Recommendations of the SEC (Nephrology & Urology) made in its 02nd/26 meeting held on 12.02.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000234 Flavoxate Hydrochloride Sustained Release Tablets 600 mg	M/s. Ravenbhel Healthcare Pvt. Ltd	In light of earlier SEC recommendations dated 09-10-2025 and 21-01-2026, firm has submitted justification for minimum effective therapeutic concentration (METC) of flavoxate and its primary metabolite, 3-methylflavone 8-carboxylic acid (MFCA) before the committee. The Committee noted that the MFCA plasma concentration in BE study at the time point 14hrs and above for the test product is not sufficient to substantiate therapeutic efficacy of the applied product. After detailed deliberation, the committee did not recommend acceptance of the study results.
FDC Division			
2.	FDC/MA/24/000133 DapagliflozinPropanediol eq. to Dapagliflozin 10 mg + Eplerenone IP 25 mg film coated tablets	M/s. Exemed Pharmaceuticals	Under Discussion.
3.	FDC/MA/23/000339, E. office No.: FDC/6/2026-eoffice Silodosin 8 mg (IR) + Mirabegron 50 mg (ER) film coated bilayered tablet	M/s. Alkem Health Sciences	As per the condition mentioned in Form CT-23 dated 30.09.2025, the firm presented Active PMS protocol before the committee. After detailed deliberation, the committee opined the following modifications in protocol: 1. Post-void residual urine test and uroflowmetry needs to be included under investigation. 2. IPSS scoring to be added. 3. The sample size should be statistically significant. 4. Qualified Urologist as Principal investigator. Accordingly, the firm should submit revised Active PMS protocol to CDSCO for further review by the committee.

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4.	FDC/MA/25/000264 Dapagliflozin Propanediol eq. to Dapagliflozin 10 mg/10 mg + Eplerenone IP 25 mg/50 mg film coated tablet	M/s. Pure & Cure Healthcare Pvt. Ltd.	The firm presented their proposal before the committee. After detailed deliberation, the committee opined that: 1. Firm did not present any scientific literature and peer reviewed journal for the proposed FDC in higher strength. 2. Committee noted that for the lower strength of the proposed FDC i.e., Dapagliflozin Propanediol eq. to Dapagliflozin 10 mg + Eplerenone IP 25 mg film coated tablet Phase III CT NOC has already been issued to other firm to conduct the Phase III clinical trial. Accordingly, the firm should submit BE and Phase III CT protocol for lower strength to CDSCO for further review by the committee.
5.	FDC/CT/26/000002 Solifenacin Succinate 6 mg eq. to Solifenacin 4.5 mg + Tamsulosin Hydrochloride IP 0.4 mg eq. to Tamsulosin 0.37 mg (MR) film coated tablet	M/s. Cipla Limited	In light of the condition mentioned in permission in Form CT-23 dated 03.10.2025; the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee opined that: 1. Firm should increase the sample size to at least 1100. 2. Firm should increase the duration of the study to 52 weeks. 3. Failure of alpha blocker monotherapy in inclusion criteria should be more objectively defined. Accordingly, the firm should submit revised Phase IV clinical trial protocol to CDSCO for further review by the committee.