

**Recommendations of the SEC (Cardiovascular) made in its 19<sup>th</sup>/24 meeting held on 15.10.2024 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	GCT/CT04/FF/2024/4 2369 Online Submission (42369)  Balcinrenone/Dapagli flozin	M/s. AstraZeneca	In light of earlier SEC recommendation dated 07.05.24, now the firm presented phase III clinical study protocol No. D6402C00012 CSP version 2.0 dated 11.01.2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	GCT/CT04/FF/2024/4 3223 Online Submission (43223)  AZD5462	M/s. Parexel International Clinical Research Private Limited	The firm didn't turn up for presentation.
<b>New Drugs Division</b>			
3.	ND/MA/24/000105  Esaxerenone Tablets 1.25, 2.5 and 5 mg	M/s Eris Lifesciences Limited	The firm presented the proposal for grant of permission to manufacture and marketing of Esaxerenone tablets 1.25, 2.5 and 5 mg along with BE study protocol and Phase III CT protocol.  After detailed deliberation, the committee recommended for grant of permission to conduct BE study and Phase III clinical trial.  The results of BE study should be presented before the committee for further review before initiation of Phase III clinical trial.