

Recommendations of the SEC (Urology) made in its 01st/25 meeting held on 29.01.25. at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000078 Tamsulosin Hydrochloride IP (As Extended Release Form) 0.4 mg + 0.4 mg I.P.+ Mirabegron (As Extended Release Form) 25mg + 50mg Tablets	M/s Pure and Cure Healthcare Pvt. Ltd	<p>The firm presented the proposal along with BE study protocol & Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the BE study.</p> <p>As regard to Phase III clinical trial protocol, the committee opined that-</p> <ol style="list-style-type: none"> 1. To include Uroflowmetry test at baseline visit and at end of study visit. 2. To include International Prostate Symptom Score (IPSS) along with Total OABSS in primary end point. 3. To include details of fluid intake in micturition diary. 4. Firm should change the test arm and design. 5. The patients who are on treatment with alpha blockers should be excluded from the study. 6. Whole abdominal ultra sound need to be performed at baseline visit. 7. Firm should revise the inclusion and exclusion criteria. <p>Accordingly, the firm should submit revised Phase III clinical trial protocol along with BE study report to CDSCO for further review by the committee.</p>