singh, Prof., Department of Medicine LLRM Medical College, Meerut
7. Dr. Subhash Giri, Prof., Department of Medicine, UCMS, New Delhi

As desired by the chairman of the Committee, a meeting of the members of the Committee was convened alongwith subject experts on 16th and 17th October 2015 to further discuss and finalize the recommendations with respect to FDCs discussed so far in the last meeting. Committee discussed all the FDCs one by one in detail and categorized each FDC appropriately as per Terms of References.

The Expert Committee adopted the blinding procedure for evaluation of the FDCs. The members also signed the Conflict of Interest. The Committee discussed all the FDCs in detail and made their recommendations. The Committee tentatively discussed in detail and categorized approximately 100 FDCs during the meeting.

The meeting ended with the vote of thanks.

(Dr. C. L. Kaul) (Dr. Bikash Medhi) (Dr. C.D. Tripathi) (Prof. Sanjay Singh)

(Dr. Sanjeev Sinha) (Dr. Tungvir Singh) (Dr. Subhash Giri)

Minutes of the Meeting of Expert Committee held on 30.11.2015 and 01.12.2015 to review proposals and advice Drugs Controller General (India) in 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)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard - Member
3. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi - Member
4. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
5. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
6. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
7. Dr. J. C. Suri, Prof., Department of Pulmonary, VMCC & Safdarjung Hospital, New Delhi
8. Dr. Sushant H. Meshram, HOD, Prof., Department of Pulmonary, GMC,& Hospital, Pune

Dr. Sanjeev Sinha could not attend the meeting.

Dr. G. N. Singh, Drugs Controller General (India) welcomed the members of Expert Committee. The Committee was sensitized about the serious problem of Antimicrobial resistance prevailing in the country and therefore approval of combinations containing antibiotics shall be made very judiciously.

The Committee was apprised that the issue is related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term "New Drug" in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India).

In respect of other FDCs falling under definition of 'New Drug' licensed by State Licensing Authorities before 1.10.2012, without the permission of DCG(I), it was decided and submitted by the Ministry of Health and Family Welfare to the Parliament Standing Committee that the DCG(I) would direct all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of

1/12/15 1/12/15 1/12/15

such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. Accordingly, DCG (I) vide letter dated 15.01.2013 requested all the State Drug Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs within 18 months.

In view of above, a large number of applications were received by CDSCO. In order to examine such a huge number of applications in a timely manner, Ministry of Health & Family Welfare vide order No. X11035/53/2014-DQC dated: 16.09.2014 constituted a Committee under the chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka. As directed by the Ministry, following actions have been initiated by CDSCO:-

1. FDCs considered as Irrational by the Committee were categorized under category 'a' and accordingly show cause notices have been issued to the concerned manufacturers.
2. FDCs requiring further deliberation with subject experts were categorized under category 'b' and further deliberations are in progress.
3. FDCs considered as rational by the Committee were categorized under category 'c' and accordingly approval letters have been issued to the concerned manufacturers.
4. FDCs requiring further generation of data were categorized under category 'd' and accordingly letters asking the firms to submit Phase IV trial protocol have been issued to the concerned manufacturers.

The members were apprised that FDCs to be discussed in the meeting have already been examined by the Committee. However in these cases, it was considered necessary to have further deliberations with subject experts to categorize these FDCs into categories 'a', 'c' or 'd' based on the rationality, safety and efficacy .

The detailed therapeutic category-wise agenda containing FDCs related to Pulmonary category were placed before the Committee. The Committee adopted the blinding procedure for evaluation of the FDCs and also signed the No Conflict of Interest. The Committee discussed each FDC in detail and categorized 406 FDCs during the meeting.

The Committee was apprised that CDSCO has received the replies to the show cause notices issued to the firms in respect of the combinations considered as irrational by the Committee and these need to be examined by the Committee on priority in public interest.

The Chairman of the Committee desired that continuous 6 days meetings shall be kept in January 2016 preferably from 4th Jan to 9th January 2016 to discuss and examine the replies received in respect of FDCs considered as irrational. The Chairman also desired that at least one additional expert of Internal Medicine be present in all these meetings and one relevant subject expert be invited, wherever necessary.

The meeting ended with the vote of thanks to the Chair.

(Dr. C. L. Kaul) (Dr. R.K. Khar) (Dr. Bikash Medhi) (Dr. C.D. Tripathi)

(Prof. Sanjay Singh) (Dr. J. C. Suri) (Dr. Sushant H. Meshram)

(Prof. Chandrakant Kokate)

Minutes of the Meeting of Expert Committee held on 14.3.2016 to review proposals and advise Drugs Controller General (India) in 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)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard – Member
3. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi - Member
4. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
5. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
6. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
7. Dr. Richa Dewan,Prof. & Head , Dept. of Medicine, MAMC, New Delhi
8. Dr. R.K. Arya, Prof. & Head, Dept. of Orthopaedics, RML Hospital, New Delhi
9. Dr. Debashish, Dept. of Neurology, MAMC, New Delhi
10. Dr. J.C. Passey, Prof. & Head, Dept. of ENT, MAMC, New Delhi
11. Dr. Rohit Saxena, Associate Prof., Dept. of Ophthalmology, AIIMS, New Delhi

Dr. Sanjeev Sinha, Prof., Dept. of Medicine, AIIMS, New Delhi did not participate in the meeting.

The Committee was apprised that the issue is related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term "New Drug" in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India).

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1.10.2012, without the permission of DCG(I), it was decided and submitted by the Ministry of Health and Family Welfare to the Parliament Standing Committee that the DCG(I) would direct all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. Accordingly, DCG (I) vide letter dated 15.01.2013 requested all the State Drug Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs within 18 months.

In view of above, a large number of applications were received by CDSCO. In order to examine such a huge number of applications in a timely manner, Ministry of Health & Family Welfare vide order No. X11035/53/2014-DQC dated: 16.09.2014 constituted a Committee

under the chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka. As directed by the Ministry, following actions have been initiated by CDSCO:-

1. FDCs considered as Irrational by the Committee were categorized under category 'a' and accordingly show cause notices have been issued to the concerned manufacturers.

2. FDCs requiring further deliberation with subject experts were categorized under category 'b' and further deliberations are in progress.

3. FDCs considered as rational by the Committee were categorized under category 'c' and accordingly approval letters have been issued to the concerned manufacturers.

4. FDCs requiring further generation of data were categorized under category 'd' and accordingly letters asking the firms to submit Phase IV trial protocol have been issued to the concerned manufacturers.

The members were apprised that FDCs to be discussed in the meeting have already been examined by the Committee. However in these cases, it was considered necessary to have further deliberations with subject experts to categorize these FDCs into categories 'a', 'c' or 'd' based on the rationality, safety and efficacy .

The detailed therapeutic category-wise agenda containing FDCs related to Ophthalmology, Analgesics, CNS, ENT categories were placed before the Committee. The Committee adopted the blinding procedure for evaluation of the FDCs and also signed the No Conflict of Interest. The Committee discussed each FDC in detail and categorized these FDCs during the meeting.

Due to inadvertent entries in respect of certain FDCs discussed in earlier meetings were re-examined and corrected by the Committee and accordingly final recommendations made by the Committee are annexed herewith as **Annexure A.**

The Chairman desired that next meeting of the Committee shall be kept in April 2016 to discuss and examine the FDCs related to other left categories. The Chairman also desired that FDCs related to Vitamins category may also be discussed again by inviting subject expert from NIN, Hyderabad, ICMR and other experts of Internal Medicine.

The meeting concluded with the vote of thanks to the Chair.

(Dr. C. L. Kaul) (Dr. R.K. Khar) (Dr. Bikash Medhi) (Dr. C.D. Tripathi)

(Prof. Sanjay Singh) (Dr. Richa Dewan) (Dr. Debashish)

(Dr. J.C. Passey) (Dr. Rohit Saxena) (DR. R. K. ARYA)

(Prof. Chandrakant Kokate)

Annexure A

List of FDCs where corrections were made in earlier recommendations

S. No.	Name of FDC	Earlier recommendations	Final Recommendations
1	Camylofin+Mefenamic Acid	d/b	d
2	Torsemide + Spironolactone	c/subjudice	subjudice
3	Boric Acid+ Borax+Naphazoline HCL+Menthol+Camphor+HPMC +BenzalkoniumChloride	c/a Chairman had already conveyed its consent on 25.1.2016 that FDC is irrational	a
4	Meropenem + Tazobactum	c	Committee noted that the FDC is yet to be launched in the market and not already existing product. Therefore recommendation of the Committee does not apply for this FDC which is yet to be launched

Minutes of the Meeting of Expert Committee held on 15.3.2016 to review proposals and advise Drugs Controller General (India) in 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)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard – Member
3. Prof. Sanjay Singh, Deptt. Of Pharmaceuticals, IIT, BHU, Varanasi - Member
4. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
5. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
6. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
7. Dr. B. Gupta, Prof. & Head , Dept. of Medicine, HinduRao Hospital, New Delhi
8. Dr. Alka Kriplani, Prof. & Head, Dept. of Gyne&Obst., AIIMS, New Delhi
9. Dr. A.K. Saxena, Ass. Prof. and Consultant, Dept. of Dermatology, Safdarjung Hospital, New Delhi

   Dr. Sanjeev Sinha, Prof., Dept. of Medicine, AIIMS, New Delhi did not participate in the meeting.

The Committee was apprised that the issue is related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term "New Drug" in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India).

In respect of other FDCs falling under definition of "New Drug" licensed by State Licensing Authorities before 1.10.2012, without the permission of DCG(I), it was decided and submitted by the Ministry of Health and Family Welfare to the Parliament Standing Committee that the DCG(I) would direct all the State Drugs Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs before CDSCO within a period of 18 months, failing which such FDCs will be considered for being prohibited for manufacture and marketing in the country. Accordingly, DCG (I) vide letter dated 15.01.2013 requested all the State Drug Controllers to ask the concerned manufacturers to prove the safety and efficacy of such FDCs within 18 months.

In view of above, a large number of applications were received by CDSCO. In order to examine such a huge number of applications in a timely manner, Ministry of Health & Family Welfare vide order No. X11035/53/2014-DQC dated: 16.09.2014 constituted a Committee under the chairmanship of Prof. C. K. Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka. As directed by the Ministry, following actions have been initiated by CDSCO:-

1. FDCs considered as Irrational by the Committee were categorized under category 'a' and accordingly show cause notices have been issued to the concerned manufacturers.

2. FDCs requiring further deliberation with subject experts were categorized under category 'b' and further deliberations are in progress.

3. FDCs considered as rational by the Committee were categorized under category 'c' and accordingly approval letters have been issued to the concerned manufacturers.

4. FDCs requiring further generation of data were categorized under category 'd' and accordingly letters asking the firms to submit Phase IV trial protocol have been issued to the concerned manufacturers.

The members were apprised that FDCs to be discussed in the meeting have already been examined by the Committee. However in these cases, it was considered necessary to have further deliberations with subject experts to categorize these FDCs into categories 'a', 'c' or 'd' based on.the rationality, safety and efficacy.

The detailed therapeutic category-wise agenda containing FDCs related to Gynaecology, Endocrinology, Dermatology categories were placed before the Committee. The Committee adopted the blinding procedure for evaluation of the FDCs and also signed the No Conflict of Interest. The Committee discussed each FDC in detail and categorized these FDCs during the meeting.

The meeting concluded with the vote of thanks to the Chair.

(Dr. C. L. Kaul) (Dr. R.K. Khar) (Dr. Bikash Medhi) (Dr. C.D. Tripathi)

(Prof. Sanjay Singh) (Dr. B. Gupta) (Dr. Alka Kriplani) (Dr. A.K. Saxena)

(Prof. Chandrakant Kokate)

Minutes of the Meeting of Expert Committee held on 18.4.2016 and 19.4.2016 to review proposals and advise Drugs Controller General (India) in 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)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard – Member
3. Prof. Sanjay Singh, Deptt. Of Pharmaceutics, IIT, BHU, Varanasi - Member
4. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
5. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
6. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
7. Dr. B. Gupta, Prof. & Head , Dept. of Medicine, HinduRao Hospital, New Delhi
8. Dr. Nihar Ranjan Dash, Addl. Prof., Dept. ~~of Gastroenterology, AIIMS~~ Gastrointestinal Surgery on Liver transplant. AIIMS, New Delhi (attended meeting on 18.4.2016)

Dr. Sanjeev Sinha, Prof., Dept. of Medicine, AIIMS, New Delhi could not attend meeting.

The Chairman welcomed the members of the Committee. The Committee was apprised that the issue is related to the grant of manufacturing licenses for sale of the Fixed Dose Combinations (FDCs) which fall under the definition of the term "New Drug" in the country without due approval by the Licensing Authority as defined under rule 21(b) i.e. Drugs Controller General (India). Committee was also apprised that based on the recommendations of the Committee, Central Government has recently prohibited 344 FDCs for manufacturing for sale, sale and distribution in the country.

The members were also apprised that FDCs to be discussed in the meeting have already been examined earlier by the Committee. However in these cases, it was considered necessary to have further deliberations with subject experts to categorize these FDCs into categories either 'a', 'c' or 'd' based on the rationality, safety and efficacy .

19/4/16 19/4/16 19/4/16 19/4/16 11.5.16

The detailed therapeutic category-wise agenda containing FDCs related to Gastroenterology, Cardiovascular etc., categories were placed before the Committee. The Committee adopted the blinding procedure as per SOP for evaluation of the FDCs and Committee members also declared No Conflict of Interest. The Committee discussed each FDC in detail and categorized these FDCs during the meeting.

The Committee desired to evaluate separately Vitamins and Minerals related preparations including micronutrients.

The Committee also desired that the next meeting shall be held in May 2016 for reviewing and compilation of the report before submitting it to the Ministry. The report related to Vitamin preparations will be discussed separately.

The meeting concluded with the vote of thanks to the Chair.

19/4/16
(Dr. C. L. Kaul)

9/4/16
(Dr. R.K. Khar)

19/04/2016
(Dr. Bikash Medhi)

19.5.16.
(Dr. Nihar Ranjan Das)

(Dr. C.D. Tripathi)

(Prof. Sanjay Singh)

19/4/16
(Dr. B. Gupta)

19.4.16.
(Prof. Chandrakant Kokate)

Minutes of the Meeting of Expert Committee held on 26.5.2016 and 27.5.2016 to review proposals and advise Drugs Controller General (India) in 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)

Members present:

1. Prof. Chandrakant Kokate, Vice-Chancellor, KLE University, Belgaum, Karnataka & Ex-President of Pharmacy Council of India - Chairman
2. Dr. C. L. Kaul, Former Director, NIPER, Consultant, Clinical Research, Jamia Hamdard – Member
3. Prof. Sanjay Singh, Deptt. Of Pharmaceutics, IIT, BHU, Varanasi - Member
4. Dr. C. D. Tripathi, Prof. & HOD (Pharmacology), Safdarjung Hospital, New Delhi – Member
5. Dr. Bikash Medhi, Department of Pharmacology, PGIMER, Chandigarh- Member
6. Dr. R.K. Khar, Former Dean & Head, Jamia Hamdard, New Delhi – Member
7. Dr. Richa Dewan, Prof. & Head , Dept. of Medicine, MAMC, New Delhi

Dr. Sanjeev Sinha, Prof., Dept. of Medicine, AIIMS, New Delhi could not attend meeting.

The Chairman welcomed the members of the Committee and requested them to re- review the recommendations in respect of FDCs grouped under category 'b' for further submission to the Ministry of Health and Family Welfare for necessary action.

The Chairman apprised all the members regarding his Meeting with Secretary (Health), Additional Secretary (F&D) and Additional Solicitor General (ASG) on 19.04.2016. He informed that the Secretary appreciated the work of the Committee and directed to expedite the review of the remaining FDCs at the

27/5/16 27/5/16 101

earliest. The Chairman also briefed the ASG regarding the methodology adopted for evaluation of FDCs.

During the deliberations of the FDCs meetings, it was felt that many FDCs have been approved by CDSCO over the period of 4 to 5 decades. Over the period of time, there have been tremendous advancements in the treatment of various diseases and their therapeutic guidelines have been updated from time to time. In light of the present scientific evidences regarding both safety and efficacy, it becomes imperative to re-examine the FDCs approved by CDSCO. **Therefore, the Committee recommends that there should be a periodic review of all previously approved FDCs which are in market beyond 10 years.** This view was also conveyed by the Chairman of the Committee to the Secretary (Health) in his meeting on 19.04.2016.

The Committee while reviewing the Vitamins and Minerals preparations, it was felt that the regulations in accordance with schedule 'V' of Drugs and Cosmetics Rules, 1945 are not updated as per the current Indian requirements. Therefore, the Chairman emphasized that different evaluation criteria be adopted for evaluation of Vitamins and Minerals related preparations including micronutrients as some of these are considered as Nutraceuticals internationally. Keeping this in view, the Committee desired that products which are under category of mixture of Vitamins and Minerals can be considered as having a general therapeutic justification and report in this regard will be submitted to Ministry separately. **The Committee recommends that schedule 'V' of Drugs and Cosmetics Rules, 1945 should be re-visited in current scenario.**

The Committee re-reviewed the recommendations in respect of all the FDCs categorised under category "b" except vitamins preparations and made corrections in case of FDCs wherever some ambiguity was observed.

The Committee also reviewed various FDCs which have been prohibited by the Central Government vide Gazette notifications dated 10.3.2016 and made its comments as under for re-consideration:

27/5/16 27/5/16

1. **S.O. No 894 : Dextromethorphan + Chlorpheniramine + Phenylephrine + Menthol**

   The Committee observed that the FDC was categorized as 'a' i.e. irrational, inadvertently in the report due to typographical error, as similar FDCs have been considered as rational i.e. category 'c' at S.Nos. 2561, 2622, 2714, 2929, 3028, 3365, 3342, 3427, 3534, and 3557 of the Committee report. Therefore, the Committee recommends that FDC of Dextromethorphan + Chlorpheniramine + Phenylephrine + Menthol shall be considered as rational.

2. **S.O. No. 741: Paracetamol + Prochlorperazine**

   The Committee observed that the FDC was categorized as 'a' i.e. irrational, inadvertently in the report due to typographical error, as similar FDCs have been considered as rational at S.Nos. 270 and 1376 of the Committee report. Therefore, the Committee recommends that FDC of Paracetamol+ Prochlorperazine shall be considered as rational.

3. **S.O. No.735: Benzoxonium chloride + Lidocaine**

   The Committee reviewed the FDC and observed that two formulations of this FDC i.e. one in chewable tablet dosage form (at S.No.407 of the Committee report) and other in mouthwash dosage form (at S. Nos. 515 and 3893 of the report) were categorized as 'a' and 'c' respectively. The Committee recommends that FDC of Benzoxonium chloride + Lidocaine chewable tablet be considered as rational, if used for local purpose and not for systemic use. Accordingly, Gazette Notification may be amended.

4. **S.O. No.740: Chlorpheniramine maleate +Ammonium chloride+sodium citrate+Menthol**

   The Committee observed that the FDC has been inadvertently categorized as 'c' i.e. rational in the report due to typographical error as this FDC has been considered as irrational at S.Nos. 500, 2804, 3004, 3279, 3330, 3433, 3443, 3448 and 2907 of the Committee report. The Committee finally categorised this FDC as 'irrational' i.e. category 'a'.

27/5/16 28/5/16

5. **S.O. No.870: Chlorpheniramine maleate + Ammonium chloride + Sodium citrate**

The Committee observed that the FDC was categorized as 'c' i.e. rational, inadvertently due to typographical error. Similar FDCs have been considered as irrational at S.Nos. 3138, 2612, and 2599 of the Committee report. The Committee recommends that FDC of: Chlorpheniramine maleate + Ammonium chloride + Sodium citrate Should be considered as 'irrational' i.e. category 'a'

The Committee was also apprised by officials of CDSCO that Ministry of Health and Family Welfare has received various representations from different stakeholders regarding reviewing of their FDCs which have been prohibited. The Ministry directed the DCG(I) office to place these representations before this Committee and recommendations of the Committee on such representations may be made available to the Ministry for further necessary action in the matter. The Chairman desired that a separate meeting for reviewing these representations may be kept once the report in respect of FDCs categorized under category 'b' is submitted to the Ministry.

The meeting concluded with the vote of thanks to the Chair.

(Dr. C. L. Kaul) (Dr. R.K. Khar) (Dr. Bikash Medhi)

(Dr. C.D. Tripathi) (Prof. Sanjay Singh) (Dr. Richa Dewan)

27/5/2016

(Prof. Chandrakant Kokate)