

Recommendations of the SEC (Reproductive & Urology) made in its 68th meeting held on 24.03.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/21/000255 Sildenafil Citrate Oro-Dispersible Granules 50/100mg	M/s. Ferring Pharmaceuticals	The firm presented their proposal along with the results of BE study. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Sildenafil Citrate Oro-Dispersible Granules 50/100mg for the already approved indication.
FDC Division			
2.	FDC/MA/21/000119 Solifenacin Succinate (as immediate release tablets) 5mg/5mg +Mirabegron (as extended release tablet) 25mg/50mg capsules	M/s. MSN Laboratories Pvt. Ltd.	The firm presented the proposal along with the results of BE study. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product with the following conditions- 1. The firm should conduct phase IV clinical trial. 2. The phase IV clinical trial protocol should be submitted within 3 months from the date of approval.
Medical Device Division			
3.	IMP/MD/2021/38932 Pessary Ring Flexible Vinyl (PORTIA)	M/s. Morulla Health Tech Pvt. Ltd.	The firm presented their proposal for grant of permission to import for sale or for distribution of the medical device before the committee. After detailed deliberation, the committee recommended that the firm should submit the efficacy and long term safety data and package insert of the product for further review by the committee.