

Recommendations of the SEC (Pulmonary) made in its 65th meeting held on 07.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/20/000043 Blisatine 10 mg + Montelukast 4mg orodispersible tablets	M/s. Synokem Pharmaceuticals Ltd.	The firm did not turn up for presentation.
2.	4-100/2016-DC (Pt. Akums) Fexofenadine HCl 60mg/30mg + Montelukast Sodium IP eq. to Anhydrous Montelukast 4mg/4mg Per 5ml suspension	M/s. Akums Drugs & Pharmaceuticals	The firm presented their proposal before the committee. The committee noted that same FDC was already deliberated by the committee for another firm and indication proposed by the applicant is also same. The committee recommended that same pathway as recommended by the committee for other firm may be followed by CDSCO for this applicant.
3.	FDC/CT/20/000056 Fluticasone Furoate 100mg + Umeclidinium Bromide 62.5mg + Vilanterol Trifenatate 25mg powder for inhalation	M/s. Glaxosmithkline Pharmaceuticals limited	The firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for amendment in the revised Phase IV clinical trial study protocol.
4.	FDC/MA/22/000340 Vilanterol Trifenatate eq. to Vilanterol 12.5mcg + Glycopyrrolate IP eq. to Glycopyrronium 25mcg + Fluticasone furoate Ph. Eur 50mcg inhaler (metered dose inhaler)	M/s. Zydus Healthcare Ltd.	The firm presented their proposal along with Phase III CT protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial with the condition that more Govt. sites should be included.
5.	FDC/MA/22/000091 Bilastine 3.3mg +	M/s. Glenmark Pharmaceuticals	In light of earlier SEC recommendation dated 07.06.2022, the firm presented the PK study protocol before the committee.

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	Dextromethorphan Hydrobromide 10mg + Phenylephrine 5mg Hydrochloride Syrup		After detailed deliberation, the committee recommended for grant of permission to conduct the PK study. The results of the study should be presented before SEC for further consideration.
GCT Division			
6.	CT/127/22 Online Submission (34427) Tozorakimab (MEDI3506)	M/s. AstraZeneca	<p>The firm presented their proposal for Phase III clinical trial protocol number D9185C00001 version 1.0 15-Sept-2022(TILIA) and Local CSP Addendum IND-1 version 1.0 dated 14-10-2022 before the committee.</p> <p>After detailed deliberation, the committee recommended that the rationale for conduct of the proposed trial is not adequate and the applicant should submit the following for further consideration by the committee.</p> <ol style="list-style-type: none"> 1. Proof of concept data for the proposed indication. 2. Published data on prevalence of proposed disease i.e. viral lungs infections/viral Pneumonia vis a vis number of patients hospitalized for viral lung infection requiring supplement oxygen or requiring ventilation in India.