

Recommendations of the SEC (Cardiovascular) made in its 11th/25 meeting held on 06.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/153/25 Online Submission (52525) LY3502970	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	<p>The firm presented phase III clinical study protocol no. J2A-MC-GZPW version no. (a) Dated 26 Sep 2025.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following conditions:</p> <ol style="list-style-type: none"> 1. DPP inhibitor should be clearly mentioned in the exclusion criteria. 2. The firm shall submit a justification for not submitting the CT protocol of IMP in the Country of origin to CDSCO. <p>Dr. Vimal Mehta didn't participate in the discussion.</p>
2.	CT/20/24 Online Submission (40475) Lipodisiran sodium (LY3819469)	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd	<p>In light of earlier SEC recommendation dated 19.08.2025, the firm presented protocol amendment (g) dated 12 May 2025 protocol no. MC-EZEF.</p> <p>Now the firm presented more data for justification in line of proposed protocol amendment including rationale on the verge of completion assumed initial sample size globally.</p> <p>After detailed deliberation, the committee recommended for of approval of protocol amendment as presented by the firm.</p>
Medical Devices Division			
3.	CI/MD/2024/139542 Conduction System Pacing (CSP) Display Research System for SmartSync Pacing System Analyzer	M/s. India Medtronic Private Limited	<p>The firm has presented their proposal for grant of permission for conduct of Clinical investigation of the applied device i.e. Conduction System Pacing (CSP) Display Research System for SmartSync Pacing System Analyzer which is indicated for use in patients undergoing CSP lead placement, manufactured by M/s. Medtronic Inc, USA.</p> <p>After detailed deliberation, the committee recommended for consideration of the</p>

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			<p>proposed study with the following conditions:</p> <ol style="list-style-type: none"> 1. The proposed study shall include a minimum of six (06) study centers of which 50% should be from Government hospitals & also 50% of the patients would be recruited in the Government centers. 2. The study protocol shall include a patient follow-up period of at least six (06) months for all enrolled subjects. 3. All devices including its components to be used in the said study, shall be provided free of cost to all study subjects.
New Drugs Division			
4.	E-22737 Trimetazidine Modified Release tablets 35 mg	M/s. Servier India private Limited	The firm did not turn up for the presentation.
SND Division			
5.	SND/IMP/18/000032 Rivaroxaban Tablets 2.5 mg	M/s. Bayer Pharmaceuticals Pvt. Ltd	<p>The firm presented the Phase IV Clinical study report for Rivaroxaban Tablets 2.5 mg before the committee.</p> <p>After detailed deliberation, the committee accepted the results of the Phase IV clinical trial study.</p> <p>Note: Dr. Ajay Mahajan did not participate in the discussion.</p>
FDC Division			
6.	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	<p>In light of the earlier SEC recommendation dated 11.09.2025, the firm presented the proposal along with BE study protocol under fed condition, revised BE study protocol under fasting condition and Phase III CT study protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study under both fed and fasting condition.</p> <p>As regard to Phase III clinical trial protocol, the committee recommended for</p>

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			<p>conduct of Phase III CT study with condition that the firm should include ABPM test at baseline, follow-up and end of the study for all the patients.</p> <p>Accordingly, firm should submit revised Phase III CT Protocol to CDSCO. After approval from CDSCO, firm should submit Phase III CT report to CDSCO for further review by the committee.</p> <p>The result of the BE study should be submitted to CDSCO for further review by the committee before initiation of the Phase III clinical trial.</p>
7.	<p>FDC/MA/25/000219</p> <p>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</p>	M/s. Windlas Biotech Limited	<p>The firm presented their proposal with rationality of the proposed FDC along with BE study protocol & Phase III clinical trial 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 and Phase III clinical trial study with condition that the firm should provide CDSCO approved BP machine free of cost to all the participants for home BP motioning and recording in diary.</p> <p>The result of the BE study should be submitted to CDSCO for further review by the committee before initiation of the Phase III clinical trial.</p>