

Recommendations of the SEC (Cardiovascular) made in its 02nd/25 meeting held on 28.01.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/148/24 Online Submission (46739) Selatogrel 16 mg/0.5mL aqueous solution	M/s Mylan Pharmaceuticals Private Limited	The firm presented phase 3 clinical study protocol no.: ID-076A301 version: 5.0 dated 09 June 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/157/24 Online Submission (46971) CDR132L 45.2 (45,2) mg/vial	M/s Novo Nordisk India Pvt Ltd	The firm presented phase 2 clinical study protocol no. NN6706-8212 version 1.0 dated 21 November 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/158/24 Online Submission (46987) CDR132L 45.2 (45,2) mg/vial	M/s Novo Nordisk India Pvt Ltd	The firm presented phase 2 clinical study protocol no. NN6706-8282 version 1.0 dated 21 November 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/64/24 Online Submission (36730) AZD5462	M/s. Parexel International Clinical Research Private Limited	The firm presented protocol amendment version 2.0/Local CSP India-2, dated 04 December 2024 protocol no. D9090C00008. After detailed deliberation, the committee recommended for approval for all the amendment except the exclusion criteria regarding ferritin level. Committee also recommended for inclusion of more geographically distributed Govt. sites in the study.
5.	CT/161/24 Online Submission (47076) Cagrilintide + Semaglutide	M/s Novo Nordisk India Pvt Ltd	The firm presented phase 3b clinical study protocol no. NN9838-7914 version 1.0 dated 10 October 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
BA/BE Division			
6.	BABE/CT05/FF/2024 /45127	M/s Cipla Limited	The firm did not turn up for presentation.

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	Torse mide and Eplerenone Tablet 20 mg/25 mg		
SND Division			
7.	SND-16011(11)/246/2024-eoffice E-58714 Metoprolol Succinate Prolonged Release Tablets I.P. 25, 50, 100 & 200 mg (Seloken® XL)	M/s AstraZeneca Pharma India Limited	The firm has presented the proposal for update of prescribing information of Metoprolol Succinate Prolonged Release Tablets I.P. 25,50,100 & 200mg (Seloken® XL) w.r.t. warning condition, Pk/Pd properties, overdose, contraindications etc based on the Company Core Data Sheet. After detailed deliberation, the committee recommended to provide additional data, published literature or approved prescribing information in other countries in support of proposed updates of Prescribing Information.
8.	SND/CT/21/000058 Ivabradine prolonged release tablets 10 mg & 15 mg	M/s Abbott India Limited	Firm has presented the report of Post Marketing Observational Study of Ivabradine Prolonged Release Tablets 10 mg & 15 mg. After detail deliberation, the committee has noted the result of Post Marketing Observational Study of Ivabradine Prolonged Release Tablets 10 mg & 15 mg presented by the firm. Further Committee opined that, data generated by the firm is for information only and not to be used for any claim to additional indications or changes in approved package insert.