Recommendations of the SEC (Nephrology & Urology) made in its 05th/26 meeting held on 28.04.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/42/26 Online Submission (55541) BI 764198	M/s. IQVIA RDS (India) Private Limited	The firm presented phase II clinical study protocol no. 1434-0027 version no. 2.0 dated 24 Dec 2025. After detailed deliberation, the committee opined that firm should submit the following for further review by the committee. 1. Participants shall be provided with appropriate follow-up care at least 12 weeks and guidance for continued medical management/SoC after study completion (21 weeks). 2. If the investigational product demonstrates clinical benefit, provisions for post-trial access or transition to an extension/rollover study may be considered. 3. Genetic testing for participants with Focal Segmental Glomerulosclerosis (FSGS), where applicable, shall be performed at the sponsor's expense. 4. At the end of the study, eGFR and proteinuria assessments shall be performed. 5. The sponsor should clarify which eGFR equation will be used in the adolescent participants (age 12 to 18 years) in the Phase II study 6. Explore the possibility to increase the number of sites and patients for representing diverse population of the country.
FDC Division			
2.	FDC/MA/24/000133 Dapagliflozin Propanediol eq. to Dapagliflozin 10 mg + Eplerenone IP 25 mg film coated tablets	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 12.02.2026, the firm presented the proposal along with Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC with the condition to

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			conduct Active PMS study. Accordingly, the firm should submit Active PMS protocol to CDSCO within 3 months of approval of the FDC for review by the committee.
3.	FDC/IMP/25/000002 Each 1000ml contains before reconstitution: Small Compartment A (250 mL) in g/L contains: Calcium chloride dihydrate 3.68g + Magnesium chloride Hexahydrate 2.44 g + Hydrochloric acid (as HCl 10% dilute) 26.3g +Water for Injection to 1000ml Large Compartment B (4750 mL) in g/L contains: Sodium chloride 6.44g + Sodium hydrogen carbonate 2.92g + Potassium chloride 0.314g + Disodium phosphate dihydrate 0.225g + Carbon Dioxide as needed to pH 7.4 – 7.5 + Water for Injection to 1000 mL Solution for haemodialysis/ haemofiltration	M/s. Vantive Healthcare Pvt. Ltd.	The firm presented the proposal along with justification for Phase III CT waiver before the committee. Committee noted that: 1. The firm deliberated their proposal along with point wise justification/document on the previous SEC recommendation dated 06.07.2023 & 07.07.2023 of M/s Baxter India Pvt. Limited. 2. Firm did not provide adequate data/justification on previous SEC recommendation. 3. Firm did not provide any clinical data in Indian population. 4. Multiple Serious Adverse events were reported in global population during treatment (especially in EU countries) After detailed deliberation, the committee did not consider the request for Phase III CT waiver and recommended to conduct Phase III CT study with the proposed FDC. Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee.
4.	FDC/MA/25/000206 Tadalafil IP 2.5 mg/5 mg + Dutasteride IP 0.5 mg/0.5 mg film coated tablets	M/s. Malik Lifesciences Pvt Ltd	The firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study. Accordingly, the firm should submit BE study report to CDSCO for further review by the committee. Further, decision on the Phase III clinical trial may be taken after review of BE study results.