Recommendations of the SEC (Neurology & Psychiatry) made in its 10th/25meeting held on 18.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2024/ 46605 Levodopa-Benserazide-Entacapone 100/ 25/ 200 mg tablets	M/s. AXIS Clinicals Limited	In light of the earlier SEC recommendation dated 16.04.2025, the firm presented their proposal along with their justification for the proposed FDC before the committee. After detailed deliberation, the committee opined that the firm has not presented the relevant safety data of the proposed FDC as desired in the last SEC meeting. Accordingly, the firm should submit the followings documents / data for further review by the committee:- (1) More elaborate data of the proposed FDC w.r.t. safety. (2) Detailed Risk Evaluation Mitigation Strategies for the FDC to ensure safety during the study.
SND Division			
2.	SND/CT/22/000068 Ketamine Solution 50 mg/ mL for Subcutaneous Injection	M/s Themis Medicare Ltd	Firm has presented the Phase-III Clinical study report vide Study no.TML/KET/01 version no.1.0 dated 19.02.2025 of the drug product Ketamine Solution 50 mg/ mL for Subcutaneous Injection before the committee. After detailed deliberation, Committee recommended to accept the Clinical study report as presented by the firm for further consideration.
3.	SND/MA/22/000238 Caroverine HCL 40 MG Capsules	M/s Lincoln Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 25.02.2025, firm presented the therapeutic justification higher strength of Caroverine HCL Capsules 40 mg and its dosage regimen upto 120 mg & 160 mg per day. Committee noted that said drug is mainly prescribed by ENT experts. Hence, Committee recommended to invite ENT experts for SEC deliberation w.r.t. followings: 1) To review rationality and justification

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			for higher strength of Caroverine HCL Capsules 40 mg and its dosage regimen upto 120 mg & 160 mg per day in applied indication. 2) To review revised Phase III clinical trial protocol with randomised, double blind, placebo controlled design for establishing safety and efficacy of Caroverine HCL Capsules 40 mg in Tinnitus. 3) To review literature and data w.r.t. clinical experience (efficacy & safety) of product in applied indication.
4.	SND/MA/24/000102 Chlordiazepoxide Tablets IP 15 mg and 20 mg	M/s.Abbott Healthcare Pvt. Ltd	In light of the earlier SEC recommendation dated 19.11.2024, firm has presented the Bioequivalence clinical study report of Chlordiazepoxide Tablets IP 20 mg before the committee. After detailed deliberation, the committee recommended to accept the BE study report and for grant of permission to manufacture & marketing of Chlordiazepoxide Tablets IP 15 mg and 20 mg (Intermediate strengths) for anxeity disorders, withdrawl symptoms of acute alcoholism and preoperative apprehension and anxeity
5.	SND/MA/22/000163 Buprenorphine Hydrochloride sublingual films (8/6/4 mg)	M/s Zim laboratories Limited	In light of earlier SEC recommendation dated 28.02.2025, the firm presented revised Phase III Clinical trial study Protocol AIIMSA3364 ver.02 dated 15.04.2025 and Pilot study protocol for validation of the questionnaire for assessing product acceptance and subjective effects of sublingual Buprenorphine before the Committee. After detailed deliberation, the Committee recommended for grant of permission to conduct Phase III clinical trial study as per revised protocol presented by the firm subject to the condition that Pilot study for validation of the questionnaire for assessing product acceptance and subjective effects of sublingual Buprenorphine to be performed in 16 subjects before initiation of the study.

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			Accordingly, firm should submit Phase III Clinical study report to CDSCO for further review by the Committee.
New Drug Division			
6.	ND/MA/25/000037 Brexpiprazole Tablets 0.25 mg/ 0.5 mg/ 1 mg/ 2 mg/ 3 mg/ 4 mg	M/s Exemed Pharmaceuticals	The firm presented their proposal for grant of permission to conduct the BE study (Protocol no- BN25-005, Version-00, dated: 11.02.2025) and Phase III Clinical Trial study (Protocol No. CT/2025/03, Version: 00, Dated: 28.01.2025) for Brexpiprazole Tablets, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct bioequivalence study and Phase III Clinical Trial, as per the protocols presented. Further, the firm should submit BE study report to CDSCO for review by the committee before initiating the Phase III Clinical Trial
FDC Division			
7.	FDC/MA/23/000287 Gabapentin IP (SR) + Methylcobalamin IP + Nortriptyline Hydrochloride eq. to Nortriptyline IP (600 mg+1500 mcg+10 mg/ 300 mg+1500 mcg+ 10 mg) film coated bilayered tablet	M/s Ravenbhel Healthcare Pvt. Ltd	In light of earlier SEC recommendation dated 16.04.2025, the firm presented the Phase III clinical trial report along with justification before the committee. The committee noted that there is no statistically significant difference observed in efficacy of test product in Arm A (lower strength) and Arm B (higher strength). After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC only in lower strength i.e. Gabapentin IP (SR) + Methylcobalamin IP + Nortriptyline Hydrochloride eq. to Nortriptyline IP (300 mg+1500 mcg+10 mg) film coated bilayered tablet after submission of data including dissolution data and justification for BE waiver for lower strength as per the BE Study guideline.
8.	FDC/MA/24/000184	M/s Akums Drugs &	The firm presented the proposal along with BE & Phase III clinical trial protocol

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	Rizatriptan Benzoate IP eq. to Rizatriptan 10 mg + Meloxicam IP 20 mg uncoated orally disintegrating Tablet	Pharmaceuticals Limited	before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. As regard to Phase III clinical trial protocol, the committee opined that: 1. Placebo should not be used as a comparator. 2. Patient with frequency of migraine attack more than 2 in a month should be included in inclusion criteria and above mentioned criteria for 6 months prior to starting study. 3. Patients on Prophylaxis medication should not be included in the study and same may be mentioned in the exclusion criteria. Accordingly, the firm should submit BE study report along with revised Phase III clinical trial protocol to CDSCO for further review by the committee.