

Recommendations of the SEC (Neurology & Psychiatry) made in its 08th/25 meeting held on 15.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/116/24 Online Submission (45269) Lumateperone (ITI-007)	M/s IQVIA RDS (India) Private Limited	In light of earlier SEC Recommendation dated 29.10.2024, the firm presented waive-off condition that the firm should submit separate protocol for pharmacokinetic study in statistically significant Indian subjects, vide study Protocol no ITI-007-452, Amendment 1 dated 03 Jul 2024. After detailed deliberation, the committee opined that the firm shall submit safety data for further review by the committee. (Dr. Sunil Narayan didn't participated)
2.	CT/20/25 Online Submission (48001) LOU064 (Remibrutinib)	M/s Novartis Healthcare Private Limited	The firm presented phase III clinical study Protocol No.: CLOU064O12301 Version No. 01 dated 11-JUN- 2024 After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/143/23 Online Submission (37899) OAV101	M/s Novartis Healthcare Private Limited.	The firm presented protocol amendment version 04 dated 01 August 2024 protocol no. COAV101A12308. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
4.	r-DNA- 11013(12)/14/2025- eoffice Ocrelizumab 300 mg concentrate for solution for infusion	M/s. Roche Products (India) Pvt Ltd	The firm presented the proposal for update in Package Insert Version 02 dated September 2024 for the drug product Ocrelizumab 300 mg concentrate for solution for infusion 300 mg/10 mL (30mg/mL) to include updates in sections of Undesirable effects, use in special populations and clinical/efficacy studies based on the human data collected across clinical trials, a prospective pregnancy registry, literature and post-marketing experience. The committee noted that the proposed updates in Package Insert are not approved in USFDA and EMA. After detailed deliberation, the committee

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			recommended the firm to submit trimester wise safety data in pregnant population who have administered the said drug product and EMA approval of proposed updates in Package Insert to CDSCO for further evaluation before the committee
SND Division			
5.	SND-16011(11)/52/2025-eoffice Risdiplam Powder for Oral Solution 0.75mg/ml	M/s Roche Products (India) Pvt. Ltd	The firm presented the Post Marketing Surveillance study protocol no. ML43557 version no.2.0 dated 03.04.2025 of Risdiplam Powder for Oral Solution 0.75 mg/ml before the committee. After detailed deliberation, the committee recommended to mention the number of patients of the age group of less than 2 months to be enrolled in the PMS Protocol. Accordingly, firm shall submit the revised protocol to the CDSCO for further review by the committee.
New Drug Division			
6.	ND/CT/25/000026 Lumateperone capsule 42 mg	M/s Sun Pharma Laboratories Limited	The firm presented Phase IV clinical trial protocol of Lumateperone capsules 42 mg (ICR/25/001), before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase-IV Clinical trial as per protocol presented by the firm.
FDC Division			
7.	FDC/MA/23/000287 Gabapentin IP (SR) + Methylcobalamin IP + Nortriptyline Hydrochloride eq. to Nortriptyline IP (600mg+1500mcg+10 mg/300mg+1500mcg+10mg) film coated bilayered tablet	M/s. Ravenbhel Healthcare Pvt. Ltd	The firm did not turn up for the presentation.
8.	FDC/CT/25/000027 Bupropion	M/s Exemed Pharmaceuticals	The firm did not turn up for the presentation

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	Hydrochloride (As Extended Release) IP 105 mg + Dextromethorphan Hydrobromide IP 45 mg film coated bilayer tablet		