

**Recommendations of the SEC (Neurology & Psychiatry) made in its 21<sup>th</sup>/25 meeting held on 22.12.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/160/25 Online Submission (52882)  LY3537031	M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd	The firm presented phase II clinical study protocol no.: J2S-MC-GZMJ amendment no. (a) dated 23-OCT-2025 and amendment no. (b) dated 17 December 2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more government site shall be included in the study.
2.	CT/164/25 Online Submission (53084)  LY3537031	M/s Clinical Trials Eli Lilly and Company India Pvt. Ltd	The firm presented phase II clinical study protocol no.: J2S-MC-GZMK amendment no. (a) dated 23-OCT-2025 and amendment no. (b) dated 17 December 2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/161/25 52922 Online Submission (52922)  Trospium Chloride + Xanomeline Tartrate	M/s. Bristol-Myers Squibb India Pvt. Ltd.	The firm presented phase III clinical study protocol no.: CN0120046- Original Protocol dated 22-July-2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/149/25 Online Submission (52450)  DT-216P2 (DT-216 for Injection) 20mg/vial	M/s. JSS Medical Research Asia Pacific Private Limited	The firm presented phase I/II clinical study protocol number: DTX-216P2-101 Protocol Version:5.0 dated 02 December 2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following conditions: 1. Monitor the additional safety parameters: - liver enzyme & function, kidney function, cardiac parameters, Safety laboratory assessments (Chemistry, Hematology, Coagulation, Urinalysis), Injection-Site Adverse Events, Adverse Events

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			Leading to Study Discontinuation...etc. 2. Independent DSMB (country specific) shall be organized to closely monitor the long-term safety related issues (minimum 3 years) and quarterly report submitted to the Ethics Committee and CDSCO.
5.	CT/155/25 Online Submission (52719) Evenamide	M/s. Clinirx Research Pvt Ltd.	The firm presented phase III clinical study protocol no.: NW-3509/022/III/2024 version no. 2.1 dated 31-JUL-2025.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
<b>BA/BE Division</b>			
6.	BA/BE/CT05/FF/2024 /46605 Levodopa-Benserazide-Entacapone 100/25/200mg tablets	M/s. AXIS Clinicals Limited.	The firm did not turn up for the presentation.
<b>FDC Division</b>			
7.	FDC/MA/25/000029 Sumatriptan succinate IP 70mg (eq. to 50mg of Sumatriptan base) + Naproxen sodium USP 500mg film coated tablet	M/s Torrent Pharmaceuticals Ltd.	The firm presented their proposal along with justification for BE & Phase III CT waiver before the committee.  The committee noted that similar FDC i.e Sumatriptan 85 mg + Naproxen 500 mg Tablets, Sumatriptan (as succinate ) 50mg + Naproxen sodium 550mg tablets, Sumatriptan + Naproxen (50mg + 275mg) Tablets is already approved by CDSCO.  After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC after submission of data including dissolution data & justification for BE waiver as per the BE Study guideline and the firm should conduct the Phase IV clinical trial.  Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.

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8.	FDC/MA/25/000216  Etizolam IP 0.25/0.5mg/0.5mg + Propranolol Hydrochloride IP 20mg/20mg/40mg film coated tablet	M/s. Akums Drugs and Pharmaceuticals Ltd.	<p>In light of DTAB subcommittee report dated 28.12.2021 where in expert committee recommended “To conduct Phase IV Clinical Trial evaluate efficacy and safety of the FDC in comparison with Etizolam, with efficacy as the primary objective in statistically significant number of patients for the indication as approved by SEC. The Clinical Trial protocol must receive approval of the SEC and the study must be completed within one year.” Accordingly, the firm presented the Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined that the presented Phase IV CT protocol is not inline with the above DTAB subcommittee recommendation.</p> <p>Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.</p>