The expert committee deliberated the following proposals on **23.04.14** and recommended the following:

Agenda no.	Drug	Recommendation
1	Chlorpheniramine Maleate 2.5 mg + + Dextromethophan HBr 5 mg + Guaiphenesin 50 mg + Ammonium chloride 60 mg + Menthol 1 mg per 5 ml Syrup	The committee's observation on rationality safety and efficacy of the FDCs under reference Agenda 1, 2, 3, 4 The committee carefully examined the composition of each FDC, their indications as are available by the manufacturer's submission and also heard the manufacturer's presentations and arguments. In view of the above, the committee observes the following: 1. The products of agenda 1 and 2 combines expectorants and cough suppressants. Thus the product does not target an identifiable patient group. The medical rationale for combining the actives is insufficient. 2. The products of agenda 3 and 4 contain actives like levocetrizine (anti-histamine), phenylephrine (decongestant), ambroxol (mucolytic-expectorant) and paracetamol; the indications are dry cough, allergic rhinitis, body ache and fever, upper respiratory affections etc. The medical rationale for combining these actives is inadequate and the FDCs tend to accommodate diverse types of patient situations and symptoms which usually do not co-exist. Thus a clear identifiable patient group for the FDCs was missing. 3. However, it was also observed that the indications presented in the applications submitted and those at the time of presentations were discrepant. 4. There is also apparent lack of pharmacokinetic and pharmacodynamic compatibility - while levocetrizine is usually given once a day, phenylephrine or ambroxol would require more frequent administration. Use of Paracetamol in some of the referred FDCs seems un- warranted, not to speak of the strength of the Paracetamol used (325 mg), which seems inadequate to treat fever or body-ache in adult subjects. 5. **Safety & Efficacy**: In all the FDCs as referred to, no comments can be made on their safety or efficacy, since no data are readily available. Some manufacturers submitted some feedback from prescribers on safety and effectiveness which on closer scrutiny were found to be of very poor quality and could not be acceptable. 6. Nevertheless, the committee also takes note of the
2	Dextromethorphan Hydrobromide 5 mg + Phenylephrine HCl 5 mg + Ammonium Chloride 50 mg + Menthol 2.5 mg syrup	
3	levocetrizine HCl 2.5 mg + ambroxol HCl 60 mg + phenylepherineHCl 5 mg + paracetamol 325 mg tablets	
	LevoCetrizine Dihydrochloride IP 5mg +Phenylephrine HCl IP 5mg +Ambroxol IP 30mg +Paracetamol IP 325mg Tablets	
	LevoCetrizine Dihydrochloride 2.5mg +Phenylephrine HCL 5mg +Paracetamol 325mg +Ambroxol 60mg Uncoated Tablet	
	LevoCetrizine HCl IP 5mg +Ambroxol HCl IP 30mg +Phenylephrine HCL IP 5mg +Paracetamol IP 325mg Tablets	
	LevoCetrizine HCl IP 2.5mg/5mg +Paracetamol IP 500mg/325mg +Ambroxol HCl IP 30mg/60mg +Phenylephrine HCl IP 5mg Uncoated tablet	
	LevoCetrizine HCl IP 2.5mg/2.5mg +Phenylephrine HCl IP 5mg/10mg +Ambroxol HCl IP 60mg/60mg +Paracetamol IP 500mg/325mg Tablets	
	LevoCetrizine HCl IP 5mg +Phenylephrine HCl IP 5mg +Ambroxol HCl IP 30mg +Paracetamol IP 325mg Uncoated Tablets	
	LevoCetrizine HCl IP 5mg +Phenylephrine HCl IP 5mg	

	+Ambroxol HCl IP 60mg +Paracetamol IP 325mg Tablets	fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. 7. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulations and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. The whole of the above exercise for protocol submission should be completed within 3 months.
	LevoCetrizine HCl 2.5mg +Paracetamol 325mg +Phenylephrine HCl 10mg +Ambroxol HCl 30mg Uncoated Tablets	
	LevoCetrizine HCl 5mg +Phenylephrine HCl 5mg +Ambroxol HCl 30mg +Paracetamol 325mg Tablets	
	LevoCetrizine IP 2.5mg +Phenylephrine IP 5mg +Ambroxol IP 60mg +Paracetamol IP 325mg Uncoated Tablets	
	Paracetamol IP 500mg/325mg +Levocetrizine HCl IP 2.5mg/5mg +Phenylephrine HCL IP 5mg/5mg +Ambroxol HCl IP 60mg/30mg Tablets	
4	LevoCetrizine Hcl IP 2.5mg +Ambroxol Hcl IP 30mg +Phenylpherine Hcl IP 5mg +Paracetamol IP 250mg per 5ml Suspension	
5	Paracetamol IP 325mg + Chlorpheniramine Maleate IP 2mg +Phenylephrine HCl IP 5mg Tablets	The strength of Paracetamol appears inadequate to take care of headache, body ache or fever as claimed by the manufacturers in the indication. Necessary correction may be made in this regard. However, it was also observed that the indications presented in the applications submitted and those at the time of presentations were discrepant. **Safety & Efficacy**: 1. In all the FDCs as referred to, no comments can be made on their safety or efficacy, since no data are readily available. Some manufacturer's submitted some feedback from prescribers on safety and effectiveness which on closer scrutiny were found to be of very poor quality and could not be acceptable. 2.Nevertheless, the committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large.
	Paracetamol IP 325mg +Phenylephrine HCl IP 5mg +Chlorpheniramine Maleate IP 2mg Solid Oral/Tablets	
	Phenylephrine hydrochloride 5 mg + chlorpheniramine maleate 4 mg + paracetamol 325 mg uncoated tablet	
	Paracetamol 325mg +Phenylephrine HCL 10mg +Chlorampheniramine Maleate 2mg uncoated Tablet	

		3.Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. **The whole of the above exercise for protocol submission should be completed within 3 months.**
	Paracetamol 250mg +Phenylephrine HCL 2.5mg +Chlorampheniramine Maleate 1mg uncoated dispersible Tablet	The dosage form (dispersible tablet) does not accommodate the specific dosing need for the wide age range of children in which the product is being promoted. The committee recommends the manufacturer should be asked forthwith to 1. reconsider the rational basis of their formulations and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. **The whole of the above exercise for protocol submission should be completed within 3 months.**
6	Acebrophylline 50mg +Guaiphenesin IP 50mg +Terbutaline Sulphate IP 1.25mg per 5ml Syrup Terbutaline Sulphate 1.25mg +Acebrophylline 50mg +Guaiphenesin 50mg per 5 ml Syrup	The committee recommended the FDC for symptomatic treatment of cough associated with COPD. However the committee felt that no comments can be made on their safety or efficacy, since no data are readily available. The committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted with the committee and with their concurrence the study may be recommended. **The whole of the above exercise for protocol submission should be completed within 3 months.**
7	Acebrophylline 200mg +Montelukast Sodium IP 10mg +Desloratadine 5mg Film Coated Bilayered Tablets	The committee recommended the FDC for bronchial asthma. However the committee felt that no comments can be made on their safety or efficacy, since no data are readily available.

		The committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted with the committee and with their concurrence the study may be recommended. **The whole of the above exercise for protocol submission should be completed within 3 months.**
8	Acebrophyllline 200mg +Montelukast Sodium IP eq. to Montelukast 10mg Tablets	The committee recommended the FDC for patients with chronic bronchial asthma not adequately controlled with ICS & LABA. However the committee felt that no comments can be made on their safety or efficacy, since no data are readily available. The committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted with the committee and with their concurrence the study may be recommended. The whole of the above exercise for protocol submission should be completed within 3 months.
9	Acetaminophen 125mg +Guaiphenesin 25mg +Dextromethorphan Hydrobromide 7.5mg + Phenylepherine HCl 5g +Chlorpheniramine Maleate 1mg per 5 ml Syrup	The manufacturer did not turn up for the presentation. However the committee observed the following: 1. The product combines expectorants and cough suppressants. Thus the product does not target an identifiable patient group. The medical rationale for combining the actives is insufficient. 2. **Safety & Efficacy**: The committee felt that no comments can be made on safety or efficacy, since no data are readily available. 3. Nevertheless, the committee also takes note of the fact, the FDC is in the market for quite some . 4. Therefore, in fine, the committee recommends the

		manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulation and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. **The whole of the above exercise for protocol submission should be completed within 3 months.**
10	Acetaminophen 500mg +Phenylephrine HCL 10mg +Chlorpheniramine Maleate 2mg +Caffeine 30mg Tablet Caffeine (Anhydrous) IP 30mg +Paracetamol IP 325mg +Phenylephrine HCl IP 2.5mg +Chlorpheniramine Maleate IP 2mg Uncoated tablet Caffeine IP 30mg +Chlorpheniramine Maleate IP 2mg +Paracetamol IP 500mg +Phenylephrine HCl IP 5mg Uncoated Tablets Chlorpheniramine Maleate IP 2mg +Phenylephrine HCl IP 5mg +Paracetamol IP 325mg +Caffeine Anhydrous IP 30mg Uncoated Tablets paracetamol 325mg + phenylephrine HCL 10 mg+ chlorpheniramine Maleate 2 mg + caffeine 30 mg tablets paracetamol 500 mg + phenylephrine hydrochloride 10 mg + caffeine 30 mg + chlorpheniramine maleate 2mg uncoated tablet .Paracetamol IP 500mg +Chlorpheniramine Maleate IP 2mg +Phenylephrine HCl IP 5mg +Caffeine IP 16 mg Uncoated Tablets Paracetamol IP 325mg +Phenylephrine HCl IP 5mg +Caffeine IP 16mg +Chlorpheniramine Maleate IP	The strength of Paracetamol in some cases appears inadequate to take care of headache, body ache or fever as claimed by the manufacturers in the indication. Necessary correction may be made in this regard. However, it was also observed that the indications presented in the applications submitted and those at the time of presentations were discrepant. 1. <u>Safety & Efficacy</u>: In all the FDCs as referred to, no comments can be made on their safety or efficacy, since no data are readily available. Some manufacturers submitted some feedback from prescribers on safety and effectiveness which on closer scrutiny were found to be of very poor quality and could not be acceptable. 2. Nevertheless, the committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. 3. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulations and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. The whole of the above exercise for protocol submission should be completed within 3 months. As regard to Paracetamol IP 325mg +Phenylephrine HCl IP 10mg +Chlorpheniramine Maleate IP 2mg +Caffeine anhydrous IP 30mg Tablets, firm claimed that the FDC is pre-1988 as per IMS Health data and they submitted a paper also

	2mg Uncoated Tablets	in this regard. However adequate evidence shall be provided in this regard for this particular strength, failure of which will attract the above decision. The committee observed that there is a heterogeneity of caffeine dosages in these FDCs. Rationale for the same may be provided.
	Paracetamol IP 325mg +Phenylephrine HCl IP 10mg +Chlorpheniramine Maleate IP 2mg +Caffeine anhydrous IP 30mg Tablets	
	Paracetamol IP 325mg +Phenylephrine HCl IP 5mg +Chlorpheniramine Maleate IP 2mg++Caffeine anhydrous IP 30mg Film Coated Tablets	
	Paracetamol IP 325mg +Phenylephrine HCL IP 10mg +Chlorpheniramine Maleate IP 2mg +Caffeine IP 30mg Uncoated tablets	
	paracetamol 325mg + phenylephrine hydrochloride 10 mg + chlorpheniramine maleate 2 mg + caffeine 30 mg uncoated tablet	
	Paracetamol 325mg +Phenylepherine HCl 10mg +Chlorpheniramine Maleate 2mg +Caffeine 30mg Uncoated tablet	
	Paracetamol 500mg +Phenylepherine HCl 5mg +Chlorpheniramine Maleate 2mg +Caffeine 30mg Tablets	
	Paracetamol 500mg/500mg/325mg +Phenylephrine HCL 10mg/10mg/10mg +Chlorpheniramine Maleate 2.5mg/5mg/5mg + caffeine 30mg/30mg/30mg Uncoated tablet	
	Paracetamol 500/500/325/325/325/325/325 mg +Phenylephrine HCL 5/5/5/10/10/10mg +Chlorpheniramine Maleate 2/2/2/4/2/4mg + caffeine 15/20/30/16/30/15mg Tablet	
	Paracetamol 325mg +Phenylphrine HCl IP 10mg +Chlorpheniramine Maleate IP 4mg +Caffeine 20mg Uncoated	

	Tablets Phenylephrine HCl IP 5mg/ 5mg +Chlorpheniramine Maleate IP 2mg/2 mg +Caffeine IP 30mg/20 mg +Paracetamol IP 325mg/325 mg Tablets	
	Day Time tablet (6 tablets) Paracetamol Ip 500 mg+ Phenylephrine HCl 10 mg + caffeine (anhydrous) IP 32 mg film coated tablet. **Night time tablets (3 tablet)** Paracetamol 500 mg+ Phenylephrine HCl 10 mg+ chlorphenirmine Maleate 2 mg film coated tablet	The medical rationale for combining the actives is inadequate and there is absence of pharmacokinetic rationale in using single dose of 2 mg dose of chlorpheniramine per day. **Safety & Efficacy**: 1. The committee felt that no comments can be made on safety or efficacy, since no data are readily available. 2. Nevertheless, the committee also takes note of the fact, the FDC is in the market for quite some . 3. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to 1. reconsider the rational basis of their formulation and make fresh submissions justifying medical rationale, and then 2. to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted before the committee and with their concurrence the study may be recommended. **The whole of the above exercise for protocol submission should be completed within 3 months.**
11	Acetyl Cysteine BP 300mg +Ambroxol HCl IP 30mg Film Coated Tablets Ambroxol HCl IP 30mg +Acetyl-Cysteine USP 300mg Film Coated Tablets Ambroxol Hydrochloride IP 30mg +N-Acetyl L-Cysteine USP 300mg Tablets Acetylcysteine BP 300mg +Ambroxol HCl IP 30mg Uncoated Tablets	The committee recommended the FDC for symptomatic productive cough. However the committee felt that no comments can be made on their safety or efficacy, since no data are readily available. The committee also takes note of the fact, most of such products are in the market for quite some time and the manufacturers besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted with the committee and with their concurrence the study may be recommended. **The whole of the above exercise for protocol submission**

		should be completed within 3 months.
12	Acetylcysteine 300mg + Ambroxol Hydrochloride 60 mg hard gelatin capsules	The committee recommended the FDC for symptomatic productive cough. However the committee felt that no comments can be made on their safety or efficacy, since no data are readily available. The committee also takes note of the fact, FDC is in the market for quite some time and the manufacturer besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted with the committee and with their concurrence the study may be recommended. **The whole of the above exercise for protocol submission should be completed within 3 months.**
13	Montelukast sodium 10 mg + levocetrizine dihydrochloride 5mg + ambroxol hydrochloride 60 mg film coated Tablet Montelukast Sodium IP 10mg +LevoCetrizine Dihydrochloride IP 5mg +Ambroxol HCl IP 75mg Uncoated Bilayered Tablets Montelukast Sodium 10mg +LevoCetrizine HCl IP 5mg +Ambroxol HCL IP 75mg Uncoated Tablets LevoCetrizine HCl 5mg +Montelukast Sodium IP eq. to Montelukast 10mg +Ambroxol HCl IP 75mg Tablets	The committee recommended the FDC for allergic rhinitis with co- morbid asthma. However the committee felt that no comments can be made on their safety or efficacy, since no data are readily available. The committee also takes note of the fact, FDC is in the market for quite some time and the manufacturer besides other things have argued in favor of better patient adherence and general acceptance by prescribers at large. Therefore, in fine, the committee recommends the manufacturers should be asked forthwith to generate credible safety and efficacy data for specific indication(s) following well designed scientific study protocol. Such protocols should be submitted with the committee and with their concurrence the study may be recommended. The whole of the above exercise for protocol submission should be completed within 3 months.

The expert committee deliberated the following proposals on **04.06.14** and recommended the following:

Agenda no.	Drug	Recommendation
1	Each Kit contains 3 tablets of Serratiopeptidase (enteric coated 20000 units) IP 10mg +Diclofenac Potassium BP 50mg & 2 tablets of Doxycycline HCL IP 100mg	The committee opined that co-pack containing an antibiotic and anti-inflammatory agent is not justified. Further the firm was also not able to produce any published literature with respect to the proposed co-pack. Hence, the committee did not recommend.
2	Aceclofenac 100mg + paracetamol 325 mg + thiocolchicoside 4 mg film coated tablet	The committee noted that this FDC is already marketed in the country. The concomitant use of anti-inflammatory, analgesic and muscle relaxants are required in certain musculo-skeletal conditions for short term use in adults. As these are already being marketed and no ADR has been reported so far, the committee opined that, the firm's shall generate data through phase-4 trial with in a one year and accordingly protocol shall be submitted within 3 months. This committee also opined that no new manufacturer should be allowed for manufacturing this FDC, till the safety and efficacy data through phase – 4 trial is generated and submitted for review. The committee was also apprised that no new FDC of already existing FDC's in the market should be licensed by any State Licensing Authority (SLA) to any new manufacturer after 01.10.2012.
	aceclofenac 100 mg + paracetamol 325 mg + thiocolchiside 4 mg/8 mg film coated tablet	
	Aceclofenac 100mg/100mg +Paracetamol 325mg/325mg +Thiocolchicoside 4mg/8mg Film coated Tablet	
	Aceclofenac 100mg/100mg +Paracetamol 325mg/325mg +Thiocolchicoside 4mg/8mg Film coated Tablets	
	Aceclofenac 100mg +Paracetamol 325mg +Thiocolchicoside 8mg Film Coated Tablets	
	Aceclofenac 100mg +Paracetamol 500mg +Thiocolchicoside 4mg/8mg Film Coated Tablets	
	Aceclofenac 100mg +Parcetamol 325mg +Thiocolchicoside 4mg/8mg Film coated Tablets	
3	Aceclofenac IP 200 mg (In extended release form) + Rabeprazole sodium 20 mg (in delayed release form) uncoated Tablet	As the FDC is already approved in the capsule form, the committee recommended that BE study shall be conducted and report shall be produced before the committee.
4	Aceclofenac IP 100mg +Paracetamol IP 325mg +Rabeprazole Sodium IP 10mg (in Enteric Coated form) Film coated tablets	The committee noted that aceclofenac + Paracetamol & aceclofenac + rabeprazole is already approved by the DCG(I) earlier. The Rabeprazole is used for prevention of aceclofenac induced gastritis and hence its use in three drug combination is justified. As these are already being marketed and no ADR has been reported so far, the committee opined that, the firm's shall generate data through phase-4 trial with in a one year and accordingly protocol shall be submitted within 3 months. This committee also opined that no new manufacturer should be allowed for manufacturing this FDC, till the safety and efficacy data through

		phase – 4 trial is generated and submitted for review. The committee was also appraised that no new FDC of already existing FDC's in the market should be licensed by any State Licensing Authority (SLA) to any new manufacturer after 01.10.2012.
5	Drotaverine HCl IP 80mg + Clidinium Bromide USP 2.5mg + Chlordiazepoxide IP 5mg Film Coated Tablets	There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend.
6	Lornoxicam 8mg +Paracetamol IP 325mg +Serratiopeptidase IP 15mg Tablets(30,000 units of serratiopeptidase)	There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend.
	Lornoxicam IP 8mg +Paracetamol IP 325mg +Serratiopeptidase IP 15mg (30,000 unit of serratiopeptidase as enteric coated granules) Film Coated bilayered tablets	
7	Lornoxicam IP 100mg +Paracetamol IP 325mg + Tramadol IP 37.5mg Film Coated tablets	There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend.
	Tramadol hydrochloride 37.5 mg + paracetamol 325 mg + lornoxicam 8 mg film coated bilayered tablet	
8	Lornoxicam 8mg +Paracetamol 325mg +Trypsin-Chymotrypsin 150000 AU of enzyme activity (as enteric coated granules) Film coated Tablets	There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend.
9	Paracetamol IP 300mg +Mefenamic Acid IP 150mg +Ranitidine HCL 100mg +Dicyclomine HCl IP 10mg Tablets	There is no scientific evidence as well as justification for use of this combination. Hence the committee did not recommend.
10	Tramadol HCl 37.5 mg + paracetamol 325 mg + dicyclomine HCl 10 mg Hard gelatin capsules	The committee opined that you should submit the supporting data of each of the ingredient for each of the indication and also for the combination. If data in support of concomitant use of the three drugs in these indications is found satisfactory, the firm is required to generate the clinical data.
	Tramadol HCl 37.5mg +Dicyclomine HCl 20mg +Paracetamol IP 500mg Uncoated Tablets	
	Dicyclomine hydrochloride 10 mg/20 mg + tramadol hydrochloride 50 mg/ 37.5 mg + Acetaminophen 325 mg/325 mg hard gelatin capsule	
11	Naproxen 300mg/550mg +Paracetamol IP 325mg Film Coated Tablets	There is no scientific justification, the only published literature of this combination has used Paracetamol 4g/day which is much higher than the proposed dose in the FDC. Hence, the committee

		did not recommend.
12	Tapentadol 50mg +Paracetamol 325mg film coated Tablets	The firm did not turn up for the presentation. The committee noted that the proposal had already been discussed in NDAC on 17.03.2012 and the committee agreed with the recommendations of the NDAC. Hence the committee did not recommend.

The expert committee deliberated the following proposals on **11.06.14** and recommended the following:-

Agenda no.	Drug	Recommendation
1	Azithromycin 125mg/250mg/500mg + Cefixime 100mg/200mg/200mg Tablets	This FDC is not a standard antibiotic combination. This is not the first line combination to be used in any clinical condition and there is no published scientific data in combining this two drugs. Also in the NDAC meeting held on 23.08.2013, it was observed that misuse potential of this FDC is very high. Although the FDC may be useful for certain population of patients of multi-drug resistant typhoid fever or moderate to severe lower respiratory tract infections, the misuse potential is very high which will cause antimicrobial drug resistance. The firms did not produce any data on pharmacokinetic and pharmacodynamic interaction as well as safety & efficacy of the FDC. This FDC is also not approved anywhere in the world. Hence it is not recommended for approval.
	Cefixime (As Trihydrate) IP 200mg +Azithromycin Drihydrate IP 250mg Film Coated Tablets	
	Cefixime 200/200mg + azithromycin 250/500mg Tablet	
	Cefixime Trihydrate IP 200mg +Azithomycin Dihydrate IP 500mg Film Coated tablets	
	Cefixime Trihydare 100mg +Azithromycin Dihydrate 125mg Uncoated bilayered Dispersible tablets	
	Azithromycin (as Dihydrate) 250mg/500mg +Cefixime(as Trihydrate) 200mg/200mg Film coated Tablets	
2	Cefixime IP (as trihydarte) eq. to anhydrous Cefixime 200mg +Acetyl Cysteine USP 300mg Film Coated Tablets	The firm did not turn up for presentation. Cefixime is an antibiotic and acetyl cysteine is a mucolytic agent. The safety & efficacy data along with the regulatory status in other countries shall be ascertained from the company for further deliberation in the next meeting.
3	Cefixime IP as Trihydrate eq. to anhydrous Cefixime 400mg +levofloxacin Hemihydrate IP eq. to Levofloxacin 500mg Film coated Tablets	Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) guidelines do not mention treatment with this FDC in outpatient management of CAP. Further the firm also did not present any data on safety and efficacy of FDC and

		the FDC is not approved anywhere in the world. Hence, the committee did not recommend for approval.
4	Cefpodoxime Proxetil IP 200mg +Azithromycin Dihydrate IP 250mg Film Coated tablets	Infectious Disease Society of America (IDSA)/ American Thoracic Society (ATS) recommends the combination of B-lactam + Macrolide for the treatment of community acquired pneumonia and cefpodoxime has been mentioned as one of the B-lactams. However, the dosage of Azithromycin is 500 mg on day one followed by 250 mg once daily for 4 days while cefpodoxime has to be given 200 mg twice daily for 7 days. Therefore, there is a mismatch in the dosage schedule of Cefpodoxime + Azithromycin. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the FDC for CAP is not recommended for approval. In gonorrhea, the recommended dose is either azithromycin 1g as single dose or cefpodoxime 400 mg single dose. Therefore the proposed FDC is not recommended for approval.
	Cefpodoxime Proxetil 200mg +AzithromycinDihydrate 250mg Film Coated Tablets	
	Cefpodoxime 200 mg +Azithromycin 500mg Film coated Tablets	
	Cefpodoxine proxetil 200mg +Azithromycin Dihydrate 250 mg film coated tablet	
	Azithromycin Dihydrate IP eq. to Azithromycin 250mg/500mg +Cefpodoxime Proxetil IP eq. to Cefpodoxime 200mg Film Coated tablets	
5	Cefpodoxine proxetil 200 mg + levofloxacin hemihydrate 250 mg Film coated tablets	IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. Further firm also did not present any data on safety and efficacy of FDC and the FDC is not approved anywhere in the world. Although concomitant therapy of two drugs may be required in some patients of CAP however there is no dose compatibility. It was observed that misuse potential of this FDC is very high which will cause antimicrobial drug resistance. Hence, the committee did not recommend for approval.

6	Levofloxacin 250mg/500mg +Azithromycin 250mg/500mg Film coated Tablets	IDSA/ATS guidelines does not mention treatment with this FDC in outpatient management. **The guidelines recommends the use of** levofloxacin alone in out patient management of CAP. Hence the committee did not recommend for approval. Levofloxacin is not recommended for MDR typhoid fever, in any of the recommended treatment guidelines. Hence this FDC is not recommended for approval in MDR typhoid fever.
	Azithromycin Dihydrate 250mg/500mg + Levofloxacin Hemihydrate 250mg/500mg Tablets	
	Azithromycin 250 mg/500 mg + Levofloxacin Hemihydrate 250 mg/500 mg film coated tablet	
	Azithromycin 250mg/500mg +Levofloxacin 250mg/500mg Film coated Tablets	
7	Beclomthasone Dipropionate 0.025%w/v + Clotrimazole 1%w/v + Chloramphenicol 5%w/v +Gentamycin Sulpahte 0.3%w/v + Lignocaine HCl 2%w/v Ear Drops	The firm did not turn up for presentation. The firm has also not submitted specific justification for use of corticosteroid with two antibiotics, one antifungal and one local anesthetic in FDC for proposed indication. Further safety & efficacy data is also not submitted by the firm and therefore the committee did not recommend for approval.
8	Ciprofloxacin HCl IP 250mg +Phenazopyridine HCl USP 200mg Film Coated Tablets	Ciprofloxacin is an antibiotic and phenazopyridine is urinary analgesic for symptomatic relief. Normally ciprofloxacin is used for 5 to 7 days but phenazopyridine is not recommended for more than 2 days due to its serious side effects. Hence, this combination is not rational and the committee did not recommend for approval.
9	Roxithromycin IP 150mg +Serratiopeptidase 10mg eq to 20000 units (as enteric coated granules) Film Coated Tablets	The firm did not turn up for presentation. Roxithromycin is an macrolide antibiotic and serratiopeptidase is an proteolytic enzyme having anti-inflammatory effects. The standard treatment guidelines do not recommend such a combination. Hence the committee did not recommend for approval.

The expert committee deliberated the following proposals on 22.08.14 and recommended the following:

S.No.	Name of FDC & Firm	Recommendations
1	Octinoxate 7.5 % w/w + avobenzone 3.0 % w/w + oxybenzone 3 .0 % w/w + zinc oxide 2.0 % w/w topical lotion	The committee opined that firm shall document the duration of the effect as claimed, by way of generating the evidence in at least 200 subjects. The firm may be asked to submit the protocol accordingly, within 3 months before the committee.
	Octinoxate USP 7.5%w/w +Avobenzone USP 2%w/w +Oxybenzone USP 3%/w/w +Processed Zinc Oxide 2%w/w Topical Gel	
2	Acriflavine HCl 0.12gm +Thymol 5.00mg +Cetrimide 0.50gm Cream	Firm could not present any supporting data in respect of the rationality of the FDC. Moreover, the FDC is also not approved anywhere in the world. Hence, the committee did not recommend.
3	Allantoin BP 0.25%/w/w +Vitamin-E Acetate 0.25w/w +Tea tree oil 0.50%w/w Medicated Soap	The firm did not turn up for presentation. The committee opined that the proposed medicated soap will not provide any additional therapeutic benefit in soap form over individual ingredients. Further, there is no rationality also in combining these ingredients and presenting in a soap form for using as a cleansing agent for pimple prone skin as claimed by the firm. Hence the committee did not recommend.
4	Allantoin BP 0.20%w/w +Vitamin-E Acetate 0.25%w/w +Tea tree oil 0.25%w/w +Titanium Dioxide IP 0.50%w/w Medicated Soap	The firm did not turn up for presentation. The committee opined that the proposed medicated soap will not provide any additional therapeutic benefit in soap form over individual ingredients. Further, there is no rationality also in combining these ingredients and presenting in a soap form for using as a cleansing agent for pimple prone skin as claimed by the firm. Hence the committee did not recommend.
5	Allantoin 0.2%w/w +Dimethieone 1.0%w/w +Urea 10.0%w/w +Propylene 5.0%w/w +Glycerin 5.0%w/w +Liquid paraffin 8.0%w/w Cream	Firm did not turn up for presentation. The FDC is not rational as ingredients present in the FDC have antagonistic functions. Further, there are no supporting documents to prove that the FDC is rational for the proposed indication. Hence, the committee did not recommend.
6	Clindamycin Phosphate BP eq. to Clindamycin 100mg +Clotrimazole IP 200mg Vaginal suppository	Committee opined that FDC is rational. However, superiority of the combination over alternative treatment needs to be proven in Indian patients and accordingly protocol shall be submitted within 3 months and study should be completed within 1 year and study data should be presented before the
	.Clotrimazole 200mg +Clindamycin 100mg Vaginal suppository	
	clindamycin phoasphate 100 mg + clotrimazole 200 mg capsule	
	clindamycin phosphate 100 mg +	

	clotrimazole 100 mg soft gelatin vaginal suppository clotrimazole 200 mg + clindamycin 100 mg Extended Release vaginal tablet	committee to decide further.
7	Clindamycin Phosphate BP Eq. to Clindamycin 100mg +Clotrimazole IP 200mg +Lactic Acid Bacillus 1.5 Billion Spores Soft Gelatin veginal	Committee opined that the FDC is not rational. As firm did not present any evidence with regards to its superiority and further drug resistant lactic acid bacillus spores in this combination may spread community drug resistance. Hence, the committee did not recommend.
8	Cyproteron Acetate 2mg +Ethinylestradiol IP 0.035mg +Folic Acid IP 5mg Film Coated Tablets	The committee opined that the FDC is rational. However, the superiority of the combination needs to be proven over FDC of Cyproteron acetate 2mg +Ethinylestradiol 0.035mg Film coated tablet. Accordingly protocol shall be submitted within 3 months and study should be completed within 1 year and study data should be presented before the committee to decide further.
9	Cyproteron acetate 2mg +Ethinylestradiole 0.035mg Film coated tablet	The committee recommended for the manufacturing & marketing of the FDC for polycystic ovarian syndrome only.
10	1.MiconazoleNitrate 2.0%w/w +Fluocinolone Acetonide 0.01%w/w lotion Miconazole Nitrate IP 2%w/w +Flucinolone Acetonide IP 0.01%w/w Cream Miconazole Nitrate IP 2.00%w/w +Fluocinolone Acetonide IP 0.01%w/w Ointment Miconazole Nitrate IP 2%w/w +Fluocinolone Acetonide IP 0.01%w/w Cream Miconazole nitrate 2.00%w/w +Fluocinolone acetonide 0.01%w/w cream Miconazole Nitrate 2%w/w +Fluocinolone Acetonide 0.01%w/w	The firm(s) presented before the committee. The committee opined that the FDC in the form of lotion & cream is useful in Candidal intertrigo and seborrhoeic dermatitis alone. The committee did not recommend for other applied indications. Further, the committee opined that the FDC in ointment form is not useful and may not uniformly provide the actual amount of drug due to lack of spreadability. Hence, the committee did not recommend for manufacturing & marketing in the ointment form.

	+Methyl Paraben 0.15%w/w Cream	
11	Fluocinolone Acetonide 0.025%w/w +Miconazole Nitrate 2.0%w/w +Neomycin Sulphate 0.5%w/w Cream	This is a FDC of steroid, aminoglycoside & anti-fungal which is not justified and no evidence is available that this FDC will be more beneficial or superior to the individual ingredients. The patients will be over exposed to unnecessary medication. Hence, the committee did not recommend.
12	Fluocinolone Acetonide 0.01%+Neomycin sulpahte 0.5%+Clotrimazole 1.0% topical cream	The firm did not turn up for presentation. This is a FDC of steroid, aminoglycoside & anti-fungal which is not justified and no evidence is available that this FDC will be more beneficial or superior to the individual ingredients. The patients will be over exposed to unnecessary medication. Hence, the committee did not recommend.

The expert committee deliberated the following proposals on 27.08.14 and recommended the following:

S.No.	Name of FDC & Firm	Recommendations
1.	Benfothiamine 75mg +Metformin HCl 500mg Tablets Benfotiamine 75 /100 mg + metformin HCl 500 mg film coated tablets Metformin HCl 500mg +Benfotiamine 75mg Tablets	The committee noted that the proposed FDC was also discussed earlier by NDAC on 06.10.2012. There is not enough published data particularly in the human subjects regarding the efficacy. The data presented by the firm(s) has been examined scientifically and firm has presented only animal study data. The firm fails to present clinical data about synergistic effect of this FDC over other drugs present in FDC. Moreover no scientific publication recommends this combination. This combination is also not approved anywhere in the world. Hence the committee did not recommend for the manufacturing and marketing of this FDC.
2.	Glibenclamide IP 5mg +Metformin HCl IP 850mg Uncoated Tablets Metformin HCl 800mg +Glibenclamide 5mg uncoated Tablets	The committee noted that FDC of Glibenclamide IP 5mg +Metformin HCl IP 850mg (SR) is already approved. The firm(s) was unable to present any scientific data/evidence in favour of Glibenclamide IP 5mg +Metformin HCl IP 850mg (IR). Also the FDC of Glibenclamide IP 5mg +Metformin HCl IP 800mg (IR) was also discussed by the committee and the committee opined that there is no unmet need for both the proposed strengths. Hence the committee did not recommend.
3.	Glibenclamide+MetforminHCl+ Pioglitazone HCl 5mg+500mg+7.5mg film coated Tablets	The usual dose of pioglitazone is 15 mg. Firm presented two studies, one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. The Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Hence the proposed FDC is not recommended.
4.	Gliclazide 80 mg + metformin hydrochloride 500 mg uncoatedTablets Gliclazide 40mg +Metformin HCl 500mg uncoated Tablets Metformin HCl 500mg +Gliclazide 80mg uncoated Tablet	The immediate release form of Gliclazide & metformin are already in use and they can be used maximum upto the dosage of metformin 2g per day in divided doses and gliclazide 320 mg in divided doses. The present proposals of FDC of 40mg gliclazide /500mg of metformin and 80mg gliclazide /500mg of metformin will not exceed the total daily dose of either of the drugs. Hence the committee recommended for the manufacturing & marketing of the proposed strengths of FDC.
5.	Glimepiride 3mg/4 mg + Metformin hydrochloride 1000/1000 mg tablets () Glimepiride IP 2mg + Metformin HCl (ER) 850mg Film Coated Tablets () Glimepiride IP 3mg/4mg	The NDAC in the meeting held on 6.10.12 examined the issue of combination of Glimepiride + Metformin in various strengths. The committee opined that the Glimepiride 1mg/2mg + Metformin 500/500mg SR, and Glimepiride 1mg/2mg + Metformin 1000/1000mg SR, already approved in the country which meets the requirement of majority of patients. And further permutation of the combination of this

	+Metformin .HCl IP 1000mg (ER) Uncoated Bilayered tablet	FDC will lead to confusion, prescription error, dispensing error and increased risk of hypoglycemia. The committee also noted that DCG (I) has already approved Glimepiride 0.5mg + Metformin hydrochloride 500 mg tablets on 20.01.2014. This committee concurs with the previous comments of NDAC and reiterates that no additional strengths of the combination of glimepiride and metformin is required. Hence the committee did not recommend the proposed strengths of the FDC.
	Glimepiride IP 1mg/2mg +Metformin HCl (as sustained release) 500mg/500mg Tablets	
	Glimepiride IP 2mg +Metformin HCl IP 500mg Uncoated Tablets	
	Glimepiride 1mg/2mg/3mg +Metformin HCl 850mg/850mg/850mg (SR) uncoated bilayered Tablets	
	Glimepiride 4mg +Metformin HCl SR 1000mg uncoated bilayered tablet	
	Metformin hydrochloride 500mg(SR) + glimepiride 0.5 mg uncoated bilayered tablet	
6.	Glimepiride IP 1mg/2mg +Pioglitazone HCl IP 7.5mg/7.5mg +Metformin HCl IP 500mg/500mg (SR) uncoated bilayered Tablets	The usual dose of pioglitazone is 15 mg. Firm(s) presented two studies one Indian study of pioglitazone 7.5 mg with other Oral hypoglycemic drugs and Japanese study of comparison of 7.5 mg of pioglitazone with15 mg of pioglitazone. The scientific evidence from both the studies is not enough to justify 7.5 mg dose of pioglitazone in FDC. Committee also opined that there is no sufficient pharmacokinetic and pharmacodynamic data. Further the committee also noted that the proposed FDC in proposed strengths has already been deliberated by NDAC on 22.08.2012 and NDAC did not recommend the FDC. This committee also endorsed the comments of the NDAC and did not recommend. Moreover the firm(s) also did not present any additional data to counter the comments of NDAC made on 22.08.2012. However, the proposal for Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets is already approved by DCG(I) on 16.08.2005 and hence this strength was not deliberated.
	Glimepiride IP 1mg/2mg +Pioglitazone HCl IP 7.5mg/7.5mg +Metformin HCl IP 500mg/500mg (SR) unoated bilayered Tablets	
	Glimepiride 1mg/2mg + pioglitazone hydrochloride 7.5mg/7.5 mg + metformin hydrochloride 1000 mg/ 1000 mg (SR) uncoated bilayered tablets	
	Glimepiride 1mg/2mg + pioglitazone hydrochloride 7.5mg/7.5 mg + metformin hydrochloride 850 mg/ 850 mg (SR) uncoated bilayered tablets	
	Metformin HCL 1000/1000/500/500mg(SR) +Pioglitazone HCL7.5/7.5/7.5/7.5mg + Glimepiride 1/2/1/2mg(as micronized) uncoated bilayered Tablets	
	Metformin HCL 500mg (SR)+Pioglitazone HCL 7.5mg/7.5 mg + Glimepiride 1mg/2mg uncoated bilayered Tablets	

	Metformin HCl 500mg +Pioglitazone HCl 7.5mg +Glimepiride 1mg Tablets	
	7.Metformin HCl 850mg (ER) +Pioglitazone 7.5mg +Glimepride 2mg uncoated bilayered Tablets	
	Pioglitazone HCl 15mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg Tablets	
	Pioglitazone HCl 7.5mg +Metformin HCl 500mg(SR) +Glimepiride 1mg/2mg uncoated bilayered Tablets	
7.	Glipizide IP+Metformin HCl IP 2.5mg+400mg tablet	The firm could not present any scientific data with respect to the proposed strength of FDC. The committee opined that the proposed strength is not going to add any benefit to the patient over the already approved strengths of the FDC. Hence the committee did not recommend.
8.	Mecobalamin JP 750mcg +Metformin HCl IP 500mg/1000mg(SR) Film Coated Tablets ()	The committee noted that the FDC is covered under 294 category and the matter is subjudice.
	Metformin HCl IP 500mg/1000mg(SR) +Methylcobalamin 750mcg/1500mcg JP uncoated bilayered Tablets	
	Metformin HCl IP 500mg(SR) +Methylcobalamin JP 500mcg Uncoated Tablets	
	Metformin HCl IP 1000mg(SR) +Methylcobalamin JP 750mcg Film Coated Tablets	
	Methylcobalamin 750 mcg/750 mg/1550 mcg + metformin HCL 500 mg/1000 mg/1000mg(SR) film oated bilayered tablets ()	
9.	Metformin HCl ER 1000mg +Gliclazide MR 60mg +Voglibose 0.2mg uncoated bilayered tablet	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.
10.	Metformin HCl IP SR 1000mg +Atorvastatin Calcium IP 20mg Film Coated Tablets	The committee opined that there is no advantage of proposed fixed dose combination of atorvastatin and metformin. The dose of atorvastatin depends on the clinical condition and risk factors and accordingly, the dose may range from 10 mg to 80 mg. So the FDC will not be useful in titration of doses. Hence the committee did not recommended the proposed strength.

The expert committee deliberated the following proposals on 05.09.14 and recommended the following:

S.No.	Name of FDC	Recommendations
1.	Magnesium hydroxide 98 mg + Aluminium hydroxide 0 .291 mg (added as Aluminium hydroxide paste + Oxetacaine 10 mg per 5 ml oral liquid	Committee noted that combination formulations containing L-Oxetacaine, Aluminium Hydroxide and Magnesium Hydroxide was approved by DCG (I) in June 1966. The firms made a detailed presentation before the committee. The FDCs under consideration have been in the market for a considerable period and they contain the same ingredients as the DCG (I) approved FDCs. Committee recommended the proposed FDC for dyspepsia and related symptoms and the product shall not be used for more than seven days.
	Dried aluminium hydroxide gel 300 mg + magnesium hydroxide 100 mg + Oxetacaine 10 mg Liquid suspension	
	Oxetacaine 10mg +Aluminium Hydroxide 0.291mg +Magnesium Hydroxide 98 mg per 5 ml Oral Suspension	
	Dried Aluminium hydroxide gel 150 mg +magnesium hydroxide 150 mg + Oxetacaine 5 mg per 5 ml suspension	
	Oxetacaine BP 10mg +Aluminium Hydroxide eq. to dried Aluminium Hydroxide Gel IP 0.291gm eq. to 0.380gm (added as Aluminium Hydroxide Paste) +Magnesium Hydroxide IP 98mg (added as Magnesium Hydroxide Paste) per 5 ml Suspension	
2.	Aluminium hydroxide paste 250mg +Magnesium hydroxide paste 250mg +Simethicone 50mg +Oxetacaine 10mg per 5 ml Oral suspension	Committee noted that the FDC of Dried Aluminium Hydroxide Gel IP 600mg +Magnesium Hydroxide IP 300mg + Simethicone IP 25mg +Oxetacaine BP 10mg per 5ml Suspension was approved in 2010 by DCG(I). The FDCs under consideration have been in the market for a considerable period and they contain the same ingredients as the DCG (I) approved FDCs. Committee recommended the proposed FDC for dyspepsia and related symptoms and the product shall not be used for more than seven days.
	Aluminium hydroxide paste 250 mg + Magnesium hydroxide Paste 250 mg + Simethicone 50mg +Oxetacaine 10mg per 5 ml Suspension	
3.	Alginic Acid 200mg +Sodium Bicarbonate 70mg +Dried Aluminium Hydroxide	The committee opined that internationally there is no authentic

	300mg +Magnesium Hydroxide 150mg uncoated Tablets	reference for inclusion of sodium bicarbonate in a combined antacid formulation. Sodium bicarbonate is a systemic alkalinizer and not a locally acting antacid. There is risk of systemic adverse effects on chronic use of such products. Hence the committee did not recommend such FDC.
	Alginic Acid 200mg +Sodium Bicarbonate 70mg +Dried Aluminium Hydroxide 150mg +Magnesium Hydroxide 75mg Chewable uncoated Tablets	
4.	Each ml Contains Activated Dimethicone IP 40mg +Dill Oil BP 0.005ml +Fennel Oil 0.0007ml Oral Liquid	The committee opined that there is no data presented by the firm for use of all three ingredients (Activated Dimethicone IP +Dill Oil BP +Fennel Oil) in combination. The committee observed that the concerned firms may be asked to conduct appropriately designed RCTs (Randomised Controlled Trials) to generate evidence for efficacy and safety. Accordingly, protocol shall be submitted within 3 months and Clinical trial shall be completed within 18 months. Decision on continued marketing of this FDC will be taken based on the outcome of Clinical trial.
	Each ml Contains Dill Oil 0.005ml +Fennel Oil 0.0007ml +Simethicone Emulsion USP 40mg Oral Liquid	
	Each ml Contains Dimethicone IP 40mg +Dill oil BP 0.005ml +Fennel oil USP 0.0007ml Syrup	
	Each ml Contains Simethicone emulsion 40 mg + fennel oil 0.007 ml + Dill oil 0.005 ml drop suspension	
	Each ml Contains Simethicone Emulsion USP eq. to Simethicone USP 40mg +Dill Oil BP 0.005ml +Fennel oil USP 0.0007ml Oral Drops.	
	Each ml Contains Simethicone emulsion 40mg +Dill oil 0.005ml +Fennel oil 0.0007 ml Coligo drops	
	Each ml Contains Simethicone 40mg +Dill Oil 0.005ml +Fennel oil 0.0007ml Oral Liquid	
5.	Activated Dimethicone IP 50mg +Magnesium Hydroxide IP 250mg +Dried Aluminium Hydroxide Gel IP 250mg +Sorbitol Solution 1.25gm per 5 ml Suspension	Committee was not in favour of FDCs with sorbitol as one of the ingredients, as sorbitol (particularly in last few years) has been shown to exacerbate the symptoms of functional gastrointestinal disorders and sorbitol restriction is advised in the patients suffering from these diseases as per published data. Hence the committee did not recommend its inclusion in these FDCs.
	Activated Dimethicone 50mg+Magnesium Hydroxide 250mg +Dried Aluminium Hydroxide 250mg +Sorbitol Solution (70%) Non-Crystallizing 0.650gm Oral Liquid	
	Aluminium Hydroxide Paste IP 300mg +Magnesium Hydroxide Paste IP 200mg +Activated Dimethicone IP 125mg +Sorbitol Solution 750mg per 5 ml Syrup	

	Aluminium Hydroxide paste 300mg +Magnesium hydroxide paste 250mg +activated dimethicone 40mg + Sorbitol solution 1000mg per 5 ml liquid oral	
6.	Activated Simethicone IP 40mg +Magnesium Hydroxide IP 400mg as magnesium Hydroxide paste + Dried Aluminium Hydroxide Gel as dried Aluminium Hydroxide paste IP400mg per 5 ml Suspension)	One of the firm claimed that FDC of Dried Aluminium Hydroxide BP 300mg + Magnesium Hydroxide BP 150mg + Simethicone BP 40mg Uncoated Tablets /Suspension is licensed Pre 1988, therefore, firm shall submit appropriate evidences in this regard to the office of DCG(I). As regard to FDC of Simethicone 50.0mg +Dried Aluminium Hydroxide Gel 250.0mg +Magnesium Hydroxide 250.0mg per 10 ml Suspension, Committee opined that the strengths of the ingredients seem to be too low to produce any therapeutic benefit. In the absence of hard evidence, such FDCs may not be recommended. Rest of the formulations in the proposed strengths may be recommended.
	Aluminium hydroxide Paste 250mg +Magnesium hydroxide Paste 250mg +Simethicone IP 50mg per 5 ml Oral Suspension	
	Aluminium hydroxide 250mg + magnesium hydroxide 250mg + Simethicone 50 mg per 5 ml suspension	
	Dried Aluminium Hydroxide BP 300mg +Magnesium Hydroxide BP 150mg +Simethicone BP 40mg Uncoated Tablets/Suspension	
	Simethicone 50 mg + magnesium hydroxide gel 250 mg + Aluminium hydroxide gel 250 mg per 5 ml suspension.	
	Simethicone 50.0mg +Dried Aluminium Hydroxide Gel 250.0mg +Magnesium Hydroxide 250.0mg per 10 ml Suspension	
7.	Alpha Amylase (1:2000) 10mg +Papain 20mg per 5 ml Syrup	Committee opined that in the absence of hard data in respect of safety and efficacy of the product, the firms may be asked to generate evidence by way of conducting randomized controlled Clinical trials. Accordingly, protocol shall be submitted within 3 months and Clinical trial shall be completed within 18 months. Decision on continued marketing of this FDC will be taken based on the outcome of Clinical trial.
	Alpha Amylase IP (1:800)100mg +Papain IP 50mg Syrup per 5 ml	
	Fungal Diastase IP 50mg +Papain IP 10mg Syrup per 5 ml	
	Fungal Diastase IP (1:800)12.5mg +Papain IP 7.5mg Syrup per 5 ml	
	Fungal Diastase IP 50mg +Papain IP 60mg Syrup per 5 ml.	
	Diastase IP (1:800)100mg +Papain IP 60mg sugar coated Tablets	
	Fungal Diastase (1:800)IP 50mg +Papain IP 60mg per 5 ml Syrup	
8.	Alpha Amylase (1:800) 50mg +Pepsin IP (1:3000) 10mg Syrup	Committee opined that in the absence of hard data in respect of safety and efficacy of the product, the firms may be asked to generate evidence by way
	A-Amylase (Fungal Diastase 1:800 from Aspergillus oryzae) IP 62.5mg +Pepsin IP	

	20mg Each 10 ml after dissolving the tablet Solution for Oral administration	of conducting randomized controlled Clinical trials. Accordingly, protocol shall be submitted within 3 months and Clinical trial shall be completed within 18 months. Decision on continued marketing of this FDC will be taken based on the outcome of Clinical trial.
	alpha-amylase (1:800) 62.5 mg from Aspergillus oryzae + pepsin 20 mg per 10 ml oral syrup	
	Diastase IP (Fungal Diastase derived from Aspergillus oryzae) (1:1200) 33.33mg + Pepsin IP (1:3000) 5 mg per ml Syrup	
	Diastase IP (1:1200)50mg + Pepsin (1:3000) 10mg per 5ml Oral Liquid	
	Diastase (1:800) 33.33mg +Pepsin (1:3000) 5mg Drops	
	Diastase (1:1200)50mg +Pepsin(1:3000) 10mg Syrup	
	Fungal Diastase (1:1200) IP 50mg +Pepsin (1:3000) IP 10mg per5 ml Syrup	
	Fungal Diastase (1:2500) 62.5mg +Pepsin IP 20mg Oral Liquid	
	fungal diastase (1:1200)50 mg + pepsin (1:3000) 10 mg per5 ml syrup	
	Fungal Diastase IP (1:1200) IP 50mg +Pepsin IP (1:3000) 10mg Hard Gelatin Capsules/ 15 ml syrup	
	Fungal Diastase IP (1:1200) IP 50mg +Pepsin IP (1:3000) 10mg per 5 ml Syrup	
	Fungal Diastase (1:1200) 50mg +Pepsin(1:3000) 10mg Syrup	
	Alpha Amylase IP (1:800) 125mg +Papain IP 40mg Syrup per 10 ml after dissolving the tablet	