

Recommendations of the SEC (Neurology & Psychiatry) made in its 20th/25 meeting held on 10.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/130/20 Online Submission (32645) Fenebrutinib	M/s. Roche Products (India) Private Limited	In light of earlier SEC Recommendation dated 25.02.2025, the firm presented protocol amendment version 7.0 dated 15 February 2024 protocol no. GN42272. Now the firm presented CIOMS report, SAE reports and minutes of meeting of ethics committee along with all clinical records of the participant who expired enrolled in the trial and compensation order. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/146/25 Online Submission (52403) Tenecteplase	M/s. IQVIA RDS (India) Private Limited	The firm presented phase III clinical study Protocol no.: 1123- 0060 version no. 1.0 dated 25-JUL-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/147/25 Online Submission (52392) Trospium Chloride + Xanomeline	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented phase III clinical study protocol no.: CN0120051, amendment no. 01 dated 29-MAY-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/148/25 Online Submission (52364) Trospium Chloride + Xanomeline	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented phase III clinical study Protocol no.: CN0120025 original protocol dated 24 -Feb-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
New Drugs Division			
5.	ND/MA/25/000037 Brexpiprazole tablets 0.25 mg/0.5 mg/1mg/ 2 mg/3 mg/4 mg	M/s Exemed Pharmaceuticals	In light of earlier recommendation dated 18.06.2025, the firm presented the BE study report of Brexpiprazole Tablets 2 mg (Project No.: BN25-005; Version: 00 dated 05.10.2025), before the committee. After detailed deliberation, the committee considered the results of BE study. The firm should submit Phase-III clinical trial study report to CDSCO for further

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			review by the committee.
6.	ND/MA/23/000156 Brexiprazole Tablets 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg	M/s Torrent Pharmaceuticals Ltd	<p>In light of earlier SEC recommendation dated 08.11.2023 & 09.11.2023, firm presented Phase III CT report of Brexiprazole tablets 0.25 mg/0.5 mg/1 mg/2 mg/ 3 mg/4 mg before the committee.</p> <p>After detailed deliberation, the committee considered the Phase III clinical trial result and recommended for grant of permission for manufacturing and marketing of Brexiprazole tablets 0.25 mg/0.5 mg/1 mg/2 mg/3 mg/4 mg for the proposed indication in adults patients of schizophrenia.</p> <p>The committee also reviewed the prescribing information and opined that the firm should highlight the warning in elderly population with dementia-related psychosis treated with antipsychotic drugs and patients receiving antidepressants in prescribing information in line with internationally approved prescribing information.</p> <p>Accordingly, the firm should submit revised Prescribing Information to CDSCO for review including proposed indication in adults and highlighting above said warning statement before grant of Marketing Authorization.</p> <p>Further, the committee recommended that the proposed drug product should be sold by retail under the prescription of neurologist and psychiatrist only.</p>
SND Division			
7.	SND/MA/25/000095 Topiramate extended release capsule USP 25/50/100/200 mg	M/s. Zydus Lifesciences Limited	<p>The firm presented the proposal for grant of permission to manufacture and market of Topiramate extended release capsule USP 25/50/100/200 mg along with BE studies (Fasting & Fed conditions) reports and justification for Phase III Clinical Trial study waiver before the committee.</p> <p>The firm has informed that Topiramate Capsules/Tablets were approved in India since 1999. Topiramate extended release capsule 25/50/100/200 mg was approved for applied indication by USFDA in</p>

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			<p>2012. Firm also informed that, they are undertaking to conduct Phase-IV clinical trial.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Topiramate extended release capsule USP 25/50/100/200 mg for applied indication with condition to conduct Phase-IV clinical trial.</p> <p>Accordingly, the firm should submit Phase-IV clinical trial protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.</p>
FDC Division			
8.	<p>FDC/MA/24/000183</p> <p>Gabapentin IP 200/300 mg (as Film Coated Tablet) + Duloxetine Hydrochloride IP Eq. to Duloxetine 20/30 mg (As Delayed Release Pellets) Hard Gelatin Capsule</p>	<p>M/s Pure and Cure Healthcare Pvt. Ltd</p>	<p>In light of earlier SEC recommendation dated 16.04.2025, firm presented their proposal along with BE study protocol under Fed condition & Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study under Fed condition.</p> <p>As regard to Phase III clinical trial the committee noted the following:</p> <ol style="list-style-type: none"> 1. Firm should include observational blind for assessment of visual analog scale (VAS) in protocol. 2. Scale should be used for any abuse potential/dependence of the FDC. 3. It is suggested that anti-epileptic drug level may be estimated in plasma level. <p>Accordingly, firm should submit revised Phase III clinical trial protocol to CDSCO for further review by the committee.</p>