

**Recommendations of the SEC (Pulmonary) made in its 68<sup>th</sup> meeting held on 21.03.2023 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/CT/22/000017  Almitrine and Ifenprodil 50mg & 20mg Tablets	CDRI-CSIR	Firm presented the Phase-III clinical trial protocol before the committee.  After detailed deliberation, the committee noted that the applicant has not provided adequate preclinical data / proof of concept for the proposed drugs, rationale for inclusion / exclusion criteria and rationale for the proposed study.  The committee recommended that the applicant should submit above data to CDSCO for further review by the committee.
<b>FDC Division</b>			
2.	FDC/MA/20/000043  Blisatine 10mg + Montelukast 4mg orodispersible tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm did not turn up for presentation.
3.	FDC/MA/22/000187  Fluticasone Furoate 200mcg + Vilanterol 25mcg Powder for inhalation	M/s. Sun Pharma Laboratories Ltd.	As per the condition mentioned in Form CT-23 dated 31.10.2022; the firm presented the active PMS study protocol before the committee. After detailed deliberation, the committee recommended for conducting the active PMS study with following conditions:  1. The follow-up of the study should be up to 06 months.  2. The details of last visit including the test parameters should be mentioned at 06 months accordingly.  3. Telephonic follow up should be done at 4 <sup>th</sup> and 5 <sup>th</sup> month to assess the symptom analysis so as to rule out any worsening or exacerbation.  The result of the study should be presented before the committee for review.
4.	FDC/MA/20/000119  Montelukast Sodium	M/s. Akums	As per the condition mentioned in Form CT-23 dated 09.05.2022; the firm presented the Phase IV clinical trial

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	IP eq. to Montelukast 4mg + Bilastine 410mg oral dispersible tablets		protocol before the committee. After detailed deliberation, the committee recommended for conducting the Phase IV clinical trial.  The result of the study should be presented before the committee for review.
5.	FDC/MA/21/000168  Glycopyrrolate IP 9mcg + Budesonide IP 160mcg + Formoterol Fumarate dihydrate IP eq. to Formoterol fumarate 4.8mcg per actuation delivers inhalation aerosol	M/s. Glenmark Pharmaceuticals Ltd.	As per the condition mentioned in Form CT-23 dated 13.05.2022, firm presented the Phase IV Clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for conducting the Phase IV CT with following conditions:  1. The follow-up of the study should be up to 06 months.  2. The details of last visit including the test parameters should be mentioned at 06 months accordingly.  3. Telephonic follow up should be done at 4 <sup>th</sup> and 5 <sup>th</sup> month to assess the symptom analysis so as to rule out any worsening or exacerbation.  The result of the study should be presented before the committee for review.
6.	FDC/MA/22/000066  Budesonide 400mcg + Glycopyrronium 25mcg + Formoterol Fumarate 12mcg Dry Powder for Inhalation	M/s. Glenmark Pharmaceuticals Ltd.	As per the condition mentioned in Form CT-23 dated 06.07.2022, firm presented the Phase IV clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for conducting the Phase IV CT with following conditions:  1. The follow-up of the study should be up to 06 months.  2. The details of last visit including the test parameters should be mentioned at 06 months accordingly.  3. Telephonic follow up should be done at 4 <sup>th</sup> and 5 <sup>th</sup> month to assess the symptom analysis so as to rule out any worsening or exacerbation.

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			The result of the study should be presented before the committee for review.
7.	FDC/MA/22/000203 Levosalbutamol Sulphate IP eq. to Levosalbutamol 0.25mg + Ambroxol Hydrochloride IP 7.5mg + Guaiphenesin IP 12.5mg Oral drops	M/s. Akums	In light of earlier SEC recommendation dated 10.01.2023, the firm presented the PK study protocol before the committee. After detailed deliberation, the committee recommended for conducting the PK study. The result of the study should be presented before the committee for review.
8.	FDC/MA/23/000002 Mometasone furoate eq. to 136mcg of Mometasone Furoate 160mcg + Glycopyrronium bromide eq. to 46mcg of Glycopyrronium PhEur 63mcg + Indacaterol acetate eq. to 114mcg of Indacaterol 173mcg Inhalation Powder	M/s. Lupin Ltd.	As per the condition mentioned in Form CT-23 dated 07.11.2022; the firm presented the Phase IV clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for conducting the Phase IV CT with following conditions:  1. Adverse events should be elaborated.  2. The follow-up of the study should be up to 06 months.  3. The details of last visit including the test parameters should be mentioned at 06 months accordingly.  4. Telephonically follow up should be done at 4 <sup>th</sup> and 5 <sup>th</sup> month to assess the symptom analysis so as to rule out any worsening or exacerbation.  The result of the study should be presented before the committee for review.
9.	04-01/2022-DC (Misc. 47) Chlorpheniramine Maleate IP 2mg+Phenylephrine HCl IP 5mg drop/ml	Nil	The issue regarding use of the FDC of Chlorpheniramine Maleate IP 2mg + Phenylephrine HCl IP 5mg drop/ml was discussed before the committee. The committee opined that one Pediatrician may be invited in next meeting for their opinion in the mater.
10.	FDC/MA/23/000034 Paracetamol 160mg + Phenylephrine HCl	M/s. Stedman	The firm did not turn up for presentation.

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	5mg + Chlorpheniramine maleate 1mg Oral liquid, suspension		
11.	FDC/MA/23/000032  Dextromethorphan HBr 10mg + Phenylephrine HCl 5mg + Chlorpheniramine Maleate 1mg syrup	M/s. Stedman	The firm did not turn up for presentation.
12.	FDC/MA/22/000091  Bilastine 3.3mg + Dextromethorphan Hydrobromide 10mg + Phenylephrine Hydrochloride 5mg Syrup	M/s Glenmark Pharmaceuticals	In light of earlier SEC recommendation dated 28.04.2022 & 07.12.2022, the firm presented the PK study report. After detailed deliberation, the committee considered the PK study report. Accordingly, the committee recommended that the firm should present the Phase III clinical trial protocol in detail for further review by the committee.
13.	FDC/MA/22/000304  Each capsule contains: Indacaterol (as acetate) equivalent to Indacaterol 150mcg + Glycopyrrolate IP equivalent to Glycopyrronium 50 mcg + Mometasone Furoate IP 160mcg Dry Powder for inhalation	M/s Glenmark Pharmaceuticals	The firm presented the in-vitro comparison data before the committee. The firm informed the committee that the product is already approved by CDSCO on 07.11.2022 with condition to conduct the Phase IV CT. After detailed deliberation, the committee considered in-vitro comparison data and recommended for grant of permission to manufacture and market the FDC with condition to conduct the Phase IV CT. Accordingly, Phase IV CT study protocol should be submitted to CDSCO within three months from the date of approval for review by the committee.
<b>GCT Division</b>			
14.	CT/168/22 Online Submission (35220)  BI 1015550	M/s. IQVIA RDS	The proposal was deferred.
15.	CT/171/22 Online Submission (35282)  BI 1015550	M/s. IQVIA RDS	The proposal was deferred.