

Recommendations of the SEC (Renal) made in its 03rd/24 meeting held on 24.04.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/134/22 Online Submission (31875) TIN816	M/s. Novartis	<p>The firm presented protocol amendment version 02 dated 25 January 2024 protocol number CTIN816A12201 for the study “A randomized, multi-centric, placebo-controlled, participant and investigator-blinded study to evaluate the safety, tolerability and efficacy of TIN816 in adult patients at risk for acute kidney injury following cardiac surgery”.</p> <p>The committee reviewed DSMB reports and SAEs reported in related studies.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment with the condition that the firm should submit all future DSMB reports to all concerned, including CDSCO for periodic review.</p>
2.	CT/66/22 Online Submission (30150) Crovalimab	M/s. Roche	<p>The firm presented protocol amendment version 5 dated 29 July 2022 and protocol amendment version 6 dated 16 May 2023 protocol number BO42353.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.</p>