Recommendations of the SEC (Nephrology & Urology) made in its 06th/26 meeting held on 13.05.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/61/26 Online Submission (54922) SC0062	M/s. George Institute Services India Private Limited	The firm presented phase III clinical study protocol number: P01351, version no.2.0 dated 20 November 2025. After detailed deliberation, the committee opined that the firm shall submit the following for further review by the committee. 1. Phase I and Phase II clinical study data generated in South Asian populations along with available ethnic sensitivity data, for the proposed IMP. 2. Post-Marketing Surveillance (PMS) data, along with the current global regulatory approval status of the subject IMP, as it was stated during the presentation that the molecule is reported to have already been approved/ authorized in certain countries. 3. Clarification is required regarding the nature of the proposed clinical trial, specifically whether it is intended to be conducted as an academic clinical trial, as the current submission made to CDSCO does not adequately specify this aspect.
SND Division			
2.	SND/MA/25/000268 Bethanechol Chloride 50 mg tablets	M/s. Sun Pharma Laboratories Limited	In light of the earlier SEC recommendation dated 13.01.2026, the firm presented their proposal to conduct the BA/BE study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the protocol submitted and submit the results to CDSCO.
FDC Division			
3.	FDC/MA/23/000003 Mirabegron (PR) 25	M/s. Ravenbhel Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 20.08.2024, the firm presented Phase III CT report before the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	mg/50 mg/25 mg/50 mg + Tamsulosin Hydrochloride IP (PR) 0.2 mg/0.2 mg/0.4 mg/ 0.4 mg film coated tablets		After detailed deliberation, the committee opined that the firm should submit baseline demographic data including uroflowmetry and ultrasound comparison data within the group to CDSCO for further review by the committee.
4.	FDC/MA/23/000018 Silodosin 8 mg + Solifenacin Succinate 5 mg Capsule	M/s. MSN Laboratories Private Limited	The firm did not attend the meeting.
5.	FDC/CT/25/000067 Mirabegron (PR) 50 mg/25 mg + Solifenacin Succinate IP 5 mg/5 mg film coated bilayered tablet	M/s. Mascot Health Series Pvt. Ltd.	In light of earlier SEC recommendation dated 13.01.2026 and as per condition mentioned in permission in Form CT-23 dated 07.12.2023; 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.
6.	FDC/CT/25/000126 Sodium Hyaluronate 800 mg + Chondroitin Sulphate Sodium 1000 mg + Lidocaine Hydrochloride 200 mg per 50 mL Intravesical Solution	M/s. Tech Observer India Pvt. Ltd.	The firm presented the proposal before the committee. After detailed deliberation, the committee opined that: 1. Firm should submit rationality and scientific justification for the proposed FDC and indication. 2. Individual drugs usage for proposed indication is not approved by CDSCO. 3. The proposed FDC is also not approved internationally. 4. Firm did not present definite evidence from Indian relevance. 5. Firm should submit scientific literature in per reviewed journal for proposed FDC and its indication. Accordingly, the firm should submit above mentioned data to CDSCO for further review by the committee.