

Recommendations of the SEC (Nephrology and Urology) made in its 03rd/26 meeting held on 25.03.2026 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/10/25 Online Submission (47645) LNP023	M/s. Novartis Healthcare Private Limited	In light of earlier SEC recommendation dated 18.02.2025, the firm presented phase IIa clinical study protocol no. CLNP023A2201 version number: 00 (Original Protocol) dated: 28 Aug 2024. Now the firm presented clarification, clinical data with detail methodology. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that any injury related to biopsy is considered as SAE.
2.	CT/78/25 Online Submission (50002) VAY736 (Ianalumab)	M/s. Novartis Healthcare Private Limited	In light of earlier SEC recommendation dated 22.07.2025, the firm presented phase III clinical study Protocol No.: CVAY736K12301E1 Version No. 00 dated 14-AUG- 2024. Now the firm presented clarification for scientific rationale for study design, benefit /risk assessment. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
3.	CT/166/25 Online Submission (53090) Ertapenem + Zidebactam	M/s. Wockhardt Limited	The firm presented phase II clinical study protocol no. W-6777-202, version 2.0 dated 10 February 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
New Drugs Division			
4.	ND/CT/25/000094 Methenamine Hippurate Tablets USP 1 gm	M/s. Lyrus Life Sciences Pvt Ltd	In the light of earlier SEC recommendation dated 13.11.2025, firm presented revised Phase-IV CT protocol (Protocol no. LYR-MHP-002-25, Version No.: 02 and Date 22 Dec, 2025) before the committee. After detailed deliberation, committee recommended that the firm should revise the protocol with the following points: 1. Sample size should be recalculated considering the safety and efficacy

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			<p>end points.</p> <ol style="list-style-type: none"> 2. Urinary pH monitoring should be done more frequently. 3. The committee reviewed the protocol and recommended that the Principal Investigators should be Urologist. <p>Accordingly, the firm should submit the revised Phase IV CT protocol within one month to CDSCO for further review by the committee.</p>