

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	<p>In light of earlier SEC recommendation dated 20.02.2024, the firm presented their proposal along with BE study report and Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee considered BE study report. As regard to Phase III clinical trial protocol following modifications are suggested:</p> <ol style="list-style-type: none"> 1. Empagliflozin should be taken as a separate reference arm. 2. BNP level measurement should be excluded and instead pro-BNP level should be used accordingly to age and co-morbidity with cut-off value. 3. All LV strain imaging echocardiogram assessment /evaluation should be done at the core laboratory by qualified and independent observer. 4. In Primary endpoint criteria 5% improvement in LV ejection fraction cannot be the only criteria. 5. In Exclusion criteria clinically uncontrolled systemic diseases, uncontrolled respiratory disease, uncontrolled psychiatric disease, uncontrolled endocrine disease should be defined. <p>Accordingly, firm should submit the revised Phase III CT protocol to the CDSCO, for further review by the committee.</p>