Recommendations of the SEC (Cardiovascular) made in its 11th/24 meeting held on 05.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/23/000003 Edoxaban film coated tablets 60mg	M/s. Zuventus Healthcare Limited	In light of the recommendations of SEC (Cardiology & Renal) dated 19.04.2023, the firm presented their BE study report for grant of permission to manufacture and market Edoxaban 15, 30, & 60mg film-coated tablets, along with a request for CT waiver. The committee noted that the Edoxaban had lower risk of bleeding without comprising efficacy, more efficacy as compared to other NOACs and no drug interactions with PPI and the drug is approved in US, Japan and Canada. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the Edoxaban 15, 30, & 60mg film-coated tablets for the proposed indications with a condition to conduct Phase IV clinical trial for both the indications. Accordingly, the firm should submit the Phase IV CT protocol to CDSCO within 3 months of approval for further evaluation by the committee.
FDC Division			
2.	FDC/CT/24/000034 Cilnidipine IP 20mg + Telmisartan IP 40mg film coated tablets	M/s. Ajanta Pharma Limited	In light of the condition mentioned in permission in Form CT-23 dated 15.11.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined the following modification: 1. Serum Creatinine test should be done additionally at Follow up visit Week 4/ Day 28 (±2). 2. Renal Doppler test should be done prior to inclusion of patients in the study. Accordingly, revised Phase IV clinical trial protocol should be submitted to

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			CDSCO for review, after approval from CDSCO, the firm should submit Phase IV CT study report to CDSCO for further review by the committee.
3.	FDC/MA/24/000095 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Bisoprolol Fumarate IP (10mg+1.25mg, 10mg+2.5mg, 10mg+5mg & 10mg+10mg) film coated tablet	M/s. Akums Drugs and Pharmaceutical Limited	The firm presented the proposal before the committee along with the Phase III clinical trial protocol for two strengths i.e. Bisoprolol 5mg/10mg + Dapagliflozin 10mg/10mg tablets and request for BE study waiver. After detailed deliberation, the committee considered the request for waiver of BE study and recommended for grant of permission for conduct of the Phase III clinical trial. The report of the Phase III clinical trial should be submitted to CDSCO for further review by the committee.
4.	FDC/MA/23/000087 Ezetimibe 10mg + Atorvastatin Calcium 80mg tablets	M/s. Pure & Cure	In light of the earlier SEC recommendation dated 12.04.2023, the firm presented the proposal along with BE study report and justification for CT waiver before the committee. The committee noted that the said FDC is already approved in the USA, Australia, etc. After detailed deliberation, the committee considered the BE study report as well as the request for Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the FDC with the condition to conduct the Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.