

Recommendations of the SEC (Nephrology & Urology) made in its 01st/26 meeting held on 13.01.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/177/25 Online Submission (53470) Utreglutide (GL0034) Solution for injection 1.0 mg/mL	M/s Sun Pharmaceutical Industries Limited	The firm presented phase I clinical study \protocol no. UTRE-25-01 version no. 1.0 dated 19 Nov 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. The monitoring of calcium level and parathyroid hormone level in lab parameter testing. 2. Participants with the renal Impairment eGFR< than 30 without dialysis and eGFR< 15 with or without dialysis shall be incorporated in inclusion criteria.
BA/BE Division			
2.	BABE/CT05/FF/2025/ 47272 Mycophenolate sodium for injection 720 mg/vial, 739 mg/vial, 690 mg/vial	M/s Lupin limited	The firm presented the Study Protocol No.LBC-P-170-24 Version No.01 Date 14-Jul-2025 for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the Bioavailability study for export purpose only.
New Drugs Division			
3.	ND/CT/22/000048 Finerenone film coated tablets 10 mg and 20 mg	M/s Bayer Pharmaceuticals Pvt. Ltd.	The firm presented the Phase IV clinical trial report (B004583; version: 0.1 Dated 04.11.2025) of the drug Finerenone film coated tablets 10 mg and 20 mg, before the committee. After detailed deliberation, the committee considered the results of the Phase IV clinical trial study.
4.	ND/MA/25/000167 Vibegron tablets 75 mg	M/s Hetero Labs Limited	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Vibegron Tablets 75 mg along with Phase-III Clinical Trial Protocol vides Protocol No. HCR/III/VIBOAB/08/2025, Version no. 1.0 dated 20-08-2025 and BE report (Protocol No. 069-24, Version no. 0.0) of drug Vibegron Tablets 75 mg before the

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			<p>committee</p> <p>After detailed deliberation, the committee noted the BE study result as presented by the firm.</p> <p>Further, the committee recommended that the firm should compare the Vibegron Tablet 75 mg with the Mirabegron Tablet 50 mg. Accordingly; the firm should submit the revised Phase III clinical trial protocol to CDSCO for further review by committee.</p> <p>Furthermore, the committee option that the clinical trial sites should be geographically distributed across the country.</p>
SND Division			
5.	SND/MA/25/000268 Bethanechol Chloride Tablets USP 50 mg (Additional Strength)	M/s Sun Pharma Laboratories Limited	<p>The firm presented proposal for grant of permission to manufacture and market Bethanechol Chloride Tablets USP 50 mg (Additional higher Strength) along with justification for BE & CT study waiver before the Committee.</p> <p>After detailed deliberation, the Committee opined that firm should conduct BA/BE study and present the results of study comparing the therapeutic window/index before the Committee.</p> <p>Accordingly, the firm should submit BA/BE study protocol to CDSCO.</p>
FDC Division			
6.	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.	<p>In light of the condition mentioned in permission in Form CT-23 dated 24.09.2022; the firm presented the Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> 1. Firm should provide voiding diary at baseline and subsequent follow-up visits. 2. Firm should exclude endoscopy test from the study schedule. 3. Firm should revise the exclusion

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			<p>criteria and exclude patients with narrow angle glaucoma.</p> <p>4. Firm should include only investigator with urology and not general surgeon to be part of the trial.</p> <p>Accordingly, the firm should submit revised Phase IV CT protocol to CDSCO for further review by the committee.</p> <p>(Committee noted that Dr. Sameer Trivedi is one of the investigators of the study.)</p>
7.	<p>FDC/MA/25/000166</p> <p>Acetylcysteine 150 mg + Taurine 500 mg film coated tablets</p>	<p>M/s. Fourts (India) Laboratories Pvt. Limited</p>	<p>In light of DTAB subcommittee report dated 28.12.2021 wherein expert committee recommended "After detailed deliberation, the Committee recommended that firms in the current scenario while continuing the manufacturing and marketing are required to conduct a well-designed structured Phase IV Clinical trial in adequate sample size keeping efficacy as primary objective and study should be completed within one year." for the proposed FDC.</p> <p>Accordingly, the firm presented the Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee observed that:</p> <ol style="list-style-type: none"> 1. There is no robust efficacy study data available in the literature as of now for the proposed FDC. Hence the committee recommended to submit a comparative study specifically emphasizing efficacy as a primary end point. 2. Firm should revise inclusion and exclusion criteria as per new study design. 3. Firm should modify duration of the study as per the clinical indication. 4. Firm should ensure the use of other medication such as ACE inhibitors/ARB and SGLT 2

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			<p>inhibitors in maximum tolerated doses.</p> <p>5. Firm should modify the study outcome and explain the sample calculation.</p> <p>Accordingly, the firm should submit revised Phase IV CT protocol including above modifications to CDSCO for further review by the committee.</p>
8.	<p>FDC/MA/25/000174</p> <p>Acetylcysteine 150 mg + Taurine 500 mg film coated tablets</p>	<p>M/s Pharose Remedies Limited</p>	<p>In light of DTAB subcommittee report dated 28.12.2021 wherein expert committee recommended "After detailed deliberation, the Committee recommended that firms in the current scenario while continuing the manufacturing and marketing are required to conduct a well-designed structured Phase IV Clinical trial in adequate sample size keeping efficacy as primary objective and study should be completed within one year." for the proposed FDC.</p> <p>Accordingly, the firm presented the Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee observed that:</p> <ol style="list-style-type: none"> 1. There is no robust efficacy study data available in the literature as of now for the proposed FDC. Hence the committee recommended to submit a comparative study specifically emphasizing efficacy as a primary end point. 2. Firm should revise inclusion and exclusion criteria as per new study design. 3. Firm should modify duration of the study as per the clinical indication. 4. Firm should ensure the use of other medication such as ACE inhibitors/ARB and SGLT 2 inhibitors in maximum tolerated doses. 5. Firm should modify the study outcome and explain the sample

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			<p>calculation.</p> <p>Accordingly, the firm should submit revised Phase IV CT protocol including above modifications to CDSCO for further review by the committee.</p>
9.	<p>FDC/MA/25/000227</p> <p>Empagliflozin 10 mg/10 mg + Eplerenone IP 25 mg/50 mg film coated tablet</p>	<p>M/s Pure & Cure Healthcare Pvt. Ltd.</p>	<p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> 1. Firm did not present published scientific literature in peer reviewed journal in support of the FDC. 2. Firm should submit approval status of Eplerenone for CKD. 3. Firm should submit adequate/justified rational for the proposed FDC. <p>Accordingly, the firm should submit above data for further review by the committee.</p>