Recommendations of the SEC (Neurology & Psychiatry) made in its 6th/26 meeting held on 13.05.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/25/000012 Olanzapine/ Samidorphan tablets (5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg, and 20 mg/10 mg)	M/s. MSN Laboratories Private Limited	In light of earlier recommendation dated 29.10.2025, the firm presented revised Phase-III Clinical trial protocol (Protocol Number: 005/FDC- OL-SA/MSN/2025, Version No: 2.0, dated 21-Jan-2026) before the committee. After detailed deliberation, the committee recommended for conducting the Phase III clinical trial as per the revised protocol submitted by the firm.
2.	ND/MA/23/000121 Brexpiprazole tablets 0.25 mg/0.5 mg/1mg/2 mg/3 mg/4 mg	M/s. Hetero Labs Limited	In light of earlier SEC recommendation dated 28.01.2025, the firm presented the BE study report for Brexpiprazole tablets 2 mg before the committee. The committee considered the BE study result. The committee noted that drug Brexpiprazole tablets 0.25 mg/0.5 mg/1 mg/2 mg/3 mg/4 mg is already approved in the country for manufacture and market on 16.02.2026. The committee recommended for grant of permission to manufacture and market of drug Brexpiprazole tablets 0.25 mg/0.5 mg/1 mg/2 mg/3 mg/4 mg for the proposed indication subject to the condition that- The drug should be sold by retail on the prescription of a Neurologist and Psychiatrist only.
3.	ND/MA/26/000002 Cenobamate tablets 12.5 mg/25 mg/50 mg /100 mg/150 mg/ 200 mg	M/s. Synokem Pharmaceuticals Ltd.	The firm presented the proposal for the grant of permission to manufacture and market of Cenobamate Tablets 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg and 200 mg along with the BE protocol for Cenobamate Tablets 12.5 mg and Phase III clinical trial protocol of Cenobamate Tablets (12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg & 200 mg) before the committee. After detailed deliberation, the committee recommended to revise the BE protocol in

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			order to avoid the inadvertent inclusion of pregnant women in this study, a gynecologist service may be availed to evaluate the women subjects in the study. Accordingly, the committee opined that the revised BE protocol shall be submitted to CDSCO. Further, the committee recommended for grant of permission to conduct BE study only for Cenobamate 12.5 mg strength Tablets and to conduct Phase III clinical trial as per the protocol presented by the firm. Also, the committee opined that the firm should submit Bioequivalence study report to CDSCO for review by the committee before initiating the Phase III clinical trial.
4.	ND/MA/26/000023 Mirogabalib Besylate Tablets 2.5 mg, 5 mg, 10 mg and 15 mg	M/s. Torrent Pharmaceuticals Ltd	The firm has presented the proposal for grant of permission to manufacture and market Mirogabalin Besylate Tablets 2.5 mg, 5 mg, 10 mg and 15 mg along with BE waiver justification and Phase III Clinical Trial Protocol (Protocol Number: CT/MIRO/NEUP/2025/3_1, Version No. 2, dated 8-Sep-2025) before the committee. After detailed deliberation, the committee considered the request for bio waiver and recommended for grant of permission to conduct Phase III clinical trial of Mirogabalin Besylate Tablets 2.5 mg, 5 mg, 10 mg and 15 mg as per the protocol presented by the firm. The results of Phase III Clinical Trial should be submitted to CDSCO for further review by the committee
5.	ND/CT/25/000104 Lasmiditan Tablets 50 mg / 100 mg	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of earlier recommendation dated 20.01.2026, the firm presented revised Phase IV clinical trial protocol (Protocol Number: BRPL/CT/LASMI/32/23, Protocol Version No. : 2.0, Dated: 23 Jan 2026) before the committee. After detailed deliberation, the committee recommended for conducting the Phase IV clinical trial of Lasmiditan Tablets 50 mg/

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			100 mg as per the revised protocol presented by the firm.
FDC Division			
6.	FDC/IMP/25/000001 Carbidopa USP (anhydrous) 35 mg/52.5 mg/ 70mg/87.5 mg + Levodopa USP 140 mg/210 mg/280 mg/350 mg extended release capsule	M/s. Amneal Healthcare Pvt. Ltd.	In light of the earlier SEC recommendation dated 20.01.2026, the firm presented the proposal along with justification before the committee. After detailed deliberation, the firm did not present any scientific justification for essentiality and desirability of the proposed FDC. The committee also noted that the proposed FDC in different strengths are already approved in India with same indication. In view of above, the committee did not recommend for import and marketing the proposed FDC in the country.
7.	FDC/MA/25/000216 Etizolam IP 0.25/ 0.5 mg/0.5 mg + Propranolol Hydrochloride IP 20 mg/20 mg/40 mg film coated tablet	M/s. Akums Drugs and Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 22.12.2025, the firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined that the firm should submit the scientifically designed protocol for conducting the study with specific focus on objectives (efficacy as a primary objective as per recommendation of DTAB sub-committee), sample size calculation and selection criteria for the study. Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.