

Recommendations of the SEC (Endocrinology & Metabolism) made in its 16th/24 meeting held on 19.09.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/24/000018 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg/10mg + Gliclazide IP (SR) 30mg/60mg + Metformin Hydrochloride IP (SR) 500mg/500mg film coated bilayered tablet	M/s. Eris Lifesciences Limited	In light of the earlier SEC recommendation dated 22.02.2024, the firm presented BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended for grant of permission to manufacture and market the FDC with the condition to conduct the Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months from approval of the FDC, for further review by the SEC.