Recommendations of the SEC (Nephrology & Urology) made in its 07th/26 meeting held on 14.07.2026 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.	In light of earlier SEC recommendation dated 28.04.2026, the firm presented phase II clinical study protocol no.: 1434-0027 version no. 2.0 dated 24 Dec 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/89/26 Online Submission (57586) FUB523	M/s. Novartis Healthcare Private Limited.	The firm presented phase IIIb clinical study protocol no.: CFUB523A12302B version no. 00 dated 14-Jan-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
3.	BIO/CT04/FF/2026/55400 Darbepoetin Alfa Intravenous solution for Injection	Dr. Reddy's Laboratories Limited.	The firm presented the proposal to conduct a Phase-1 comparative pharmacokinetic study for intravenously administered Darbepoetin alfa (DRL_DA), titled "A Single Dose, Double-Blind, Two-Period, Two-Sequence, Crossover, Comparative Pharmacokinetic Study of DRL_DA, and EU-approved Reference Medicinal Product (Aranesp®), administered by the Intravenous Route to Male Healthy Volunteers" vide Protocol No. DA-01-009, version 1.0, dated 30-Jun-2025. The committee noted the following: 1. Subcutaneous solutions for injection available as single-dose vials and single-dose pre-filled syringe is approved by this office vide permission no. MF-246/2010 dated 23 Mar 2010. 2. Similar studies DA-01-002 & DA-01-005 using intravenously administered Darbepoetin alfa (DRL_DA), approved by this office in the year 2015 & 2022 respectively, did not meet the primary PK endpoints due to higher fill volume variabilities in 60 mcg PFS. Now, the firm has proposed to conduct the said DA-01-009 study by using the drug product manufactured at its new

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			manufacturing facility, which is equipped with technologically advanced filling equipment. After detailed deliberation, the committee recommended the grant of permission to conduct the proposed study vide Protocol No. DA-01-009, version 1.0, dated 30-Jun-2025; subject to the condition that the firm shall submit the complete Clinical Study Report (CSR) to the CDSCO for further evaluation by the committee.
4.	BIO/CT04/FF/2025/53256 Alteplase 2 mg Lyophilized powder for reconstitution in single use vial for intracatheter instillation	M/s. Reliance Life Sciences Pvt. Ltd.	In light of earlier SEC recommendation dated 16.04.2026, the firm presented the revised proposal to conduct Phase III clinical trial titled "A Prospective, multi-center, open label, two-arm, comparative clinical study to evaluate the efficacy and safety of RLS-Alteplase 2 mg with Cathflo® Activase® 2 mg in complete restoration of patency and flow in hemodialysis catheter dysfunction" vide Protocol No.: RLS/VAS/2025/07; Version 2.0, Dated 12 May 2026. After detailed deliberation, the committee recommended the grant of permission to conduct the proposed Phase III clinical trial as per the presented protocol, subject to the condition that the trial shall enroll only patients with tunneled haemodialysis catheter as haemodialysis access (and exclude patients on temporary, non-cuffed HD catheters).
New Drug Division			
5.	ND/MA/25/000049 Voclosporin soft gelatin capsule 7.9 mg	M/s. Zydus Lifesciences Limited	In light of earlier recommendation dated 22.12.2025, the firm presented Phase III Clinical Trial protocol (Protocol No: CRNI/CTP/26/01, version 1.0 dated 19-May-2026) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with the condition that protocol should be revised for following: 1. e- GFR cut off values need to be specified in exclusion criteria. 2. Study dose titration of voclosporine, based upon the e-GFR, need to be clearly described. 3. Stratification based upon level of

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			proteinuria and e-GFR needs to be included. Accordingly, the firm should submit the revised Phase III clinical trial protocol to CDSCO.
6.	ND/CT/25/000094 Methenamine Hippurate Tablets USP 1gm	M/s. Lyrus Life Sciences Pvt. Ltd.	In light of earlier recommendation dated 25.03.2026, the firm presented revised Phase IV Clinical Trial protocol (Protocol no. LYR-MHP-002-25, Version No.: 04 and Date 30 Apr 2026) before the committee. After detailed deliberation, the committee recommended to submit revised protocol with the below mentioned points: 1. Include more no. of sites geographically distributed in all zones of the country 2. Include equal no. of patients in all four approved indications Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO for further review.
FDC Division			
7.	FDC/MA/23/000003 Mirabegron (PR) 25mg/50mg/25mg/50 mg + Tamsulosin Hydrochloride IP (PR) 0.2mg/0.2mg/0.4mg/0.4 mg film coated tablets	M/s. Ravenbhel Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 13.05.2026, the firm presented demographic data including uroflowmetry and ultrasound comparison data within the group of Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
8.	FDC/MA/25/000166 Acetylcysteine 150 mg + Taurine 500 mg film coated tablets	M/s. Fourts (India) Laboratories Pvt. Limited	In light of the earlier SEC recommendation dated 16.04.2026, the firm presented the revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial. Accordingly, the firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.