

Recommendations of the SEC (Neurology & Psychiatry) made in its 17th/25 meeting held on 29.10.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/182/22 Online Submission (37414) Ocrelizumab (RO4964913)	M/s. PPD Pharmaceutical Development India Private Limited	In light of earlier SEC recommendation dated 09.03.2025 and CT NOC condition no. (1) Before initiation of open label extension part of the study, the firm should submit primary analysis data of double-blind as part of study to CDSCO for further review by the committee, protocol no. WN42086. The firm has presented primary analysis data along with safety data before SEC Committee dated 29.10.2025. After detailed deliberation, the committee recommended that the firm shall initiate open label extension part of the study for the Indian patients as part of the study for protocol.
2.	CT/116/24 Online Submission (45269) Lumateperone (ITI-007)	M/s. IQVIA RDS (India) Private Limited	The firm did not turn up for the presentation.
BA/BE Division			
3.	BABE/CT05/FF/2024/ 45380 DA-5207 (Donepezil Transdermal System) 371.2 mg/Patch (10 mg/day)	M/s. Accutest Research Laboratories (I) Pvt. Ltd.	In light of the earlier SEC recommendation dated 19.03.2025, the firm has presented the amended protocol No. ARL-24-043 Version No. 02 dated 14.07.2025 before the committee. Further, firm also has presented the Research Report of in vitro human skin permeability study of Test product DA 5207 patch (371.2 mg/Patch) compared to Reference Product (176.7 mg /patch) in justification to comparing the higher strength of the test product with Reference product. After detailed deliberation, the committee recommended for grant of permission for the conduct of the study with amended protocol for export purpose only.
New Drugs Division			
4.	ND/MA/25/000012	M/s. MSN Laboratories	The firm presented the proposal for grant of permission for manufacturing and

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	Olanzapine + samidorphan Tablets 5 mg/10 mg, 10 mg/10mg, 15 mg/10 mg and 20 mg/10 mg	Private Limited	<p>Marketing of the drug Olanzapine/Samidorphan tablets (5 mg/10 mg, 10 mg/10 mg, 15 mg/10 mg, and 20 mg/10 mg) along with BE study results and Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee reviewed the BE study results and opined that the firm needs to submit justification for the linear correlation between the strengths used in BE study and other proposed strengths.</p> <p>Further, the committee reviewed the Phase III clinical trial protocol and opined that:</p> <ol style="list-style-type: none"> 1. Metabolic parameters should be part of primary endpoint along with efficacy parameters. 2. Firm should revise the inclusion criteria w.r.t. assessment scale used for mania and schizophrenia. 3. Firm needs to clearly define the sub group analysis in the study protocol. 4. To increase the follow-up period to 4 weeks to monitor the withdrawal effects of samidorphan. <p>Accordingly, firm should submit revised CT protocol to CDSCO for further review by the committee.</p>
5.	ND/MA/24/000122 Cenobamate Tablets (12.5 mg/ 25 mg/ 50 mg/100 mg/ 150 mg/ 200 mg)	M/s. Exemed Pharmaceuticals	<p>The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Cenobamate tablets 12.5 mg, 25 mg, 50 mg, 100 mg, 150 mg, and 200 mg along with BE study results and Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee considered BE results presented by the firm and recommended for grant of permission to conduct Phase III clinical trial as per the protocol presented subject to the condition that</p> <ol style="list-style-type: none"> 1) Firm should perform LFT every 4 weeks during the trial.

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			<p>2) Follow-up period should be increased to 4 weeks from the last dose.</p> <p>Accordingly, firm should submit the revised protocol to CDSCO.</p>
SND Division			
6.	<p>SND/IMP/25/000075</p> <p>Naloxone Hydrochloride Nasal Spray, 4 mg/Spray (Metered dose spray)</p>	<p>M/s. Amneal Healthcare Pvt. Ltd.</p>	<p>The firm presented the proposal for grant of permission for manufacturing and marketing Naloxone Hydrochloride Nasal Spray, 4mg/Spray along with Justification for BE and Clinical trial waiver before the Committee.</p> <p>The committee noted that the product is approved in India as injectable and the applied drug formulation approved in USA as Nasal spray for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression.</p> <p>After detailed deliberation, the Committee recommended for grant of permission to manufacture and market Naloxone Hydrochloride Nasal Spray, 4mg/Spray for proposed indication with BE and CT waiver with condition to conduct Phase IV Clinical trial study.</p> <p>Accordingly, the firm should submit Phase IV study protocol to CDSCO within 03 months of approval of marketing authorization.</p>
FDC Division			
7.	<p>FDC/MA/24/000003</p> <p>Gabapentin IP (ER) 600 mg/300 mg + Duloxetine Hydrochloride IP eq. to Duloxetine (as delayed release) 20mg/20 mg film coated tablet</p>	<p>M/s. Ravenbhel Healthcare Pvt. Ltd</p>	<p>In light of earlier SEC recommendation dated 19.03.2025, the firm presented their proposal along with revised Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended following modification in Phase III clinical trial protocol:</p> <p>In case of breakthrough pain instead of using drug Gabapentin proposed FDC itself need to be used and any additional adverse event may be recorded or</p>

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			<p>analysed separately due to increased dose of Duloxetine.</p> <p>Accordingly, the revised Phase III CT Protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase III CT report for review by the committee.</p>
8.	<p>FDC/IMP/25/000001 Carbidopa USP (anhydrous) 35 mg/52.5 mg/70 mg/87.5 mg + Levodopa USP 140 mg/210 mg/280 mg/350 mg extended-release capsule</p>	<p>M/s. Amneal Healthcare Pvt. Ltd.</p>	<p>The firm presented their proposal along with request for BE & Phase III CT waiver before the committee.</p> <p>The committee noted that the said FDC is already approved in the USA.</p> <p>The firm informed that they have conducted Phase I, II and III Clinical Trial as part of Clinical Development Program. However, the firm didn't present any safety and efficacy data generated in Indian Population.</p> <p>Accordingly, the firm should submit the above data to CDSCO for further review by the committee.</p>