

Recommendations of the SEC (Urology) made in its 03rd/25 _{meeting held on 18.03.2025 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 50mg/100mg	M/s Ferring Pharma	<p>Firm present their proposal for change in warning condition no. iii of Sildenafil Citrate oro-dispersible Granules 50mg/100mg from “To be sold by retail on the Prescription of an Urologist, Psychiatrist and Endocrinologist only” to “To be sold by retail on the Prescription of an Registered Medical Practitioner” along with rational and safety study data before the Committee.</p> <p>After detailed deliberation, the Committee opined that the presented safety data on 50 subjects is insufficient. Further, there are chances to misuse of this product. Therefore, the Committee did not recommended for change in warning condition (Package insert) in the existing permission.</p>
2.	SND/MA/24/000022 Flavoxate XR Tablet 600mg and 800mg (Additional Dosage Form & Strength)	M/s Martin & Harris Laboratories Limited	<p>Firm presented their proposal for grant of permission to manufacture and marketing of Flavoxate XR Tablet 600mg and 800mg along with BA study protocol no. C1B03236 dated 19-Jan-2024 before the committee.</p> <p>After detailed deliberation, the Committee recommended to grant of permission to conduct BA study as per protocol presented by the firm with suggestion to incorporate the urine sampling also for testing of drug and its metabolite.</p>