Recommendations of the SEC (Cardiovascular) made in its 18th/24 meeting held on 17.09.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/64/24 Online Submission (43223) AZD5462	M/s. Parexel International Clinical Research Private Limited	In light of earlier SEC recommendation dated 12.06.2024, the firm presented the phase 2b clinical study protocol no. D9090C00008, version 1.0 dated 31 January 2024, more justification for NYHA FC Class IV patients to include in the study protocol. After detailed deliberation, the committee recommended to include New York Heart Association (NYHA) Functional Class II & III patients only in study protocol.
2.	CT/45/24 Online Submission (42369) Bakinrenone/ Dapagliflozin	M/s. AstraZeneca	The proposal may only be deliberated before SEC after availability of Renal expert as a special invitee.
FDC Division			
3.	FDC/MA/22/000248 Bisoprolol Fumarate IP + Telmisartan IP + Chlorthalidone IP (2.5mg/5mg/10mg + 20mg/40mg/80mg + 6.25mg/12.5mg/12.5 mg) uncoated tablets	M/s. Windlas Biotech	In light of earlier SEC recommendation dated 23.04.2024, the firm presented the proposal along with justification for sample size before the committee. The committee observed high intra-subject variability i.e. more than 30% for the drug Telmisartan in the BE study report. After detailed deliberation, the committee opined that the firm should submit fresh BE Protocol with more number of subjects to CDSCO for further review by the committee.
4.	FDC/MA/24/000002 Sacubitril + Valsartan (as sodium salt complex) 50mg (24mg+26mg)/ 100mg(49mg+51mg)/ 200mg(97mg + 103mg) Film coated sustained release tablet	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 13.08.2024, the firm presented the proposal along with justification for variability of the kinetic data of the BE study report along with BE study protocol under Fed condition and Phase III CT protocol before the committee. After detailed deliberation, the committee considered the BE study report under fasting condition and recommended to conduct BE study under Fed condition.

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			As regard to Phase III CT study, the committee recommended to conduct the study with following conditions: 1. Patient with a plasma level of NT-pro BNP should be more than 120pg/mL in inclusion criteria. 2. Serum pregnancy test should be done in each visit. 3. Patients should be on Sacubitril + Valsartan (as sodium salt complex) 100mg(49mg+51mg) tablet stable dosing more than 1 month in inclusion criteria. 4. Patients with clinically significant impaired hepatic function (SGOT&SGPT should be more than 1X the UNL and/or Total bilirubin more than 1X the UNL) in Exclusion criteria. Accordingly, the revised Phase III clinical trial protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase III clinical trial report and BE report under Fed condition for further review by the committee.