

Recommendations of the SEC (Neurology & Psychiatry) made in its 98th meeting held on 08.11.2023 & 09.11.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/IMP/20/000075 (Dy.No.7441) Satralizumab	M/s. Roche Products Pvt. Ltd.	The firm did not turn up for presentation.
SND Division			
2.	SND/CT/23/000015 Buprenorphine SR Injection 100mg Variant I & Variant II	M/s. Rusan Pharma Limited	<p>The firm presented clinical trial protocol having two phases in the proposed study, “A Phase I, open label, randomized, three treatments, parallel, Pharmacokinetic, safety and tolerability study of Buprenorphine sustained release injection 100mg variant I and variant II of Rusan Pharma Ltd, India compared with ‘SUBOXONE (Buprenorphine/Naloxone) 12/3 mg sublingual tablet manufactured by Indivior UK Ltd. Slough, Berkshire, SLI 3UH, United Kingdom in 16 normal, Healthy adults, human subjects from day 1 to 11” (Protocol No.01/23, version No. 01, dated 10th Jan 2023). The firm has also presented Phase-II study protocol from day 21-56 before the committee.</p> <p>After detailed deliberation, the committee opined that the firm has proposed the protocol to be conducted in two stage. However, the stages are mentioned as Phase-I, Phase-II and such type of terminology mislead/not provide the correct status of the proposed study. Therefore, the committee recommended to revised the protocol along with scientific justification to CDSCO for further review by the committee</p>
3.	SND/MA/23/000216 Cariprazine Capsules 0.75 mg	M/s. Mascot Healthseries Private Limited	The firm did not turn up for presentation.
FDC Division			
4.	FDC/MA/23/000108 Gabapentin IP (as film coated tablets) 200mg/300mg + Duloxetine Hydrochloride IP eq.	M/s. Synokem Pharmaceuticals Ltd.	<p>In light of the earlier SEC recommendation dated 17.08.2023, the firm presented their proposal along with BE study and Phase III clinical trial protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to</p>

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	to Duloxetine (as delayed release pellets) 20mg/30mg Hard Gelatin Capsules		conduct the proposed BE study and Phase III clinical trial study with the condition that BE study report should be presented before the SEC prior to initiation of the Phase III clinical trial study.
Medical Device Division			
5.	IMP/MD/2023/94777 Nerve Electrical Stimulator (Brand Name: Nerivio®)	M/s. Dr.Reddy's Laboratories Limited	<p>The firm presented proposal for grant of permission to import the Nerve Electrical Stimulator (Brand Name: Nerivio®) intended for acute and/or preventive treatment of migraine with or without aura in patients 12 years of age or older. It is a prescription use, self-administered device for use in the home environment at the onset of migraine headache or aura for acute treatment, or every other day for preventive treatment. This device is a new device and there is no predicate device approved by the Central Licensing Authority.</p> <p>The firm presented the Clinical study data generated on total 702 patients in USA (pilot (71 patients data) +pivotal Clinical studies (631 patients data)) and Post marketing follow-up data on 14406 patients data globally. The firm also presented the published data supporting the Clinical efficiency of the device. The firm also informed that the said device is approved in USA and they have sold 47451 units in the US market since year 2020.</p> <p>Based on the above data, the committee was satisfied with the Clinical data to prove the safety and efficiency of device and recommended for consideration of the proposal. However the firm shall submit the protocol to conduct Post marketing Clinical Investigation to the Central Licensing Authority to generate safety and performance data of the device in the Indian population.</p>
BA/BE Division			
6.	File No. 12-09/2023/BA-BE/MISC-17/DC (BABE/CT05/FF/2023/36831) Carbidopa and	M/s. Cliantha Research Limited, Ahmedabad	<p>The firm presented their proposal along with the BE Study protocol for export purpose only.</p> <p>After detailed deliberation, the committee recommended for conduct the study as per the presented protocol.</p>

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	Levodopa Controlled-Release Tablets (50mg/200 mg)		
7.	File No. 12-09/2023/BA-BE/MISC-18/DC (BABA/CT05/FF/2023/37229) Carbidopa and Levodopa Controlled-Release Tablets (25mg/100mg, 37.5mg/150mg, 50mg/200 mg, 25mg/150mg)	M/s. Cliantha Research Limited, Ahmedabad	The firm presented their proposal along with the BE Study protocol for export purpose only. After detailed deliberation, the committee recommended for conduct of the study as per the presented protocol.
8.	File No. 12-09/2023/BA-BE/MISC-23/DC (BABA/CT05/FF/2023/37922) Carbidopa and Levodopa Controlled Release Tablets 62.5mg/250mg	M/s. Cliantha Research Limited, Ahmedabad	The firm presented their proposal along with the BE Study protocol for export purpose only. After detailed deliberation, the committee recommended for submission of the following documents: 1) Detailed justification and rationale for conducting BA study in Healthy Subjects instead of patients. 2) Justification and rationale for using RLD Sinemet 50/200 instead of RYTARY 61.25/245.
9.	File No. 12-09/2023/BA-BE/MISC-29/DC(BABA/CT05/FF/2023/38728) Lithium Carbonate Extended-Release Tablets 900 mg	M/s. Veeda Clinical Research Limited, Ahmedabad	The firm presented their proposal along with the BE Study protocol for export purpose only. After detailed deliberation, the committee recommended for submission of the following documents: 1) Justification for the BE study between the Lithium Carbonate Extended-Release Tablets 450 mg (Reference) twice a day and Lithium Carbonate Extended-Release Tablets 900 mg (Test) single dose along with Regulatory communication. 2) Dose dumping study of the subject test product. Accordingly, the firm should submit the

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			above information for re-deliberation by the SEC.
10.	File No. 12-09/2023/BA-BE/MISC-32/DC(BABE/CT05/FF/2023/38794) Carbidopa + Levodopa Extended-Release Capsules 87.5 mg/350 mg	M/s. Alembic Pharmaceuticals Limited Vadodara	The firm presented their proposal along with the BE Study protocol for export purpose only. After detailed deliberation, the committee recommended for submission of the following documents: 1) Detailed justification and rationale for conducting BA study in Healthy Subjects instead of patients. 2) Data on In-vitro drug release study of test product and dose dumping study. 3) Safety and Tolerability data of previously conducted studies and relevant published literature from peer reviewed journals.
New Drugs Division			
11.	ND/MA/23/000156 Brexipiprazole tablets 1mg/2mg/3mg/4mg	M/s Torrent	The firm presented the proposal for grant of permission to manufacture and market of Brexpiprazole tablets 0.25mg, 0.5mg, 1mg, 2mg, 3mg, 4mg indicated for the treatment of schizophrenia in adult patients along with Phase III clinical trial protocol and BE study report before the committee. After detailed deliberation, the committee recommended to conduct the Phase III clinical trial subject to the condition that the clinical trial sites should be geographically distributed in the country.
12.	ND/IMP/23/000066 Brexipiprazole tablets 1mg/2mg/3mg/4mg	M/s Otsuka	The firm presented its proposal to import and marketing of Brexpiprazole tablets-1mg, 2mg, 3mg, 4mg indicated for the treatment of schizophrenia in adult patients along with global Phase III clinical trial report and justification for the waiver of local clinical trial before the committee. The committee opined that there is no unmet medical need in the country. The global clinical trial data presented by the firm on Indian patients was not found sufficient to demonstrate efficacy and

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			safety. The firm need to conduct Phase III clinical trial on Indian Patients. Accordingly clinical trial protocol should be submitted for review