

Recommendations of the SEC (Cardiovascular) made in its 04th/26 meeting held on 05.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/14/26 Online Submission (54631) Ferric derisomaltose	M/s. Pharmaceutical Research Associates India Private Limited	<p>The firm presented phase III clinical study protocol no. P-Monofer-CHF-02 version 3.0 (amendment 2) dated 09 April 2025.</p> <p>After detailed deliberation, the committee opined that the firm shall submit revised protocol with following observation for further review by the committee.</p> <ol style="list-style-type: none"> 1. A plan of action has not been specified for several subtypes of heart disease, such as congenital and valvular heart disease. 2. The protocol does not specify periodic measurement of symptomatic chronic heart function. 3. The protocol provides very limited periodic laboratory test parameters. 4. It should be kindly justify ethically the use of oral iron in control group when there is recommendation for use of IV iron in guidelines for anemia in heart failure. You may compare your investigational product with Inj Ferric carboxymaltose. 5. Details of the standard of care and risk assessment for patients who develop hypersensitivity or anaphylaxis are not evaluated in the protocol. 6. Predefined withdrawal criteria are not specified in the protocol.
2.	CT/27/26 Online Submission (55043) Lerodalcibep	M/s. Medpace Clinical Research India Pvt Ltd	<p>The firm presented phase IIIb clinical study protocol no. LIB003-008, version no. 1.1 dated 28 October 2025.</p> <p>After detailed deliberation, the committee opined that the firm shall submit revised protocol with following observation for further review by the committee.</p> <ol style="list-style-type: none"> 1. The protocol does not specify cut-off points for follow-up of enrolled patients and documentation procedure for the withdrawal policy. 2. The firm should specify how much blood would be drawn for investigations (total and during each

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			<p>follow-up). The amount of blood should be within the permitted limits.</p> <p>3. The objection of the study has raised the concern that why children in the control group should receive pricks with the placebo when they receive no therapeutic benefit. It is a well known fact that children develop psychological abnormalities like speech problems and bed-wetting with repeated painful stimuli. The injectables should be administered only if mandatory for their own health. Therefore, the control group should not receive placebo injections. Accordingly the study protocol should be revised.</p> <p>4. The protocol lacks specific details on risk assessment and risk mitigation for participants in the placebo-controlled study, including psychological effects.</p> <p>5. After completion of the clinical trial, if safety and efficacy are proven, the sponsor shall provide an open-label extension for at least 5 years.</p>
BA/BE Division			
3.	BABE/CT05/FF/2025/52218 Iercanidipine hydrochloride 20mg +Valsartan 160 mg tablets	M/s. Lambda Therapeutic Research Limited	<p>Firm presented the BA/BE study Protocol No. 0107-25 Version No. 1.0 Protocol Date 10-JUL-2025 before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only.</p>
4.	BABE/CT05/FF/2025/52521 Bempedoic acid/Ezetimibe/ Atorvastatin tablets 180/10/40mg	M/s. Advity Research Private Limited	<p>Firm presented the BA/BE study Protocol No. AR179-25 Version No. 01 Protocol Date 22-SEP-2025 for export purpose only before the committee.</p> <p>After detailed deliberation, the committee opined that the firm has not presented the suitable justification/rationale for the proposed FDC i.e. Bempedoic acid/Ezetimibe/Atorvastatin tablets 180/10/40 mg. Accordingly, the firm shall submit the same for further deliberation in the committee</p>
5.	BABE/CT05/FF/2025/53205 Fixed Dose	M/s. Veeda Clinical Research Limited	<p>Firm presented the BA/BE study Protocol No. 25-VIN-0531 Version No. 01 Protocol Date 11-NOV-2025 before the committee.</p>

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	Combination of Sacubitril, Valsartan and Empagliflozin Tablets 97/103/10 mg		After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only.
FDC Division			
6.	FDC/MA/22/000248 Bisoprolol Fumarate IP + Telmisartan IP + Chlorthalidone IP (2.5mg/5mg/10mg + 20mg/40mg/80mg + 6.25mg/12.5mg/12.5mg) uncoated tablets	M/s. Windlas Biotech Limited	In light of the earlier SEC recommendation dated on 05.03.2025, the firm presented their proposal along with BE study report and revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee considered the BE study report and recommended for grant of permission to conduct the Phase III clinical trial as per the revised protocol. Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee.
7.	FDC/MA/23/000247 Telmisartan IP + Amlodipine Besilate IP eq. to Amlodipine + Bisoprolol Fumarate IP (40mg+5mg+2.5mg)/ (40mg+5mg+5mg) film coated tablet	M/s. Ravenbhel Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 12.06.2024, the firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC in both strengths.
8.	FDC/MA/25/000146 Nebivolol Hydrochloride IP eq. to Nebivolol 2.5 mg + Telmisartan IP 40mg uncoated bilayered tablet	M/s. Windlas Biotech Limited	In light of the earlier SEC recommendation dated 23.07.2025, the firm presented the proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended for grant of permission for manufacturing and marketing 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.