

Recommendations of the SEC (Neurology & Psychiatry) made in its 03rd26 meeting held on 17.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/28/26 Online Submission (55127) Salanersen	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study protocol no. 277SM303 version no. 2.0 dated 05 January 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/31/26 Online Submission (55128) EPX-100 Clemizole HCl	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented phase III clinical study protocol no. EPX-100-003, amendment 6.0 dated 04 February 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Shefali Gulati didn't participate in the discussion.
Biological Division			
3.	BIO/CT04/FF/2025/52727 Lecanemab concentrate For solution for infusion 100 mg/mL	M/s. Eisai Pharmaceuticals India Private Limited	The firm did not attend the meeting.
New Drugs Division			
4.	ND/32/2026-eoffice Risdiplam Powder For Oral Solution 0.75 mg/ml [Evrysdi]	M/s Roche Products (India) Private Limited	The firm did not attend the meeting.
5.	ND/CT/25/000064 Rimegepant Orally Disintegrating Tablets 75 mg	M/s. Pfizer Limited	In the light of earlier SEC recommendation dated 11.11.2025, firm presented revised Phase-IV CT protocol (Protocol no. C4951088, Protocol amendment 1 dated 16.12.2025) along with revised Prescribing Information (LPD No. LPDNUR112025 dated November 2025) before the committee. After detailed deliberation, committee recommended the conduct of Phase-IV Clinical Trial as per the revised protocol. Also, the committee considered the updated prescribing information as

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			<p>presented by firm.</p> <p>The results of Phase-IV Clinical Trial should be submitted to CDSCO for further review by the committee.</p>
FDC Division			
6.	<p>FDC/CT/25/000132</p> <p>Etizolam IP 0.25/0.5mg + Propranolol Hydrochloride IP 20mg/20mg tablet</p>	<p>M/s. Macleods Pharmaceuticals Ltd.</p>	<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 in the inclusion criteria diagnosis of disorder(s) should be specified.</p> <p>Accordingly, the revised Phase IV clinical trial protocol should be submitted to CDSCO for review. Further, after approval from CDSCO, the firm should submit Phase IV CT study report to CDSCO for further review by the committee.</p>
7.	<p>FDC/MA/26/000008</p> <p>Gabapentin IP (as film coated tablet) 100mg/200mg/300mg/400mg + Duloxetine Hydrochloride IP eq. to Duloxetine (as delayed release pellets) 20mg/20mg/20mg/20mg hard gelatin Capsules</p>	<p>M/s. Pure & Cure Healthcare Pvt. Ltd.</p>	<p>The firm presented their proposal along with BE study protocol under both Fasting and Fed condition & Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee considered the essentiality and desirability of the proposed FDC and recommended for grant of permission to conduct the BE study (Fasting and Fed condition) & Phase III clinical trial.</p> <p>The result of the BE study (Fasting and Fed condition) should be submitted to CDSCO for further review by the committee before initiation of the Phase III clinical trial.</p>

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			(Dr. Manjari Tripathi has not participated in the deliberation)
8.	FDC/MA/24/000184 Rizatriptan Benzoate IP eq. to Rizatriptan 10mg + Meloxicam IP 20mg uncoated orally disintegrating Tablet	M/s. Akums Drugs & Pharmaceuticals Limited	<p>In light of the earlier SEC recommendation dated 18.06.2025, the firm presented the proposal along with BE study report and revised Phase III CT study protocol before the committee.</p> <p>After detailed deliberation, the committee considered the BE study report. As regard to Phase III clinical trial protocol, the committee recommended for grant of permission to conduct Phase III CT study with the proposed FDC.</p> <p>Accordingly, the firm should submit Phase III CT report to CDSCO for further review by the committee.</p>