

Recommendations of the SEC (Cardiovascular) made in its 12th/24 meeting held on 12.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/64/24 Online Submission (43223) AZD5462	M/s. Parexel International Clinical Research Private Limited	The firm presented Phase Iib clinical trial study protocol No. D9090C00008. After detailed deliberation, the committee opined that more justification to be submitted for including class FC IV patients in the dose ranging Phase Iib study for further review by the committee.
2.	CT/43/23 Online Submission (33106) Milvexian	M/s. IQVIA RDS	The firm presented protocol amendment 1 dated 22-Feb-2024 protocol no.70033093ACS3003. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. (Dr. K.M.K. Reddy did not participate in the deliberation).
3.	CT/99/23 Online Submission (32980) Pegozafermin	M/s. Medpace Clinical Research India Pvt. Ltd.	The firm presented protocol amendment version 3.0 dated 15 Feb 2024 protocol no.BIO89-100-231. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/66/23 Online Submission (32890) Mavacamten	M/s. Bristol-Myers Squibb India Private Limited	The firm did not turn up for the presentation.
5.	CT/13/24 Online Submission (41557) Baxdrostat Tablets 1mg/ 2mg	M/s. AstraZeneca Pharma India Limited	In light of the earlier SEC recommendation dated on 13.02.2024, the firm presented Phase III clinical trial study protocol No. D6970C00008. After detailed deliberation, the committee recommended the following: 1. PI should be a Cardiologist in a tertiary care centre. 2. Only subjects with uncontrolled hypertension to be included in the study. 3. Sample size should be justified. Accordingly, the firm should submit

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			revised protocol/justification for further review by the committee.
BA/BE Division			
6.	BABE/CT05/FF/2024 /41697 Atorvastatin + Fenofibrate Tablets 40+145 mg	M/s. Intas Pharmaceuticals Ltd.	The firm presented Protocol No.0346-22 version 01 dated 19-1-2024 and Protocol No.0012-24 version 01 dated 19-1-2024. After detailed deliberation, the committee recommended for the grant of permission to carry out BA/BE study for export purpose only.
7.	BABE/CT05/FF/2024 /42248 Fixed Dose Combination of Amlodipine and Chlorthalidone tablet 10/25 mg	M/s. Jeevan Scientific Technology Limited	The firm presented Protocol No.24-017 version 01 dated 28-2-2024 and Protocol No.24-018 version 01 dated 28-2-2024. After detailed deliberation, the committee opined that proposal is unacceptable in the present form. The firm should provide greater justification for the rationality of the proposal for further deliberation.
8.	BABE/CT05/FF/2024 /42562 Atorvastatin and Fenofibrate Tablets 80mg/160 mg	M/s. Aizant Drug Research Solutions Private Limited	The firm presented Protocol No.C24112 version 00 dated 1-3-2024. After detailed deliberation, the committee opined that proposal is unacceptable in the present form. The firm should provide greater justification for the rationality of the proposal for further deliberation.
9.	BABE/CT05/FF/2024 /42427 FDC of Extended release Torsemide 24 mg and Spironolactone 30mg Tablet	M/s. Syngene International Limited	The firm presented Protocol No.SYNCD-004-24 version 1 dated 9-2-2024. After detailed deliberation, the committee opined that more elaborate justification/evidence for the proposed FDC and clinical report of relevant studies needs to be submitted for further deliberation.
FDC Division			
10.	FDC/MA/23/000247 Telmisartan IP + Amlodipine Besilate IP eq. to Amlodipine + Bisoprolol Fumarate IP (40mg + 5mg + 2.5mg)/	M/s. Ravenbhel Healthcare Pvt. Ltd.	In light of the earlier SEC recommendation dated on 07.05.2024, the firm presented their proposal along with the source data of BE study report and revised Phase III clinical trial protocol before the committee. After detailed deliberation, the committee

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	(40mg+5mg+ 5mg) film coated tablet		<p>considered the BE report and recommended for grant of permission to conduct the Phase III clinical trial as per the revised protocol with the condition that Principal investigator in the all study sites should be Cardiologist.</p> <p>Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee.</p>