

Recommendations of the SEC (Renal) made in its 02nd/24 meeting held on 14.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/49/21 Online Submission (31223) LNP023	M/s. Novartis	The firm presented protocol amendment version 02 dated 08 November 2023 protocol No. CLNP023F12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/22/24 Online Submission (41857) Baxdrostat in Combination with Dapagliflozin Tablets	M/s. AstraZeneca	The firm presented Phase III clinical study, protocol No. D6972C00003, version 2.0 dated 12 January 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/26/24 Online Submission (41961) TIN816	M/s. Novartis	The firm presented Phase IIb clinical study protocol No. CTIN816B12202, version number 00 dated 18 June 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/82/21 Online Submission (31395) Iptacopan	M/s. Novartis	The firm presented protocol amendment version 01 dated 03 November 2023, protocol No. CLNP023A2002B. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
FDC Division			
5.	FDC/MA/23/000293 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Telmisartan (10mg+40mg/ 10mg+80mg) film coated tablet	M/s. Eris Lifesciences Limited	In light of the earlier SEC recommendation dated 11.10.2023, the firm presented BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended to initiate Phase III clinical trial for which permission has already been granted by CDSCO. The result of Phase III clinical trial should be presented before the committee for review.

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6.	FDC/MA/24/000033 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Telmisartan IP (10mg+40mg/ 10mg+80mg) tablet	M/s. Mascot Health Series Pvt. Ltd.	<p>The firm presented the proposal along with BE study protocol before the committee.</p> <p>After detailed deliberation, the committee recommended that the sample size should be increased up to 36 subjects.</p> <p>Accordingly, the revised BE study protocol should be submitted to CDSCO, for review.</p> <p>After approval from CDSCO, the firm should submit BE study report for further review by the committee along with Phase III clinical trial protocol.</p>