

Recommendations of the SEC (Cardiovascular) made in its 09th/26 meeting held on 07.07.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/CT/26/000012 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10/10mg + Bisoprolol Fumarate IP 1.25 mg/2.5 mg film coated tablet	M/s Eris Lifesciences Limited	In light of the condition mentioned in permission in Form CT-23 dated 13.12.2024; the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
2.	FDC/MA/26/000100 Bempedoic Acid 180 mg/180 mg/180 mg + Ezetimibe IP 10 mg/10 mg/10 mg + Rosuvastatin Calcium IP eq. to Rosuvastatin 10 mg/20 mg/40 mg film coated bilayer tablet	M/s Exemed Pharmaceuticals	The firm presented their proposal along with BE study protocol & Phase III clinical trial protocol before the committee. After detailed deliberation, the committee considered the rationality of the proposed FDC and recommended for grant of permission to conduct the BE study & Phase III clinical trial. Accordingly, the result of the BE study should be submitted to CDSCO for further review by the committee before initiation of the Phase III clinical trial.