Recommendations of the SEC (Cardiovascular) made in its 07th/25 meeting held on 13.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/02/24 Online Submission (37213) Ravulizumab	M/s. AstraZeneca Pharma India Limited	In light of earlier SEC Recommendation dated 06.02.2025, the firm presented protocol amendment 3.0 dated 02 December 2024 protocol no. D928DC00001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/118/23 Online Submission (38694) Survodutide (BI456906)	M/s IQVIA RDS (India) Private Limited	The firm presented protocol amendment version 4.0 dated 23 October 2024 and protocol amendment version 5.0 dated 07 March 2025 protocol no. 1404-0040. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/39/24 Online Submission (38928) Retatrutide	M/s.Eli Lilly andCompany (India) Pvt. Ltd	The firm presented protocol amendment (d) dated 21 March 2025 protocol no. J1I-MC-GZBO. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/43/25 Online Submission (49203) AZD0780 30mg Tablet	M/s AstraZeneca Pharma India Limited	The firm presented phase III clinical study Protocol No.: D7960C00012, CSP Version 1.0 dated 11 Apr 2025 and Local CSP Addendum IND-1: Version 1.0, dated 14 Apr 2025. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. Dr. Ajay Mahajan didn't participate.
5.	CT/03/23 Online Submission (37471) ISIS 678354 (Olezarsen)	M/s. Medpace Clinical Research India Pvt Ltd	In light of earlier SEC Recommendation dated 05.03.2025, the firm presented Protocol Amendment 5 dated 03 December 2024 protocol no. ISIS 678354-CS6. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.

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BA/BE Division			
6.	BABE/CT05/FF/2025/47657 Apixaban Tablets 10 mg	M/s. Cliantha Research Limited	Firm presented the BA/BE study Protocol No. C1B05306, Version No. 01, Protocol Date 20-JAN-2025 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only
SND Division			
7.	SND/MA/23/000282 Cilnidipine Extended Release Tablets 20 mg	M/s. Unique Pharmaceutical Laboratories (A Division Of J. B. Chemicals & Pharmaceuticals Limited)	The firm did not turn up for the presentation.
FDC Division			
8.	FDC/MA/23/000110 Bisoprolol Fumarate 5mg/2.5mg + Cilnidipine 10mg/10mg + Telmisartan 40mg/40mg tablets	M/s. Windlas Biotech Ltd.	In light of earlier SEC recommendation dated 29.08.2023, the firm presented the justification on rationality of FDC along with BE protocol and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee considered the justification on rationality of FDC and recommended for grant of permission to conduct proposed BE study and Phase III clinical trial study with the condition that BE study report should be presented in the SEC meeting before initiating the Phase III clinical trial.
9.	FDC/MA/24/000171 Bisoprolol Fumarate IP 5mg + Cilnidipine IP 10mg tablet	M/s Unique Pharmaceutical Laboratories	In the light of earlier SEC recommendation dated 13.08.2024, the firm presented their proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial study for which permission is already granted by CDSCO. Accordingly, Phase III clinical trial report should be submitted to CDSCO for

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			further review by the committee.
10.	FDC/MA/24/000232 Bisoprolol Fumarate IP 2.5mg/5mg + Cilnidipine IP 10mg/10mg + Telmisartan IP 40mg/40mg film coated tablet	M/s Ravenbhel Healthcare Pvt. Ltd	In light of earlier SEC recommendation dated 06.11.2024, the firm presented the justification on rationality of FDC along with BE protocol before the committee. After detailed deliberation, the committee considered the justification on rationality of FDC and recommended for grant of permission to conduct of proposed BE study. Accordingly, the firm should submit the BE study report along with Phase III CT protocol with revised indication to CDSCO for further review by the committee.