

Recommendations of the SEC (Pulmonary) made in its 13th/25 meeting held on 10.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Device Division			
1.	IMP/MD/2025/155388 Pulmonary Gas Exchange Analyser Monitor	M/s.Stage021 Medical Devices (OPC) Private Limited.	<p>The firm presented the proposal for grant of permission to import for marketing of the medical device viz. Pulmonary Gas Exchange Analyser Monitor (MediPines Gas Exchange Monitor (AGM100)) which is manufactured by M/s MediPines Corporation, United States.</p> <p>The said device is approved for marketing in USA and Canada for more than two years and the firm has submitted Post-Marketing Surveillance data and clinical evidence generated in said countries.</p> <p>After detailed deliberation the committee recommended for consideration of the said proposal, subject to the following conditions:</p> <ol style="list-style-type: none"> The following should be mentioned in the disclaimer section of the IFU/ user manual of the device: “This device is not intended for use in intensive care unit (ICU) settings and should not be used as a substitute for standard arterial blood gas (ABG) analysers or devices used for measuring ABG parameters.” The firm shall conduct a Post-marketing clinical investigation on the said device in the country in order to validate its Clinical utility on Indian population. Accordingly, the firm shall submit the clinical study protocol within six months from the date of the launch of the product in the country.
2.	MED-14/20/2025-eoffice	Dr. Ajish K. Abraham, Professor of	The applicant presented their proposal for conducting academic field validation studies of the applied

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	AI-driven mHealth app	Electronics and Acoustics ALL INDIA INSTITUTE OF SPEECH AND HEARING, MYSURU	device i.e. AI-based mHealth App for hypernasality prediction in children. After detailed deliberation, the committee opined that the proposal shall be re-deliberated along with the experts viz. Pediatrician & ENT specialist for taking further action in the matter
Biological Division			
3.	BIO/CT18/FF/2022/32804 Tezepelumab Solution for Injection (Tezspire 210 mg)	M/s AstraZeneca Pharma India Limited	The firm did not turn up for the presentation.
New Drugs Division			
4.	ND/MA/23/000120 Butamirate citrate 7.5mg/5ml	M/s. Swift Life Sciences Pvt. Ltd	<p>The firm has presented the proposal for grant of permission to manufacture and marketing of Butamirate Citrate 7.5 mg/5 ml, indicated Cough suppressant, along with Bioequivalence study protocol (Protocol ID: VRL-24-040 Protocol Version No: 01: Dated 06.11.2024) and Phase III clinical trial protocol (Protocol ID: VRL-CT-24-001 Protocol Version No: 1.0, Dated 24-Jan-2024) before the committee.</p> <p>After detailed deliberation, the committee recommended that firm should submit detailed composition of applied product along with role of each ingredient in the formulation in comparison with reference product (Innovator) in order to consider firms BE protocol.</p> <p>Further, firm needs to submit justification for not conducting BE study in Fed condition.</p> <p>The committee also recommended that proposed Phase III CT protocol to be revised as double blind comparative study of test drug vs. Standard of Care (SOC). Accordingly, firm should submit revised Phase III clinical trial protocol to CDSCO for further review by the committee</p>

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FDC Division			
5.	FDC/MA/25/000120 Indacaterol acetate eq. to Indacaterol 75 mcg + Glycopyrronium Bromide Ph. Eur. eq. to Glycopyrronium 25 mcg + Mometasone Furoate IP 80 mcg Metered Dose Inhaler	M/s Lupin Limited	In light of earlier SEC recommendation dated 18.06.2025, the firm presented the essentiality and desirability of the proposed FDC as higher strength of the FDC is already approved as DPI and detail report regarding amount of drug reaching to the lung tissue before the committee. After detailed deliberation, the committee recommended that firm should present the PK study protocol along with Phase III CT Protocol for review by the committee.
6.	FDC/CT/25/000079 Glycopyrrolate IP 9 mcg + Budesonide IP 160 mcg + Formoterol Fumarate Dihydrate IP eq. to Formoterol Fumarate 4.8 mcg per actuation delivers (ex-actuator) inhalation aerosol	M/s Glenmark Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 21.03.2023 and as per condition of Form CT-23 dated 13.05.2022, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.
7.	FDC/CT/25/000080 Glycopyrronium (as Glycopyrrolate IP) 25 mcg + Formoterol Fumarate (As Formoterol Fumarate Dihydrate IP) 12 mcg + Budesonide IP 400 mcg powder for inhalation (in capsule)	M/s Glenmark Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 21.03.2023 and as per condition of Form CT-23 dated 06.07.2022, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.
8.	FDC/CT/25/000081 Indacaterol (as acetate) eq. to Indacaterol 150 mcg + Glycopyrrolate IP eq. to Glycopyrronium 50 mcg + Mometasone Furoate IP 160 mcg powder for inhalation	M/s Glenmark Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 05.07.2023 and as per condition of Form CT-23 dated 24.04.2023, the firm presented Phase IV clinical trial report before the committee. After detailed deliberation, the committee noted and agreed to the result of the clinical trial report.