

**Recommendations of the SEC (Cardiovascular) made in its 09<sup>th</sup>/25 meeting held on 10.07.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	E-83166 Sotatercept powder for solution for injection 45 mg & 60 mg Single-dose vial (r-DNA origin)	M/s. MSD Pharmaceuticals Ltd	The firm presented the proposal for amendment in Warning statement of the drug product Sotatercept powder for solution for injection 45 mg & 60 mg Single-dose vial (r-DNA origin) from “To be sold by retail on the prescription of a “Registered Pulmonologist only” to “To be sold by retail on the prescription of a “Registered Pulmonologist or Registered Cardiologist only”.  After detailed deliberation, the committee recommended for approval of proposed amendment in the Warning statement as “To be sold by retail on the prescription of a “Registered Pulmonologist or Registered Cardiologist only
<b>SND Division</b>			
2.	SND/MA/23/000282  Cilnidipine Extended Release Tablets 20 mg	M/s. Unique Pharmaceutical Laboratories (A Division of J.B. Chemical & Pharmaceuticals Limited)	The firm did not turn up for presentation.
<b>New Drugs Division</b>			
3.	ND/CT/24/000088  Mavacamten capsules, 2.5 mg, 5 mg, 10 mg and 15 mg	M/s Bristol-Myers Squibb India Pvt. Ltd	The firm presented amendment for Phase IV clinical study protocol titled “A Phase 4, Single-Arm, Open-Label Study to Evaluate Safety, Tolerability, and Efficacy of Mavacamten in Adults with Symptomatic Obstructive Hypertrophic Cardiomyopathy in India (ROVER) (Protocol no: CV0271146, amendment 01, dated 05.02.2025)” before the committee.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
4.	ND/CT/22/000033  Vericiguat Film coated tablets 2.5 mg/5 mg/10	M/s Bayer Pharmaceuticals Pvt. Ltd.	In the light of earlier SEC recommendation dated 09.06.2022 & 10.06.2022 the firm presented Phase IV clinical trial report (B003820, version no.

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	mg		1.0 dated 05.05.2025), before the committee.  After detailed deliberation, the committee considered the results of the Phase IV clinical trial study
<b>FDC Division</b>			
5.	FDC/MA/23/000272  Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5 mg/5 mg/5 mg + Sacubitril and Valsartan as Sodium salt complex 50 mg (24 mg and 26 mg), 100 mg (49mg and 51 mg) & 200 mg (97 mg and 103 mg) tablet	M/s Exemed Pharmaceutical	In light of earlier SEC recommendation dated 04.04.2024, the firm presented their proposal along with Phase III clinical trial report before the committee.  After detailed deliberation, the committee recommended for grant of permission to manufacture and market for the proposed FDC in applied strengths, after submission of data including dissolution data and justification for BE waiver for lower strength (Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 5mg/5mg + Sacubitril and Valsartan as Sodium salt complex 50mg (24mg and 26mg), 100mg (49mg and 51mg) tablet) as per the BE Study guideline.
6.	FDC/MA/24/000006  Empagliflozin 10 mg/10 mg + Metoprolol Succinate IP 23.75 mg eq. to Metoprolol Tartrate (ER) 25mg/ Metoprolol Succinate IP 47.50 mg eq. to Metoprolol Tartrate (ER) 50 mg uncoated bilayered tablet	M/s Zydus Healthcare Limited	In light of earlier SEC recommendation dated 13.02.2025, the firm presented their proposal along with revised Phase III clinical trial protocol before the committee.  After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial.  Accordingly, the firm should submit the Phase III CT report to CDSCO for further review by the committee.
7.	FDC/MA/25/000127  Cilnidipine IP 20 mg + Metoprolol Succinate IP 47.5 mg eq. to Metoprolol Tartrate 50 mg (ER) film coated bilayered tablet	M/s Ajanta Pharma Limited	The firm did not turn up for presentation.
8.	FDC/MA/25/000136	M/s Eris Lifesciences Limited	The firm presented the proposal along with justification for BE and Phase III CT waiver before the committee.

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	<p>Combi-kit of Dapagliflozin Propanediol eq. to Dapagliflozin 10 mg/10 mg/10 mg/10 mg + Bisoprolol Fumarate IP 1.25 mg/2.5 mg/5 mg/5 mg + Sacubitril and Valsartan IP (24+26)/ 50 mg(24+26)/ 50 mg(24+26)/ 100 mg(49+51) film coated tablet</p>		<p>Committee noted that higher strength i.e., Combi-kit of Dapagliflozin 10mg/10mg/10mg/10mg + Bisoprolol Fumarate 1.25mg/2.5mg/5mg/10mg + Sacubitril and Valsartan 100mg/100mg/200mg/200mg tablet is already approved to the firm.</p> <p>After detailed deliberation, the committee considered the request for BE and Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the FDC with the condition to conduct Phase IV clinical trial.</p> <p>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.</p>