

**Recommendations of the SEC (Cardiovascular) made in its 8<sup>th</sup>/24 meeting held on 23.04.24 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/35/24 Online Submission (42175)  Finerenone	M/s. George Clinical India	The firm presented Phase III clinical study protocol number: 202301CPC version number 2.0 dated 03 October 2023.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.  Dr. Sandeep Bansal didn't participate in the proposal.
<b>FDC Division</b>			
2.	FDC/MA/22/000248  Bisoprolol Fumarate IP + Telmisartan IP + Chlorthalidone IP 2.5mg/5mg/10mg+20 mg/40mg/80mg+6.25 mg / 12.5mg /12.5mg	M/s. Windlas Biotech	In light of earlier SEC recommendation dated 12.04.2023, the firm presented the proposal along with BE study report along with Phase III clinical trial protocol before the committee.  After detailed deliberation, the committee opined that the firm should submit the justification for sample size in light of intra-subject variability observed for the drug Telmisartan in the BE study report.  Further, the committee recommended that the firm should submit the revised structured Phase III CT Protocol as per NDCT Rules, 2019 for review by the committee.
3.	FDC/MA/22/000363  Metoprolol Succinate SR 25mg/50mg + Dapagliflozin 5mg/10mg tablets	M/s. Eris Lifesciences Limited	In light of earlier SEC recommendation dated 07.06.2023, the firm presented the proposal along with Phase III clinical trial report before the committee.  After detailed deliberation, the committee opined that the firm should submit source data of the Phase III clinical trial report to CDSCO for review by the committee.