Recommendations of the SEC (Neurology and Psychiatry) made in its 7th/26 meeting held on 22.07.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/80/26 Online Submission (57123) Evenamide	M/s. Clinirx Research Pvt. Ltd	The firm presented phase III clinical trial protocol no. NW-3509/024/III/2025 version no. 1.0 dated 24- SEP-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/78/26 Online Submission (54953) Immune Globulin Intravenous (Human) 10% Solution	M/s. Pharmaceutical Research Associates India Private Limited	The firm presented phase III clinical trial protocol no. KB071 version no. 5.0 dated 16-FEB-2026. After detailed deliberation, the committee opined the firm shall submit the following for further review by the committee. 1) Comprehensive clinical safety data supporting the proposed dose of 2gm/kg of QIVIGY in patients with CIDP and efficacy data supporting the lower dose levels (1.0g/kg and 0.5g/kg).
New Drug Division			
3.	ND/MA/24/000023 Cenobamate Tablets 12.5mg, 25mg, 50mg, 100 mg, 150 mg and 200 mg	M/s. MSN Laboratories Private Limited.	In light of earlier SEC recommendation dated 16.07.2025, firm presented Phase III Clinical trial report (Report No.: MSN/CT/CENO/11/23, Version 1.1, Dated of report: 20/JUL/2026 for grant of permission to manufacture and market of new drug Cenobamate Tablets before the committee. After detailed deliberation, the committee considered the Phase III Clinical Trial result as presented by the firm and recommended for the grant of permission to manufacture and market drug Cenobamate Tablets 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg & 200 mg. The Committee also recommended that the drug should be sold by retail on the prescription of Neurologist only.
4.	ND/MA/25/000037 Brexpiprazole tablets 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 18.06.2025, the firm presented the Phase-III Clinical trial report for Brexpiprazole tablets 0.25mg/0.5mg/1mg /2mg/3mg/4mg, before the committee.

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			After detailed deliberation, the committee considered the Phase-III Clinical trial report result. The committee noted that drug Brexpiprazole tablets 0.25mg/0.5mg/1mg /2mg/3mg/4mg 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 0.25mg/0.5mg /1mg/2mg/3mg/4mg for the proposed indication.
SND Division			
5.	SND/MA/26/000034 Gabapentin Extended Release Tablets 200 mg	M/s. Alkem Laboratories Ltd.	Firm presented their proposal for manufacturing and marketing of Gabapentin Extended Release Tablets 200 mg for the applied indication along with justification for BE and CT waiver before the committee. The committee noted that Gabapentin Extended Release Tablets 200 mg is not approved anywhere in the world. After detailed deliberation, the committee recommended that firm should conduct Bioavailability study for the applied lower strength of Gabapentin Extended Release Tablets 200 mg referring clinical therapeutic index in applied age group. Accordingly, firm should submit Bioavailability study Protocol to CDSCO for further review by the committee.
6.	SND/CT21/FF/2025/47851 Quetiapine Oral Suspension 20 mg/ml	M/s. Intas Pharmaceuticals Ltd	Firm presented their proposal for manufacturing & marketing of Quetiapine Oral Suspension 20 mg/ml along with BE study report, before the committee. The committee noted that Quetiapine (As fumarate) SR 400 mg, film coated Quetiapine fumarate tablets 25 mg/50 mg/100 mg/200 mg/300 mg, Quetiapine S.R tablet 200/300 mg, Quetiapine SR Tablets 50 mg are approved by the CDSCO since 2002. After detailed deliberation, the committee

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			recommended grant of permission to manufacture & marketing of Quetiapine Oral Suspension 20 mg/ml.
7.	SND/MA/22/000238 Caroverine HCL 40 mg Capsules	M/s. Lincoln Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 18.06.2025, the firm presented their proposal for manufacturing & marketing of Caroverine Capsule 40 mg along with BE study report, before the committee. The committee noted that the drug Caroverine Capsule 20 mg was approved by the CDSCO in year 2006 for the same indication to the applicant with posology of 1 to 2 capsules of 20 mg, 3 to 4 times a day. The applied strength 40 mg capsule remains inline with already approved posology for Tinnitus indication. Further, committee opined that there is need to generate additional clinical data in the already approved indication. After detailed deliberation, the committee in principle agreed that additional dosage form of 40 mg capsule can be considered subject to condition that firm should generate additional clinical data for which firm should submit the Phase-IV Clinical Trial protocol to the CDSCO for further review by the committee.
FDC Division			
8.	FDC/MA/24/000183 Gabapentin IP 200mg/300mg (as Film Coated Tablet) + Duloxetine Hydrochloride IP Eq. to Duloxetine 20mg/30mg (As Delayed Release Pellets) Hard Gelatin Capsule	M/s. Pure and Cure Healthcare Pvt. Ltd.	In light of the earlier SEC recommendation dated 10.12.2025, the firm presented the proposal along with BE study report (under fasting and fed condition) and revised Phase III CT study protocol before the committee. After detailed deliberation, the committee considered the BE study report (under fasting and fed condition). 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. Accordingly, the firm should submit Phase III CT study report to CDSCO for further review by the committee.