

Recommendations of the SEC (Cardiovascular) made in its 06th/26 meeting held on 07.04.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/183/25 Online Submission (53767) AMLODIPINE+INDA PAMIDE+TELMISARTAN	M/s. Cliantha Research Limited	<p>The firm presented phase III clinical study protocol No.: C2A06071 version No. 01 dated 14-NOV-2025.</p> <p>After detailed deliberation, the committee recommended opined that the protocol is not acceptable due to following reasons:</p> <ol style="list-style-type: none"> 1. The title of the protocol is deficient and not reflective of the intended study population to specify “moderate to severe hypertension”. 2. The study design is insufficiently described and lacks scientific rigor, inclusion/ exclusion criteria including inadequate justification of endpoints, test/ reference treatment arms, and randomization methodology. 3. The rescue medication strategy, including withdrawal criteria, drug selection, dosing, and its impact on study endpoints is not scientifically justified. <p>In view of the above the firm shall revisit the whole protocol and submit global clinical trial protocol as per NDCT & GCP guidelines for further review by committee.</p>
New Drugs Division			
2.	ND/MA/24/000125 Esaxerenone Tablets 1.25 mg, 2.5 mg and 5 mg	M/s. Sun Pharma Laboratories Limited	<p>In light of earlier SEC recommendation dated 05.03.2025, firm presented Phase III CT report of Esaxerenone Tablets 2.5 mg and 5 mg (Clinical Study Report No.: ICR/24/016/CSR-26/001.0 dated 24.02.2026) before the committee.</p> <p>The committee noted that the firm has conducted Phase III Clinical trial on Uncontrolled and Resistant Hypertension.</p> <p>The firm agreed with the committee that the indication for approval of proposed drug product will be Uncontrolled and</p>

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			<p>Resistant Hypertension based on Phase III clinical trial results.</p> <p>After detailed deliberation, the committee considered the Phase III clinical trial result as presented by the firm and recommended for the grant of permission to manufacture and market drug Esaxerenone Tablets 1.25 mg, 2.5 mg and 5 mg for the indication Uncontrolled and Resistant Hypertension.</p> <p>Further, the committee reviewed the prescribing information (PI) and opined that the firm should clearly mention the international references from where the safety and efficacy data derived in the relevant section of prescribing information. The committee also opined that the prescribing information should mention that the drug should be prescribed to patients with eGFR more than 60 ml/min/1.73m² and potassium level less than 5 mEq/L. Accordingly, the firm should submit revised prescribing information to CDSCO</p>
FDC Division			
3.	FDC/MA/24/000138 Torsemide IP 10 mg/20 mg + Eplerenone IP 25 mg/25 mg uncoated Tablets	M/s. Exemed Pharmaceuticals	<p>In light of earlier SEC recommendation dated 13.02.2025, the firm presented Phase III CT report before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.</p>
4.	FDC/MA/25/000219 Nebivolol Hydrochloride IP eq. to Nebivolol 2.5 mg/5 mg + Telmisartan IP 40 mg/40 mg + Cilnidipine IP 10 mg/10 mg Film Coated Bilayered Tablet	M/s. Windlas Biotech Limited	<p>In light of earlier SEC recommendation dated 06.11.2025, the firm presented their proposal along with BE study report before the committee.</p> <p>After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial for which permission is already granted by CDSCO.</p> <p>Accordingly, the firm should submit the Phase III clinical trial report to CDSCO for further review by the committee.</p>
5.	FDC/MA/26/000028 Telmisartan IP 40	M/s. Windlas Biotech Limited	The firm presented their proposal along with BE study protocol under both Fasting and Fed condition & Phase III clinical trial

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	mg/20 mg (As uncoated tablets) + Amlodipine Besilate IP Equivalent to Amlodipine 5 mg/2.5 mg (As uncoated tablets) + Indapamide IP 1.5 mg/1.5 mg (as SR film coated tablets) hard gelatin capsule		<p>protocol before the committee.</p> <p>After detailed deliberation, the committee considered the rationality of the proposed FDC and recommended for grant of permission to conduct the BE study (Fasting and Fed condition) & Phase III clinical trial.</p> <p>Accordingly, the result of the BE study (Fasting and Fed condition) should be submitted to CDSCO for further review by the committee before initiation of the Phase III clinical trial.</p>
6.	<p>FDC/CT/26/000024</p> <p>Combi Kit of Each Strip Contains: Part A: Dapagliflozin propanediol USP Eq. to Dapagliflozin 10 mg/10 mg/10 mg (1 Tablet) Film coated tablet Part B: Bisoprolol Fumarate IP 1.25 mg/2.5 mg/5 mg (1 Tablet) Film coated tablet Part C: Sacubitril and Valsartan Tablet 50 mg/50 mg/50 mg/100 mg (2 Tablets) Film coated tablet</p>	M/s. Eris Lifesciences Limited	<p>In light of the condition mentioned in permission in Form CT-23 dated 19.12.2025; the firm presented the Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined that the firm should include at least 10 cardiology centers with good research experience of which 50% should be government sites and the sites should be geographically distributed.</p> <p>Accordingly, the firm should submit revised Phase IV clinical trial protocol to CDSCO for further review by the committee.</p>