

Recommendations of the SEC (Pulmonary) made in its 02nd/25 meeting held on 20.02.25 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/21/23 Online Submission (36890) PC945 (opelconazole) Nebuliser Suspension	M/s. PSI CRO Pharma Pvt. Ltd.	The firm presented protocol amendment 4 dated 30 October 2024 protocol no. PC_ASP_006. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/106/24 Online Submission (37185) Lunsekimig SAR443765	M/s. Sanofi Healthcare India Private Limited	The firm presented protocol amendment 01 version 01 dated 10 December 2024 protocol no. LTS17231. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/30/24 Online Submission (37171) BI 1015550	M/s. IQVIA RDS (India) Private Limited	The firm presented protocol amendment version 4.0 dated 11-Dec-2024 protocol no. 1305-0031. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that the firm shall submit justification for mentioning the drug as potent.
FDC Division			
4.	FDC/MA/24/000250 Fluticasone Furoate BP 200mcg + Umeclidinium Bromide Eq. toUmeclidinium62.5 mcg + Vilanterol Trifenatate Eq. toVilanterol25mcg Powder for Inhalation in Capsule	M/s Malik Life Sciences Pvt. Ltd.	The firm presented the proposal along with phase III CT protocol before the committee. After detailed deliberation, the committee opined that the firm should submit the following: <ol style="list-style-type: none"> 1. Justification for sample size. 2. Justification for selection of reference product. Accordingly, firm should submit the revised Phase III CT protocol to CDSCO for further review by the committee.
5.	FDC/MA/24/000211 Vilanterol trifenate equivalent to Vilanterol	M/s Zydus Healthcare Limited	The firm presented the proposal along with phase III CT protocol before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	25 mcg + Umeclidinium bromide equivalent to Umeclidinium + 62.5 mcg Fluticasone Furoate Ph. Eur. 200 mcg powder for Inhalation.		After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial study. Accordingly, firm should submit the Phase III CT report to CDSCO for further review by the committee.
6.	FDC/MA/24/000128 Fluticasone Furoate 200mcg +Umeclidinium bromide eq. to Umeclidinium 62.5mcg + Vilanterol trifenatate eq. to Vilanterol 25mcg dry powder for Inhalation in hard cellulose capsule	M/s Sun Pharma Laboratories Limited	In light of earlier SEC recommendation dated 24.09.2024, the firm presented the proposal along with phase III CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of proposed Phase III clinical trial with the condition that “non-inferiority margin should be 150 ml.” Accordingly, firm should submit the Phase III CT report to CDSCO for further review by the committee.
7.	FDC/MA/25/000019 Acebrophylline 100mg + Erdosteine 300mg tablet	M/s Theon Pharmaceuticals Ltd.	The firm presented the proposal along with BE study protocol & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of proposed BE study and Phase III clinical trial. The result of the BE study should be presented for review by the SEC before initiation of the Phase III clinical trial.
8.	FDC/141/2024- eoffice Levocetirizine Di-HCl 2.5mg/2.5mg + Motelukast Sodium eq. to Montelukast 4mg/5mg per 5ml oral drops	M/s Akums Drugs & Pharmaceuticals Ltd.	Firm did not turn up for presentation.