

Recommendations of the SEC (Neurology & Psychiatry) made in its 12th/25 meeting held on 16.07.2025 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/111/24 Online Submission(38957) Lumateperone	M/s IQVIA RDS (India) Private Limited	The firm presented protocol amendment 3.0 dated 24 February 2025 protocol no. ITI-007-451. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/111/24 Online Submission(39876) Lumateperone	IQVIA RDS (India) Private Limited	The firm presented protocol amendment 4.0 dated 07 May 2025 protocol no. ITI-007-451. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Medical Devices Division			
3.	IMP/MD/2024/13471 1 Supernova Revascularization Device, Neutron Reperfusion Catheter	M/s. Gurutva Medical Technology Private Limited	The applicant has presented the Clinical Investigation data generated on Indian population on the Supernova Revascularization Device for consideration of its marketing in the country as the product is not approved for marketing in the countries viz USA, UK, EU, Australia, Canada and Japan. The Clinical study data for other product viz., Neutron Reperfusion Catheter is not generated by them and they have clarified that they will exclude the said device from their applications presently. After detailed deliberation, the committee recommended for grant of approval of the Supernova Revascularization Device for its commercialization. However, the committee opined that the firm may submit the Periodic Safety Update Report on the said device as Post marketing Clinical follow-up to the Central Licensing Authority from the date of launch of the device in the country at an interval of every six months for first two years followed by submission of the said report annually for the two more successive years, to access the safety and performance in the large population

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SNDDivision			
4.	SND/MA/25/000068 Dexmedetomidine HCL solution for infusion 4 mcg/ml	M/s Neon Laboratories Ltd.	<p>Firm presented their proposal for grant of permission to manufacture and market of Dexmedetomidine Hydrochloride Solution for Infusion 4 mcg/ml (200 mcg/50 ml) vial along with justification for waiver of Phase-III clinical trial and bioequivalence study before the Committee.</p> <p>The committee noted that the application is for Ready to Use formulation.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market of Dexmedetomidine Hydrochloride Solution for Infusion 4 mcg/ml (200 mcg/50 ml) vial for applied indication subject to condition that the firm should conduct Phase-IV clinical trial.</p> <p>Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within three months from date of approval of the drug.</p>
New DrugsDivision			
5.	ND/MA/23/000135 Etifoxine Hydrochloride 50 mg Capsule (Fasting)	M/s PURE & CURE HEALTHCARE Pvt. Ltd	<p>Firm presented proposal for grant of permission to manufacture and market of new drug Etifoxine Hydrochloride capsules 50 mg along with Bioequivalence study report before the committee.</p> <p>After detailed deliberation, the committee considered BE results presented by the firm and the committee noted that new drug, Etifoxine Hydrochloride 50 mg capsule is already approved in the country for manufacture and market.</p> <p>Accordingly, the committee recommended for grant of permission to manufacture & market Etifoxine Hydrochloride capsule 50 mg for psychosomatic manifestations of anxiety subject to the condition that the firm should conduct the PMS study with primary objective of evaluating the drug dependence plus abuse in Indian patients.</p>

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			Further, committee recommended that the side-effects like hepatotoxicity, hypersensitivity including DRESS syndrome need to be clearly mentioned in Prescribing information of the drug.
6.	ND/MA/24/000023 Cenobamate Tablets 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg & 200 mg	M/s MSN Laboratories Private Limited	The firm presented BE study results of Cenobamate Tablets 12.5 mg and Phase III clinical trial protocol of Cenobamate Tablets (12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg & 200 mg) before the committee. After detailed deliberation, the committee considered BE results presented by the firm and recommended for grant of permission to conduct Phase III clinical trial as per the protocol presented by the firm subject to the condition that firm should include detailed safety evaluation of subjects and causality assessment of adverse drug reactions in the protocol.
FDC Division			
7.	FDC/MA/25/000117 Donepezil Hydrochloride IP 10 mg/10 mg/10 mg/10 mg + Memantine Hydrochloride IP (ER) 7 mg/14 mg/21 mg/28 mg hard gelatin capsule	M/s Akums Drugs & Pharmaceuticals Limited	The firm presented the proposal before the committee. After detailed deliberation, the committee opined that firm did not present any supportive data with respect to safety aspects for the proposed FDC in elderly/geriatric population in Indian patients. Accordingly, the firm should submit above data for further review by the committee.
8.	FDC/MA/25/000042 Pregabalin IP 75 mg + Dosulepin Hydrochloride IP 75 mg + Mecobalamin IP 1500 mcg hard gelatin capsules	M/s Abbott India Limited	The firm did not turn up for presentation.