

Recommendations of the SEC (Cardiovascular) made in its 23th meeting held on 11.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/39/24 35629 Online Submission (35629) Retatrutide (LY3437943)	M/s Eli lily	The firm did not turn up for presentation.
2.	CT/13/24 Online Submission (35714) Baxdrostat Tablets 1mg/2mg	M/s Astrazeneca	The firm presented protocol amendment version 2.0 dated 26 April 2024 protocol no. D6970C00008. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/20/24 36051 Online Submission (36051) Iepodisiran Sodium (LY3819469)	M/s Eli lily	The firm did not turn up for presentation.
4.	CT/66/23 36172 Online Submission (36172) Mavacamten	M/s BMS	The firm did not turn up for presentation.
SND Division			
5.	SND-16011(11)/221/2024-eoffice (Computer no E-16851) 12-15/11-DC & 12-100/2016-DC (Pt-Astrazenca-SND) Ticagrelor tablets I.P. 60 mg & 90 mg	M/s Astrazeneca Pharma India Limited	The firm presented the proposal for update of prescribing information based on the Company Core Data Sheet of Ticagrelor Tablets 60 mg and 90 mg w.r.t following: 1) Section 4.5: Interaction with other medicinal products and other forms of Interaction 2) Section 5.2: Pharmacokinetic properties. 3) CPIL point no. 2: Before you take Brilinta. 4) CPIL point no. 4: Possible side effects. After detailed deliberation, the Committee recommended for grant of approval for the proposed update in prescribing information as presented by

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			the firm.
FDC Division			
6.	<p>FDC/MA/24/000248</p> <p>Amlodipine besylate IPEq. to Amlodipine + Bisoprolol Fumarate IP (2.5mg +2.5mg, 2.5mg+5mg)</p>	M/s Exemed Pharmaceuticals.	<p>The firm presented their proposal along with justification for BE & phase III CT waiver before the committee.</p> <p>Committee noted that the proposed FDC i.e. S (-) Amlodipine besylate IP eq. to Amlodipine 2.5mg + Bisoprolol Fumarate USP 5mg is considered as rational by Prof. Kokate committee on 16.07.2015.</p> <p>Further, FDC of S (-) Amlodipine Besilate Eq. to S (-) Amlodipine 2.5 mg/ 5 mg + HCTZ 12.5 mg / 12.5 mg tablet and Bisoprolol Fumarate 2.5 mg/ 5 mg + Hydrochlorthiazide 6.25 mg / 6.25 mg Tablet are already approved for the treatment of mild to moderate hypertension on 14.04.2004 & 13.05.1999 respectively.</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 the 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>