

Recommendations of the SEC (Neurology and Psychiatry) made in its meeting held on 19.11.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/PostAppr/2024/33297 Online Submission (33297) Milvexian	M/s. IQVIA RDS	<p>In light of earlier SEC dated 24.07.2024, now the firm presented protocol amendment 2 dated 10.04.2024 protocol no. 70033093STR3001.</p> <p>After detailed, deliberation the committee opined that the firm shall submit justification /explanation for following for further review by the committee.</p> <ol style="list-style-type: none"> 1. There are high dropout rates of participating centers and from recruited patients. 2. More government sites to be included in the study. 3. Frequent monitoring of urine protein by creatinine ratio is required