

**Recommendations of the SEC (Neurology & Psychiatry) made in its 04<sup>th</sup>/25 meeting held on 19.03.2025 at CDSCO (HQ), New Delhi:**

| S. No                 | File Name & Drug Name, Strength   | Firm Name   | Recommendations  |
|-----------------------|---|---|--|
| <b>GCT Division</b>   |   |   |  |
| 1.                    | CT/182/22<br>Online Submission<br>(37414)<br>Ocrelizumab<br>(RO4964913)                                       | M/s PPD<br>Pharmaceutical<br>Development India<br>Private Limited | The firm presented waive off condition in amendment. 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 part of the study for further review by the committee) protocol no. WN42086.<br><br>After detailed deliberation, the committee recommended for condition mentioned in CT NOC stands valid and before initiation of open label extension part of the study, the firm should submit primary analysis data of double-blind part of the study for further review by the committee. |
| 2.                    | CT/121/22<br>Online Submission<br>(37431)<br>Pozelimab<br>(REGN3918)<br>and (ALNCC5)                          | M/s Parexel<br>International<br>Clinical Research                 | The firm presented protocol amendment 4 dated 20 December 2024 protocol no. R3918-MG-2018.<br><br>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm with condition that the interim analysis data shall be submitted to CDSCO.  |
| <b>BA/BE Division</b> |   |   |  |
| 3.                    | BABE/CT05/FF/2024<br>/45380<br><br>DA-5207 (Donepezil<br>Transdermal System)<br>371.2 mg/Patch (10<br>mg/day) | M/s Accutest<br>Research<br>Laboratories (I)<br>Pvt. Ltd.         | The firm presented the protocol No. ARL-24-043 ver. 01 dated 06.09.2024 for BA/BE study for export purpose only.<br><br>After detailed deliberation, the committee opined that firm should submit the followings:<br><br>(1) detailed justification for comparing the higher strength of the Test product ( <i>i.e.</i> 371.2 mg/Patch) with Reference product ( <i>i.e.</i> 176.7 mg/patch) along with data of <i>in-vitro</i> study conducted to support the equivalency in release pattern,<br><br>(2) to incorporate intention to-treat-   |

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|                     |   |                                      | <p>analysis in addition to per-protocol population in statistical analysis section of the Protocol,</p> <p>(3) During the study, possible cardiac side effects to be monitored and accordingly, the Protocol should be modified.</p> <p>Accordingly, the firm should submit above data for further review by the committee.</p>   |
| <b>SND Division</b> |   |                                      |   |
| 4.                  | SND/CT/24/000076<br><br>Zolpidem Sublingual Spray 3.85% w/v             | M/s Troikaa Pharmaceuticals Ltd      | <p>In light of earlier SEC Recommendation dated 26.11.2024 &amp; 27.11.2024. Firm presented revised Phase-IV clinical trial protocol (Protocol No. CT/57/01/24, Version 02, dated 29.01.2025) before the committee.</p> <p>After detailed deliberation, the committee opined that the firm shall incorporate scales for addictive potential in the proposed protocol.</p> <p>Accordingly, firm should submit revised Phase IV Protocol to CDSCO for further review by the Committee.</p>  |
| 5.                  | SND/MA/24/000236<br><br>Lurasidone Hydrochloride Tablets 60 mg & 120 mg | M/s MSN Laboratories Private Limited | <p>Firm presented their proposal for grant of permission to manufacture and marketing of Lurasidone Hydrochloride Tablets 60 mg &amp; 120 mg (Additional Strength) for the treatment of Patients with Schizophrenia along with BE study report of Lurasidone Hydrochloride 80 mg tablets and justification for waiver of clinical trial before the Committee.</p> <p>The firm has informed that they are already holding MA permission for Lurasidone Hydrochloride Tablets 40 mg &amp; 80 mg for the treatment of Patients with Schizophrenia which was approved by CDSCO on 18.07.2016.</p> <p>Further, firm has informed that they got approval from USFDA for all the strengths of Lurasidone Hydrochloride 40 mg, 60 mg, 80 mg &amp; 120 mg tablets.</p> |

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|                          |  |  | After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Lurasidone Hydrochloride Tablets 60 mg & 120 mg (Additional Strength) for the treatment of Patients with Schizophrenia.  |
| <b>New Drug Division</b> |  |  |   |
| 6.                       | ND/MA/23/000191<br><br>Brexiprazole Tablets<br>0.25mg/0.5<br>mg/1mg/2mg/3mg/4m<br>g  | M/s MSN<br>Laboratories<br>Private Limited           | <p>The firm presented proposal for grant of permission to manufacture and market Brexpiprazole Tablets 0.25mg/0.5 mg/1mg/2mg/3mg/4mg, along with Bioequivalence study report and Phase III Clinical trial protocol, before the committee.</p> <p>After detailed deliberation, the committee considered Bioequivalence study results and recommended for grant of permission to conduct Phase-III clinical trial study as per the protocol presented, subject to the following conditions.</p> <ol style="list-style-type: none"> <li>1. Clinical Trial Sites should be geographically distributed with 50% Government sites.</li> <li>2. Firm should include a qualified Psychiatrist by training and experience as the Principal Investigator as the drug (Brexiprazole) will be evaluated in Psychiatric patients.</li> </ol> |
| <b>FDC Division</b>      |  |  |   |
| 7.                       | FDC/MA/24/000220<br><br>Rizatriptan Benzoate<br>IP eq. to Rizatriptan<br>+ Naproxen Sodium<br>USP (5mg + 550mg<br>& 10mg + 550mg)<br>film coated tablets | M/s Akums Drugs<br>and<br>Pharmaceutical<br>Limited. | <p>The firm presented the proposal along With BE study protocol &amp; Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined the following:</p> <ol style="list-style-type: none"> <li>1. The firm did not present adequate justification/rationale for the proposed FDC.</li> <li>2. More published scientific literature in</li> </ol>  |

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|       |   |  | <p>peer reviewed journal in support of rationality and desirability of proposed FDC should be submitted.</p> <p>3. Justification in light of standard therapeutic treatment guidelines should be presented.</p> <p>4. Firm should submit international approval status of proposed FDC.</p> <p>Accordingly, the firm should submit above data for further review by the committee.</p>   |
| 8.    | <p>FDC/MA/24/000003</p> <p>Gabapentin IP (ER) 600mg/300mg + Duloxetine Hydrochloride IP eq. to Duloxetine (as delayed release) 20mg/20mg film coated tablet</p> | <p>M/s Ravenbhel Healthcare Pvt. Ltd</p> | <p>In light of earlier SEC recommendation dated 26.09.2024, firm presented the proposal along with revised Phase III clinical trial protocol.</p> <p>After detailed deliberation, the committee noted that firm did not define the titration of proposed FDC. Hence, the committee reiterated the earlier SEC recommendation dated 26.09.2024 as following should be defined in the CT protocol:</p> <ul style="list-style-type: none"> <li>• Titration of medication (proposed FDC) in case of break through pain/ non-response of pain.</li> <li>• Procedure for dose up-titration of proposed FDC.</li> </ul> <p>Accordingly, revised Phase III clinical trial protocol should be submitted to CDSCO for further review by the committee.</p> |