

Recommendations of the SEC (Urology) made in its 01st/24 meeting held on 20.02.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	CI/MD/2023/107687 Urine leak and flow capture device	M/s. Abhaya-3 CD Private Limited	<p>The firm presented proposal for grant of permission under MD-23 for conduct of Pilot clinical investigation on “Urine leak and flow capture device Brand Name-Capury” in the country before the committee.</p> <p>After detailed deliberation, the committee opined that the Clinical study plan presented before the committee is inadequate. The applicant may revise Clinical study plan by incorporating the following points:</p> <ul style="list-style-type: none"> • Clearly specify the single use in the intended use statement of the device • the assessment tool used (questionnaire), • sampling details, • study on the time duration the device can be worn, discomfort to the patient • Also the study may include at least two study sites. <p>The firm may submit the revise clinical investigation plan accordingly for review by SEC.</p>
SND Division			
2.	SND/MA/23/000283 Mirabegron Extended release Tablets 25mg and 50mg	M/s. Sun Pharmaceuticals Limited	<p>The firm proposed for Manufacturing and marketing permission of Mirabegron extended release Tablets 25 mg and 50 mg and presented BE report of Mirabegron extended release Tablets 50 mg for which permission has been taken from BA/BE Export Division before the committee.</p> <p>After detailed deliberation, the committee noted that the firm submitted 90% Confidence Interval of AUC (0-72) and AUC (0-infinity) was found to be 97.30 to 119.84 and 97.63 to 138.80 respectively against the acceptance limit within 80-125%. Hence, firm may submit justification to prove that product is Bio-equivalent with the Reference product.</p>

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			Accordingly, the firm should submit additional data to CDSCO for further review by the committee.
3.	SND/MA/21/000255 Sildenafil Citrate Oro-Dispersible Granules 50mg & 100mg	M/s. Ferring Pharmaceutical Private Limited	The firm did not turn up for presentation.