

**Recommendations of the SEC (Renal) made in its 01<sup>st</sup>/25 meeting held on 15.01.25 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/22/24 Online Submission (36292) Baxdrostat Tablets 1 mg/2mg and Dapagliflozin Tablets 10 mg	M/s AstraZeneca Pharma India Limited	The firm presented protocol amendment Version 4.0 dated 29 October 2024 protocol no. D6972C00003.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/152/24 Online Submission (46849) Baxdrostat Tablets 1 mg/2mg and Dapagliflozin Tablets 10 mg	M/s AstraZeneca Pharma India Limited	The firm presented phase 3 clinical study protocol no. D6972C00002 CSP version 2.0 dated 12 Nov 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the India specific addendum with respect to rescue criteria and management of hypotension shall be submitted to CDSCO.
3.	CT/160/24 Online Submission (46883) BAY 94- 8862/Fenerenone	M/s Bayer Pharmaceuticals Pvt. Ltd	The firm presented phase 3 clinical study Protocol no.: 19920 version 6.0 dated 17-JUN-2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	CT/159/24 47026 Online Submission (47026) BAY 94- 8862/Fenerenone	M/s Bayer Pharmaceuticals Pvt. Ltd.	The firm presented phase 3 clinical study protocol no.: 20186 amendment 4 version 5.0 dated 21-JUN-2024.  After detailed deliberation, the committee opined that firm shall submit IDMC comments with recommendation for further review by the committee.
5.	CT/82/21 Online Submission (36719) LNP023	M/s Novartis	The firm presented protocol amendment version 2 dated 14 Oct 2024 protocol no. CLNP023A2002B.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.

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6.	CT/115/20 Online Submission (36737) LNP023	M/s Novartis	The firm presented Protocol amendment version 05 dated 18 Oct 2024 protocol no. CLNP023A2301  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
<b>FDC Division</b>			
7.	FDC/MA/23/000327  Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Telmisartan IP (10mg+40mg/ 10mg+80mg) tablet	M/s Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 12.11.2024, the firm presented the proposal along with justification for Phase III clinical trial report before the committee.  After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC in lower strength i.e. Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Telmisartan IP 40mg tablet.  As regard to higher strength i.e. Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Telmisartan IP 80mg tablet the committee opined that- 1. Sample size is under power and the result is not found satisfactory. 2. Firm should conduct the phase III CT study for longer duration, in appropriately calculated sample size and also identify ADR specifically focusing Hyperkalemia and Hypotension.  Accordingly, firm should submit Phase III CT protocol for higher strength (10 mg + 80 mg) to CDSCO for further review by the committee.
8.	FDC/MA/23/000293  Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Telmisartan (10mg+40mg/	M/s Eris Lifesciences Limited	In light of earlier SEC recommendation dated 14.03.2024, the firm presented Phase III clinical trial report before the committee.  After detailed deliberation the committee opined the following: 1. Firm has conducted phase III CT study

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	10mg+80mg) film coated tablet		<p>on higher strength i.e. Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin 10mg + Telmisartan IP 80mg tablet.</p> <p>2. Sample size is under power and the result is not found satisfactory.</p> <p>3. Firm should conduct the phase III CT study for longer duration, in appropriately calculated sample size and also identify ADR specifically focusing Hyperkalemia and Hypotension.</p> <p>Accordingly, firm should submit Phase III CT protocol for both the strengths (10mg + 40 mg) (10mg + 80 mg) to CDSCO for further review by the committee.</p>