

**Recommendations of the SEC (Urology) made in its 05<sup>th</sup>/25 meeting held on 20.05.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>FDC Division</b>			
1.	FDC/MA/23/000020  Tamsulosin Hydrochloride IP (MR) 0.4 mg/ 0.4 mg + Mirabegron (ER) 25mg/50mg tablets	M/s Windlas Biotech Limited	<p>In light of the earlier SEC recommendation dated 18.02.2025, the firm presented the proposal along with revised Phase III Clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended to conduct Phase-III CT study with the conditions that:</p> <ol style="list-style-type: none"> <li>1. Uncontrolled Diabetic patients with HbA1c value above 8 should be included in exclusion criteria.</li> <li>2. Define the term “change” in the Primary Endpoints.</li> <li>3. More Government sites should be included and the sites should be geographically distributed.</li> </ol> <p>Accordingly, the firm should submit Phase III CT report to CDSCO for further review by the committee</p>