

Recommendations of the SEC (Urology) made in its 06th/25 meeting held on 22.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000207 FDC-12011(12)/07/2025- eoffice Alfuzosin Hydrochloride IP (ER) 10 mg + Tadalafil IP 5 mg uncoated bilayer tablet	M/s Sun Pharma Laboratories Limited	As per the condition mentioned in Form CT-23 dated 25.04.2025, the firm presented Active PMS protocol before the committee. After detailed deliberation, the committee recommended for conducting the Active PMS study with the condition that: <ol style="list-style-type: none"> 1. The ED score should be 22 instead of 25 in inclusion criteria. 2. The inclusion criteria should include the patients having the Prostate volume of less than or equal to 60mL. 3. The indication mentioned in the protocol should be inline with the permission granted in Form CT-23. Accordingly, the revised Active PMS protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Active PMS report for further review by the Committee.
SND Division			
2.	SND-16011(11)/82/2025- eoffice Febuxostat Extended Release Tablets 40/80 mg	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm did not turn up for the presentation.