

**Recommendations of the SEC (Cardiovascular) made in its 01<sup>st</sup>/25 meeting held on 08.01.25. at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT//39/24 Online Submission (35629) Retatrutide (LY3437943)	M/s Eli lily	The firm presented protocol amendment c dated 19 September 2024 protocol no. J1I-MC-GZBO.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT//20/24 Online Submission (36051) Lepodisiran Sodium (LY3819469)	M/s Eli lily	The firm presented protocol amendment (a) dated 19 April 2024 protocol no. J3L-MC-EZEF.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT//66/23 Online Submission (36172) Mavacamten	M/s Bristol Myers Squibb India Pvt. Ltd.	The firm presented protocol amendment version 03 dated 25 July 2024 protocol no. CV027031.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT//146/24 Online Submission (46607) BAY94-8862	M/s George Clinical India Pvt. Ltd.	The firm presented phase 3 clinical study Protocol no.: 202303CPC version no. 3.0 dated 10 - SEP- 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that more government sites shall be included in the study.
<b>New Drugs Division</b>			
5.	ND/CT/24/000088  Mavacamten capsules, 2.5 mg,5 mg,10 mg and 15 mg.	M/s Bristol-Myers Squibb India Pvt. Ltd.	In light of the condition mentioned in Import and Marketing permission (Form CT-20) dated 08.10.2024 for Mavacamten capsules, 2.5 mg,5 mg,10 mg and 15 mg, the firm presented the Phase IV clinical trial protocol titled "A Phase 4, Single-Arm, Open-Label Study to Evaluate Safety, Tolerability, and Efficacy of Mavacamten in Adults with

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			<p>Symptomatic Obstructive Hypertrophic Cardiomyopathy in India (ROVER) (Protocol no: CV0271146, Dated: 01-Jul-2024)" before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct of the Phase IV clinical trial as per protocol presented by the firm.</p> <p>Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.</p>
<b>FDC Division</b>			
6.	<p>FDC/MA/24/000274</p> <p>Metoprolol Succinate eq. to Metoprolol Tartrate (As extended release) 50 (mg) I.P. + Cilnidipine 20 (mg) I.P. Tablets</p>	<p>M/s Akums Drugs and Pharmaceutical Limited</p>	<p>The firm presented the proposal along with BE study protocol and justification for phase III CT waiver before the committee.</p> <p>After detailed deliberation, the committee did not consider the request for phase III CT waiver and recommended that firm should conduct BE study.</p> <p>Accordingly, the firm should submit the BE study report along with phase III CT protocol to CDSCO for further review by the committee.</p>
7.	<p>FDC/MA/24/000275</p> <p>Trimetazidine Hydrochloride 35 (mg) I.P. + Nicorandil 5 (mg) I.P. Tablet</p>	<p>M/s Torrent Pharmaceuticals Ltd.</p>	<p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, the committee considered Rationality of the FDC and opined that firm should conduct BE study and phase III CT study.</p> <p>Accordingly, the firm should submit the BE protocol along with Phase III CT protocol to CDSCO for further review by the committee.</p>
<b>Medical Devices Division</b>			
8.	<p>CI/MD/2024/114137</p> <p>Atrial Septal Defect BioResorbable Occluder (Brand Name: Floret™ BRO)</p>	<p>M/s. Meril Life Sciences Private Limited</p>	<p><b><i>"Under Discussion"</i></b></p>