Recommendations of the SEC (Urology) made in its 05th/24 meeting held on 20.08.2024 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000003 Mirabegron (As prolonged Release) + Tamsulosin Hydrochloride (As Prolonged Release) 25mg/50mg/25mg/ 50mg+0.2mg/0.2mg /0.4mg/0.4mg	M/s. Ravenbhel Healthcare	In light of earlier SEC recommendation dated 25.04.2024, the firm presented the proposal along with Phase III CT Protocol for two strengths i.e., Mirabegron (PR) 25mg/50mg + Tamsulosin Hydrochloride IP (PR) 0.4mg/0.4mg tablets. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with the following conditions: 1. To include Uroflowmetry test at the baseline visit and at end of study visit. 2. To include International Prostate Symptom Score (IPSS) along with Total Overactive Bladder Symptom Score (OABSS) in Primary End Point. 3. To include details of fluid intake in Micturition Diary. 4. To modify the exclusion criteria as "Patient with clinically significant bladder outflow obstruction other than BPH (except large median lobe) due to calculi, tumor or stricture." Accordingly, the revised Phase III CT Protocol should be submitted to CDSCO, for review. After approval from CDSCO, the firm should submit Phase III clinical trial report for further review by the committee.