

Recommendations of the SEC (Neurology & Psychiatry) made in its 05th/25 meeting held on 26.03.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/44/22 Online Submission (37472) 4045Casimersen 4053 Golodirsen	M/s PPD Pharmaceutical Development India Private Limited	The firm presented protocol amendment 13 version 14 dated 14 August 2024 and protocol amendment 14 version 15 dated 08 Jan 2025 protocol no. 4045-301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/14/25 Online Submission (47842) Lumateperone	M/s IQVIA RDS India Pvt. Ltd	The firm presented phase III clinical study protocol no.: ITI-007-601 version no. Original Protocol dated 30-AUG-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more geographically distributed Government sites shall be included in the study.
New Drugs Division			
3.	ND/IMP/20/000073 Risdiplam Powder for Oral Solution 0.75 mg/ml	M/s Roche Products (India) Pvt. Ltd.	The firm presented the proposal for grant permission for amendment in the warning statement of marketing authorisation permission of drug Risdiplam Powder for Oral Solution 0.75 mg/ml before the committee. After detailed deliberation, the committee recommended for the amendment in warning statement from 'To be sold by retail only under the prescription of Neurologist/Paediatric Neurologist' to 'To be sold by retail on the prescription of a Neurologist/Paediatric Neurologist or Medical Geneticist subject to the condition that- <ul style="list-style-type: none">• The Medical Geneticist should be Clinician having DM/DrNB degree in Medical Geneticist from NMC recognise institute and should have adequate experience

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>in diagnosis and treatment of SMA patients.</p> <p>Accordingly, firm should submit revise warning statement to CDSCO.</p>
4.	ND/MA/24/000122 Cenobamate Tablets (12.5 mg/ 25 mg/ 50 mg/ 100 mg/ 150 mg/ 200 mg)	M/s Exemed Pharmaceuticals	<p>The firm presented the proposal for grant of permission to manufacture and market of the new drug Cenobamate Tablets 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mg along with BE protocol and justification for waiver of local Phase III Clinical Trial before the committee</p> <p>After detailed deliberation, the committee recommended for the grant of permission to conduct BE study as per protocol presented. Further, the committee did not recommend the waiver of local Phase III Clinical Trial.</p> <p>Accordingly, the firm should submit Phase III Clinical Trial protocol to CDSCO for further review by the committee.</p>
5.	ND/IMP/24/000032 Rimegepant ODT 75 mg (Nurtec)	M/s Pfizer Limited	The firm did not turn up for presentation
SND Division			
6.	SND/MA/25/000013 Vigabatrin Tablets USP 500 mg	M/s Zenara Pharma Private Limited	<p>The firm presented the proposal for grant of permission for manufacture and marketing of Vigabatrin Tablets USP 500 mg along with bioequivalence study report under fasting condition (Study No. 132/21, Report Version: 00, Date: 19 Apr 2022) and under fed condition (Study No. 090/21, Report Version: 00, Date: 06 Apr 2022) and justification for Phase III clinical trial study waiver before the committee.</p> <p>The Committee noted that Vigabatrin powder for oral solution USP 500mg is approved in India and Vigabatrin Tablets 500 mg is approved in USA, UK, Australia, Canada & Germany.</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>After detailed deliberation, the committee recommended to accept the bioequivalence study reports and recommended for grant of permission to manufacture and market Vigabatrin Tablets USP 500 mg with Phase-III clinical trial study waiver subject to conduct PMS study.</p> <p>Accordingly, the firm should submit PMS protocol to CDSCO within 03 months from date of approval of the drug product for review by the committee.</p>
7.	<p>SND/MA/25/000001</p> <p>Lasmiditan Dispersible tablets 50 mg and 100 mg</p>	<p>M/s Pure and Cure Healthcare Pvt. Ltd.</p>	<p>The firm presented the proposal for grant of permission for manufacture and market of Lasmiditan Dispersible tablets 50 mg and 100 mg (additional dosage form) for the acute treatment of migraine with or without aura in adults along with the justification for waiver of BE & CT studies before the committee.</p> <p>The Committee noted that Lasmiditan is BCS Class I drug and Lasmiditan tablets 50mg and 100mg approved in India.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Lasmiditan Dispersible tablets 50 mg and 100 mg with BE and Phase III CT waiver.</p>
8.	<p>SND/MA/24/000256</p> <p>Prochlorperazine Maleate Extended-Release Tablets 10 mg</p>	<p>M/s Abbott Healthcare Pvt. Ltd</p>	<p>The firm presented the proposal for grant of permission for manufacture and marketing of Prochlorperazine Maleate Extended-Release Tablets 10 mg along with Bioequivalence study Protocol under fasting condition (Study Protocol no. PR/BE/24/334, Ver. no. 01, 19th Dec-2024) and justification for Phase III clinical trial study waiver before the committee.</p> <p>The firm presented that variability of Prochlorperazine has been reported in Public assessment report. Accordingly, BE study protocol with full replicate and cross-over design is proposed.</p> <p>After detailed deliberation, the committee</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>recommended for grant of permission to conduct BE study as per protocol presented.</p> <p>Accordingly, firm should submit the BE study report for further review by the committee.</p>
9.	<p>SND/MA/24/000084</p> <p>Brivaracetam in sodium chloride injection for IV infusion 0.5mg/ml and 1mg/ml 100ml infusion.</p>	M/s Intas Pharma Limited	<p>In light of earlier SEC recommendations dated 12.09.2024, the firm presented data with respect to infusion rate and equivalency of proposed formulation with approved formulation.</p> <p>After detailed deliberation the committee recommended for grant of permission to manufacture and market the drug Brivaracetam in Sodium chloride injection for intravenous infusion 0.5mg/ml and 1mg/ml 100ml infusion for the indication “As adjunctive therapy in the treatment of partial –onset seizures in patients 16 years of age and older with epilepsy”.</p>