

Recommendations of the SEC (Urology) made in its 08th/25 meeting held on 18.09.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/24/000147 Vibegron Tablets 75 mg	M/s MSN Laboratories Private Limited	<p>In the light of earlier SEC recommendation dated 17.04.2025, the firm presented revised Phase-III CT protocol titled “A phase-III, randomized, open label, active controlled, multicentre study to evaluate the safety and efficacy of Vibegron 75 mg tablet, in comparison with Mirabegron ER 25 mg/50 mg Tablet in Patients with Overactive Bladder (OAB)” (Vide protocol No. 003/VIB/MSN/2024, Version 2.0 Dated 12/JULY/2025) of drug Vibegron Tablets 75 mg.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial as per revised protocol presented by the firm with the condition that patients with refractory OAB should be excluded from the trial.</p>
FDC Division			
2.	FDC/MA/23/000319 Tamsulosin Hydrochloride IP (ER tablet) 0.4 mg/0.4 mg + Dutasteride IP (as film coated tablet) 0.5 mg/0.5 mg + Tadalafil IP (as film coated tablet) 2.5 mg/5 mg hard gelatin capsule	M/s Malik Lifesciences Pvt. Ltd.	<p>In light of the earlier SEC recommendation dated 29.11.2023 & 30.11.2023 and 21.08.2025, the firm presented the proposal along with BE study report and Phase III CT study protocol before the committee.</p> <p>After detailed deliberation, the committee considered the BE study report. As regard to Phase III clinical trial protocol, the committee noted that:</p> <ol style="list-style-type: none"> 1. Maximum urinary flow should be (Q_{max}) ranging between 5 to 15 ml/sec with a minimum voided volume > 150 ml at screening. 2. Total serum prostate specific antigen (PSA) should be ≤6 ng/mL and prostate volume of > 30 g. 3. All investigators should be MCH Urologist.

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			Accordingly, the revised Phase III CT Protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase III CT report for review by the committee.