

**Recommendations of the SEC (Neurology and Psychiatry) made in its meeting held on 25.02.25 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
2	CT/130/20 Online Submission (32645)	M/s Roche Products (India) Private Limited	<p>In light of earlier SEC Recommendation dated 18.07.2024, now the firm presented protocol amendment version 7.0 dated 15 February 2024 protocol no. GN42272.</p> <p>After detailed deliberation, the committee opined that the firm shall submit CIOMS report, SAE reports and minutes of meeting of ethics committee along with all clinical records of the participant who expired enrolled in the trial for further review by the committee.</p>