

**Recommendations of the SEC (Reproductive & Urology) made in its 73<sup>rd</sup> meeting held on 30.08.2022 at CDSCO (HQ), New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>FDC Division</b>			
1.	04-01/2019-DC(Misc. 53)  Aceclofenac 100mg + Drotaverine Hydrochloride 80mg tablet	M/s. Mapra	<p>In light of earlier SEC recommendation dated 29.08.2019, the firm presented their proposal alongwith active PMS report before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> <li>1. The firm should submit data on atleast 50 more patients for primary dysmenorrhea and ureteric colic.</li> <li>2. The name of the investigators and their qualification should also be informed to the committee.</li> </ol> <p>In view of above, the firm should present the said data before the committee for further review.</p>