

Recommendations of the SEC (Neurology & Psychiatry) made in its 06th/25 meeting held on 16.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/176/21 Online Submission (38079) LOU064 (Remibrutinib)	M/s. Novartis Healthcare Private Limited	The firm presented the proposal to increase the number of subjects from 40 to 50 vide approved Protocol No. CLOU064C12302. After detailed deliberation, the committee recommended for approval to increase in number of subjects from 40 to 50 with the condition that firm shall submit details related to ADR mucocutaneous bleeding to CDSCO.
Biological Division			
2.	BIO/CT18/FF/2024/46 935 Donanemab Injection (350 mg/20 mL solution in vial)	M/s Eli Lilly And Company	The firm presented the proposal to import and market new drug Donanemab injection 350mg/20mL solution in single dose vial for intravenous infusion for the treatment of Alzheimer's disease based on the clinical data generated from the global clinical studies along with the request for local clinical trial waiver considering the unmet medical need in the country. The committee noted that India was not a participant in the global clinical trials conducted and there is no safety and efficacy data of Indian population. The committee also noted that the drug is approved in USA, UK, Japan etc. After detailed deliberation, the committee recommended the firm to submit safety and efficacy data of Indian population for further evaluation
BA/BE Division			
3.	BABE/CT05/FF/2024/ 46605 Levodopa- Benserazide- Entacapone 100/25/200 mg tablets	M/s. AXIS Clinicals Limited	The firm presented the protocol No. 281-24 (Sponsor Study Code: 3135001) (Version 01, 23rd October 2024) for BA/BE study for export purpose only. After detailed deliberation, the committee opined that firm should submit the followings: (1) More elaborate data of the

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			<p>proposed FDC w.r.t. safety.</p> <p>(2) Detailed Risk Evaluation Mitigation Strategies for the FDC to ensure safety during the study.</p> <p>Accordingly, the firm should submit the above documents/data for further review by the committees</p>
New Drug Division			
4.	<p>ND/MA/24/000135</p> <p>Lumateperone Capsules (10.5mg, 21mg & 42mg)</p>	M/s Exemed Pharmaceuticals	<p>In light of earlier SEC recommendation dated 26.11.2024 & 27.11.2024, the firm has presented the BE study report for Lumateperone capsules 42 mg before the committee.</p> <p>The committee considered the BE study result. The committee noted that drug Lumateperone Capsules 42mg is already approved in the country on 26.12.2024.</p> <p>The committee also noted that firm has not submitted any supporting data for Lumateperone capsules 10.5 and 21mg.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the Phase-III Clinical trial protocol for the Lumateperone capsules 10.5 and 21mg.</p> <p>The committee also recommended for grant of permission to manufacture and market of drug Lumateperone capsules 42 mg only for the proposed indication subject to the condition that-</p> <p>(a) The firm should conduct Phase IV CT on Lumateperone capsules 42 mg for which Phase IV CT protocol should be submitted to CDSCO within 3 months of approval for further evaluation by the committee.</p> <p>(b) The drug should be sold by retail under the prescription of Neurologist or Psychiatrist only.</p>
SND Division			
5.	SND/MA/19/000106	M/s Torrent Pharmaceuticals	In light of earlier SEC (Neurology & Psychiatry) recommendation dated

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	Aripiprazole Tablets 2mg	Limited.	26.11.2024 & 27.11.2024, the firm presented the additional data pertains to Post Marketing Surveillance study report of Aripiprazole Tablets 2mg for the treatment of Schizophrenia in adolescent patients (13 to 17 years of age). After detailed deliberation, the committee recommended to accept the Post Marketing Surveillance study report of Aripiprazole Tablets 2mg for the treatment of Schizophrenia in adolescent patients (13 to 17 years of age).
6.	SND/MA/24/000148 Magnesium Sulfate in 5% Dextrose Injection USP (10Mg/ml)-100ml plastic bottle	M/s Otsuka Pharmaceutical India Private Limited	Experts opined that the proposal shall be deliberated in upcoming SEC (Reproductive).
FDC Division			
7.	FDC/MA/24/000183 Gabapentin IP 200/300mg (as Film Coated Tablet) + Duloxetine Hydrochloride IP Eq. to Duloxetine 20/30mgAs Delayed Release Pellets) Hard Gelatin Capsule	M/s PURE & CURE HEALTHCARE Pvt. Ltd	The firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, firm should submit BE study report along with Phase III CT protocol to CDSCO for review by the committee.
8.	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.	In light of earlier SEC recommendation dated 29.10.2024, the firm presented the proposal along with justification for Phase III clinical trial report before the Committee. After detailed deliberation, the committee opined that the proposal will be re-deliberated for wider discussion before the committee including 2-3 clinicians of Neurology & Psychiatry. Accordingly, firm should present the proposal along with justification before the committee.