

Recommendations of the SEC (Urology) made in its 02nd/25 meeting held on 18.02.2025. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2024 /45733 Dutasteride 0.5 mg +Silodosin 8 mg Capsule	M/s Genecht Research Pvt. Ltd.	The firm presented the Protocol no.: GR-24-055, Ver. 01 dated 26.09.2024 for BA/BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose with a condition to revise the inclusion criteria for age group of the Healthy volunteers to 18 – 55 years. Accordingly, the firm should submit the revised protocol to the CDSCO.
FDC Division			
2.	FDC/MA/23/000020 Tamsulosin Hydrochloride IP (MR) 0.4mg/0.4mg + Mirabegron (ER) 25mg/50mg tablets	M/s Windlas Biotech Limited	In light of the earlier SEC recommendation dated 25.07.2024, the firm presented the proposal along with revised Phase III Clinical trial protocol before the committee. After detailed deliberation, the committee opined that the following modifications are required in the Phase III CT Protocol: <ol style="list-style-type: none"> 1. Point number 1, 2, & 3 in Inclusion criteria needs to be elaborated to define which type of patients should be enrolled in the study. 2. Scientific Methodology needs to be explained in detail and assessment parameters need to be mentioned clearly. 3. Scientific terminology should be used in the Phase III CT protocol. <p>Accordingly, the firm should submit revised Phase III clinical trial protocol to CDSCO for further review by the committee.</p>