

Recommendations of the SEC (Reproductive) made in its 09th/25 meeting held on 09.10.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000234 Flavoxate Hydrochloride Sustained Release Tablets 600 mg	M/s. RAVENBHEL HEALTHCARE PVT LTD	In light of earlier SEC recommendation dated 19.12.2023 & 27.03.2024, firm has presented the BE study report of Flavoxate HCl SR Tablets 600 mg along with justification for clinical trial waiver before the committee. After detailed deliberation, the committee opined that firm shall submit the published literature/data to support minimum effective therapeutic concentration (METC) of flavoxate and its primary metabolite, 3-methylflavone-8-carboxylic acid (MFCA) required for clinical efficacy and correlate the same with the test product concentration profile over 24 hrs period in the conducted BE study. Accordingly, firm shall submit the above information to the CDSCO for further review by the committee.
2.	SND/CT21/FF/2024/44611 Magnesium Sulfate in 5% Dextrose Injection USP (10 mg/ml)-100ml plastic bottle	M/s. Otsuka Pharmaceutical India Private Limited	In light of the earlier recommendation dated 20.05.2025, the firm presented the justification for the administration of 100ml of Magnesium Sulphate in 5% Dextrose injection. The committee opined that the proposed dosage form (IV Infusion) may lead to fluid overload in Eclampsia and Pre-eclampsia patients leading to Pulmonary Oedema and is not rationale in proposed Indication. After detailed deliberation, the committee did not recommend for grant of permission for the manufacturing and marketing of the applied product.
FDC Division			
3.	04-01/2019-DC (Misc. 53) Aceclofenac 100 mg + Drotaverine Hydrochloride 80 mg	M/s. IPCA Laboratories Ltd.	In light of earlier SEC recommendation dated 20.05.2025, the firm presented the proposal along with revised Active PMS Protocol number 1 for primary dysmenorrhea and Protocol number 2 for biliary colic and ureteric colic before the

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	tablet		<p>committee.</p> <p>After detailed deliberation, the committee recommended for conducting the Active PMS study as per the above said protocols.</p> <p>The results of the study should be submitted to CDSCO for further review by the committee.</p>