

**Recommendations of the SEC (Neurology & Psychiatry) made in its 14<sup>th</sup>/25 meeting held on 26.08.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/09/25 Online Submission (47634)  Cariprazine Depot	M/s CBCC Global Research LLP	In light of earlier SEC recommendation dated 28.02.2025, now the firm presented phase I data for phase I/IIa clinical study protocol no. Mapi Cariprazine Depot Phase I/IIa-001 version no. 2 dated 22 October 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the DSMB shall closely monitor safety specifically SAEs and discoloration of skin, cutaneous tissue, lips etc. and submit additional one-week safety data following the initial one month to the Ethics Committee and CDSCO.
<b>Biological Division</b>			
2.	BIO/CT18/FF/2025/49 633  Erenumab solution for injection in prefilled pen 70 mg/ mL	M/s Novartis Healthcare Private Limited	The firm did not turn up for the presentation
3.	E-91102  Erenumab Solution for injection in prefilled syringe 70 mg/ml	M/s. Sandoz Private Limited	The firm did not turn up for the presentation
4.	BIO/CT18/FF/2024/46 935  Donanemab Injection (350 mg/20 mL solution in vial)	M/s. Eli Lilly And Company	In light of earlier SEC recommendation dated 16.04.2025, the firm presented the justification for waiver of local clinical trial in India.  The firm presented that there is no ethnic variability in Phase III safety and efficacy results between Asian and global population and the applied drug product is approved in countries including USA, UK, Japan, Singapore, Australia.  Further, the firm also submitted that there is an unmet need in India for the proposed indication. Firm also informed that biomarker based diagnostic tools has now evolved for the diagnosis of Early AD in India.

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			<p>The committee noted the justification presented by the firm.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and market the drug Donanemab Injection (350 mg/20 mL solution in vial) mg/ml indicated “for the treatment of Alzheimer’s disease. Treatment with donanemab should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials” with Phase III clinical trial waiver in India along with the condition to conduct Phase-IV in India in the approved indication.</p> <p>Accordingly, the firm should submit Phase IV study protocol to CDSCO within 03 months of approval of marketing authorization.</p>
<b>BABE Division</b>			
5.	BABE/CT05/FF/2025/49064  Cycloserine and Lurasidone HCl capsule 237.5/33 mg	M/s ZenRise Clinical Research Pvt. Ltd.	<p>The firm presented the BA/BE study protocols for export purpose only vide No.: 040-25, Version No. 01, Dated 09-APR-2025 and No.: 041-25, Version No. 01, Dated 09-APR-2025 before committee.</p> <p>After detailed deliberation, the committee recommended for grants of permission for conducts of the BA/BE study for export purpose only.</p>
<b>New Drugs Division</b>			
6.	ND/MA/25/000088  Olanzapine and Samidorphan Tablet (5 mg +10 mg, 10 mg+10 mg, 15 mg +10 mg and 20 mg +10 mg).	M/s Akums Drugs & Pharmaceuticals Limited	<p>The firm presented the proposal for grant of permission for manufacture and market of the drug Olanzapine and Samidorphan tablets (5 mg+10 mg, 10 mg+10 mg, 15 mg+10 mg and 20 mg+10 mg) along with BE study protocol and request for Phase-III clinical trial waiver before the committee.</p> <p>After detailed deliberation, the committee noted that one of ingredient of proposed FDC i.e. Samidorphan is not approved in India &amp; the proposed indication does not falls under unmet medical need and clinical trial data/literatures presented by firm does not have data of Asian patients. Hence, committee did not agree for Phase</p>

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			<p>III Clinical Trial waiver and recommended that firm should submit Phase III CT protocol to CDSCO for further review by the committee.</p> <p>Further, the committee recommended for grant of permission to conduct Bioequivalence study as per the protocol presented and opined that the firm should submit Bioequivalence study report to the CDSCO for further review by the committee.</p>
7.	ND/MA/24/000115  Remimazolam Besylate 20 mg lyophilized powder for injection	M/s Enaltec LABS PVT. LTD	<p>The firm presented the proposal for grant of permission to manufacture and market Remimazolam Besylate 20 mg lyophilized powder for injection along with phase III Clinical Trial protocol before the committee.</p> <p>The firm presented international regulatory approval status of the drug product, therapeutic rationale, risk versus benefit profile along with Phase III CT protocol including dosage and administration, inclusion and exclusion criteria, discontinuation criteria, study end points, study activity chart, study site details, scale used to measure level of alertness/sedation, assessment of safety etc.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial for drug, Remimazolam Besylate 20 mg lyophilized powder for injection as per protocol presented by the firm</p>
<b>SND Division</b>			
8.	SND/CT/24/000076  Zolpidem Sublingual Spray 3.85% w/v	M/s Troikaa Pharmaceuticals Ltd.	<p>In light of earlier SEC Recommendation dated 19.03.2025, firm presented revised Phase-IV Clinical Trial Protocol (Protocol No. CT/57/01/24, Version 03, dated 07.05.2025) before the committee.</p> <p>After detailed deliberation, the committee recommended for approval to conduct the Phase IV study as per the protocol presented by the firm</p>