

Recommendations of the SEC (Reproductive) made in its 04th/24 meeting held on 16.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	04-01/2019-DC (Misc. 53) Aceclofenac 100mg + Drotaverine Hydrochloride 80mg tablet	M/s. IPCA Laboratories Ltd.	In light of earlier SEC recommendation dated 20.03.2024, the firm presented the source data (i.e. CRF) of Active PMS study report for the indication of primary dysmenorrhea as well as colicky pain due to smooth muscle spasm (biliary colic and ureteric colic) before the committee. After detailed deliberation, the committee opined that: <ol style="list-style-type: none"> 1. Patient selected are not inline with the indication mentioned on the heading of Active PMS study. 2. Collection of data & safety assessment is not appropriate. In view of above, firm should conduct Active Post marketing surveillance after getting protocol approved from CDSCO.