

Recommendations of the SEC (Cardiovascular & Renal) made in its 124th meeting held on 19.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000003 Edoxaban Tablets 15mg/30mg/60mg	M/s. Zuventus Healthcare Ltds	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Edoxaban 15mg, 30mg and 60mg tablets along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study and the firm should submit the BE study results before the committee for further consideration.
SND Division			
2.	SND/MA/22/000169 Desidustat Tablets 100mg	M/s. Zydus Lifesciences Limited	The firm presented the proposal for package insert approval of Desidustat Tablets 100 mg. After detailed deliberation, the committee recommended that the firm should present the safety data of Desidustat Tablets 100mg from clinical trials, post marketing surveillance etc in next meeting.
FDC Division			
3.	FDC/MA/22/000363 Metoprolol Succinate SR 25mg/50mg + Dapagliflozin 5mg/10mg tablets	M/s Eris	In light of the earlier SEC recommendation dated 11.01.2023, the firm presented BE study result before the committee. After detailed deliberation, the committee accepted the BE study result and recommended that approved Phase III protocol should be sent to SEC members by CDSCO after addition of the point in inclusion criteria i.e “the patient heart rate should be stable on 50mg of Metoprolol (SR)” by the firm and submission of the protocol to CDSCO. Accordingly, decision on initiating the Phase III CT should be taken after receiving the comments from SEC members.
GCT Division			
4.	CT/166/22 Online Submission (35061).	M/s Clinatha Research	The firm presented Phase IIIa/IIIb clinical trial protocol no. ACTH-PMN-301 amendment 1 version 2 dated 27 Oct

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	SNP-ACTH (1-39) Gel		2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the trial.