

Recommendations of the SEC (Neurology & Psychiatry) made in its 12th/24 meeting held on 12.09.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/59/21 Online Submission (33769) Ofatumumab (OMB157) Siponimod (BAF312)	M/s. Novartis Healthcare Private Limited	The firm presented protocol amendment version 2.0 dated 07 May 2024 protocol no. CBAF312D2301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/45/22 Online Submission (33762) Eteplirsen (AVI-4658)	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented protocol amendment 11 version 12 dated 16 April 2024 protocol no. 4658-402. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/132/23 Online Submission (33961) Tolebrutinib –tablet, film-coated 60 mg	M/s. Sanofi Healthcare India Private Limited	The firm presented protocol amendment 05 version 01 dated 21 Dec 2023 protocol amendment 06 version 01 dated 07 May 2024, protocol amendment 07 version 01 dated 12 Jun 2024 protocol no. LTS17043. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/116/21 Online Submission (34049) OAV101	M/s. Novartis Healthcare Private Limited	The firm presented protocol amendment version 04 dated 17 May 2024 protocol no. COAV101B12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
5.	SND/MA/24/000084 Brivaracetam in sodium chloride injection for IV infusion 0.5mg/ml and 1mg/ml 100 ml infusion	M/s Intas Pharma Limited	The firm presented their proposal for grant of manufacture and marketing of Brivaracetam in sodium chloride injection for intravenous infusion 0.5mg/ml and 1mg/ml 100ml infusion along with justification for waiver of Phase-III clinical trial before the committee. The firm has informed that Brivaracetam 10mg/ml solution for injection is approved in Belgium and the proposed formulation is similar to the conventional injectable Brivaracetam formulation

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			<p>which is supplied in concentrated form and needs to be diluted in a compatible diluent prior to administration by intravenous infusion.</p> <p>After detailed deliberation, the Committee noted that the firm has not provided adequate data with respect to infusion rate and equivalency of proposed formulation with approved formulation. Therefore, the Committee opined that the firm should submit comparative data with approved injectable of Brivaracetam formulation along with supporting documents / literature to CDSCO for further review by the Committee.</p>
6.	SND/MA/24/000069 Fluvoxamine Maleate Extended Release Tablets 50 mg 50.000 milligram (mg).	M/s Pure & Cure Healthcare Pvt. Ltd	<p>The firm presented their proposal for grant of permission to manufacture and marketing of Fluvoxamine Maleate Extended Release Tablets 50 mg along with justification for waiver of Phase-III clinical trial and BE-Study protocol (Protocol no.VRL-24-004 version no.1.0 dated 12.02.2024) before the Committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study as per the protocol presented by the firm. Further, the firm should submit Bioequivalence report and get evaluated by the SEC committee for further consideration.</p>
New Drugs Division			
7.	ND/IMP/24/000044 Eplontersen Solution for Injection 45 mg/0.8 ml	M/s AstraZeneca Pharma India Ltd	Under Discussion
8.	ND/MA/23/000135 Etifoxine Hydrochloride 50 mg	M/s Pure and Cure Healthcare Pvt. Ltd	<p>The firm presented the proposal for grant of permission to manufacture and market of Etifoxine Hydrochloride 50 mg capsules along with bioequivalence study protocol under fasting condition.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct bioequivalence study as per the protocol presented by the firm for further consideration.</p>