Recommendations of the SEC (Pulmonary) made in its 04th/26 meeting held on 23.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/03/26 Online Submission (54051) NNC0487-0111 B 0.80 mg/mL NNC0487-0111 B 1.67 mg/mL NNC0487-0111 B 3.35 mg/mL NNC0487-0111 B 6.7 mg/mL NNC0487-0111 B 13.4 mg/mL NNC0487-0111 B 26.8 mg/mL	M/s. Novo Nordisk India Pvt Ltd	The firm presented phase IIIa clinical study protocol no. NN9490-8293, version no. 1.0 dated 09 October 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/08/26 Online Submission (54284) LY3841136	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented phase III clinical study protocol no. J3R-MC-YDAO, version no. Initial dated 26 September 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/11/26 Online Submission (54449) GB-0895	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study protocol no. GB-0895-301, version no. 1.0 dated 07 October 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/12/26 Online Submission (54462) GB-0895	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study protocol no. GB-0895-302, version no. 1.0 dated 07 October 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
5.	CT/26/26 Online Submission (54879) Admilparant/ BMS-986278	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase III clinical study protocol no. IM0271016, version no. Original dated 16 May 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that Before enrolling the control arm in the study, the firm shall submit the Phase II study data or interim

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			Phase II study data for Idiopathic Pulmonary Fibrosis (IPF) and Progressive Pulmonary Fibrosis (PPF) to the CDSCO for further review by the Subject Expert Committee (SEC).
FDC Division			
6.	FDC/MA/25/000266 Clarithromycin IP 500 mg + Erdosteine 300 mg film coated tablet	M/s. Macleods Pharmaceuticals Ltd.	The firm presented the proposal before the committee. After detailed deliberation, the committee opined that: 1. Firm did not present enough evidence to support the rationality of FDC. 2. Firm did not present essentiality and desirability of the proposed FDC as individual drugs are already approved. 3. The proposed FDC is not approved internationally. 4. Firm did not present any published literature from peer reviewed journal in support of significant clinical need of the FDC for proposed indication. 5. Erdosteine is not essentially required for all patients for the proposed indication as per the standard treatment guideline. In view of above, the committee did not recommend for approval of the proposed FDC.