Recommendations of the SEC (Renal) made in its 09th/24 meeting held on 22.10.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/CT04/FF/2024/45340 Online Submission (45340) WAL0921	M/s George	The firm presented phase 2 clinical study Protocol no: WAL0921 – 02, Version no. 1.0 dated 06 May 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with the condition that study shall be conducted at tertiary care centers and number of subjects to be enrolled shall be upto 45 only.
2.	GCT/CT04/FF/2024/44106 Online Submission (44106) Sodium Zirconium Cyclosilicate (SZC)	M/s Fortrea	The firm presented phase 3 clinical study Protocol no: D9481C00001 version 8.0 dated 14 November 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that blood let volume chart shall be included in the protocol.
3.	GCT/PostAppr/2023/29948 Online Submission (29948) Atacicept	M/s Medpace	The firm didn't turn up for presentation.
4.	GCT/PostAppr/2024/34846 Online Submission (34846) Sibeprenlimab (VIS649) Pre-filled 2 ml Syringes	M/s George	The firm presented protocol amendment 2.0 dated 21- March 2024 protocol no. 417-201-00012. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
FDC Division			
5.	FDC/MA/24/000224 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Telmisartan IP (10mg+40mg/	M/s Pure and Cure Healthcare Pvt. Ltd.	The firm presented the proposal along with BE study protocol & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study.

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	10mg+80mg) film coated tablet		As regard to Phase III clinical trial protocol, the committee opined that the firm should include one more arm for concomitant administration of Dapagliflozin Tablets 10mg and Telmisaratan Tablets 40mg. Accordingly, BE study report should be submitted along with revised Phase III clinical trial protocol to CDSCO for further review by the committee.