

Recommendations of the SEC (Cardiovascular) made in its 04th/25 meeting held on 13.02.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/24/000006 Empagliflozin 10mg/10mg + Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate (ER) 25mg/ Metoprolol Succinate IP 47.50mg eq. to Metoprolol Tartrate (ER) 50mg uncoated bilayered tablet	M/s Zydus Healthcare Limited	Under Discussion
2.	FDC/MA/24/000138 Torsemide IP 10mg/20mg + Eplerenone IP 25mg/25mg uncoated Tablets	M/s Exemed Pharmaceuticals	In the light of earlier SEC recommendation dated 13.08.2024, the firm presented their proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission is already granted by CDSCO. Accordingly, Phase III clinical trial report should be submitted to CDSCO for further review by the committee.
3.	FDC/MA/23/000342 Chlorthalidone IP + Cilnidipine IP + Bisoprolol Fumarate IP (6.25mg + 5mg + 5mg & 12.5mg + 10mg + 10mg) film coated tablet	M/s Akums Drugs & Pharmaceuticals Ltd.	In the light of earlier SEC recommendation dated 06.12.2023 & 07.12.2023, the firm presented their proposal along with revised BE protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, the firm should submit BE study report along with Phase III clinical trial protocol to CDSCO for further review by the committee