

**Recommendations of the SEC (Urology) made in its 06<sup>th</sup>/24 meeting held on 22.10.2024 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>SND Division</b>			
1.	SND/MA/23/000283  Mirabegron Extended Release Tablets 25mg and 50mg	M/s. Sun Pharmaceuticals	<p>In light of earlier SEC recommendation dated 20.02.2024, the firm has presented BE results along with EMA and USFDA guidelines. Firm informed the committee that the test drug is highly variable and the same pattern is observed in Test and reference both. However, the committee noted that the variability is due to molecule not the formulation.</p> <p>After detailed deliberation, the committee opined that BE study showed high variability w.r.t. C<sub>max</sub>. The committee noted that for highly variable drugs partial or fully replicate crossover study design is required. Accordingly, firm is required to provide the justification on BE study design used to generate the data.</p>