

**Recommendations of the SEC (Reproductive) made in its 01<sup>st</sup>/26 meeting held on 21.01.2026 at CDSCO HQ New Delhi:**

<b>S. No</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendations</b>
<b>New Drug Division</b>			
1.	ND/MA/25/000155  FDC of Drospirenone and Estetrol Tablets (3 mg + 14.2 mg)	M/s. Sun Pharma Laboratories Limited	<p>The firm has presented the proposal for grant of permission to manufacture and market of Drospirenone and Estetrol Tablets (3 mg + 14.2 mg) along with BE study report (Study No: CS24127, dated 03-Sep-2025) and Phase III Clinical Trial Protocol (Protocol No: ICR/24/014, Protocol Version No: 1.0, dated 24-Apr-2025) before the committee.</p> <p>After detailed deliberation, the committee considered the BE study results of Drospirenone and Estetrol Tablets (3 mg + 14.2 mg) and recommended for grant of permission to conduct Phase III clinical trial as per the protocol presented.</p> <p>The results of Phase III Clinical Trial should be submitted to CDSCO for further review by the committee.</p>
<b>SND Division</b>			
2.	SND/MA/23/000234  Flavoxate Hydrochloride Sustained Release Tablets 600 mg	M/s. RAVENBHEL HEALTHCARE PVT LTD	<p>The firm submitted the proposal for marketing and manufacturing Flavoxate Hydrochloride Sustained Release Tablets 600 mg along with BE study report before the Committee.</p> <p>The expert noted that the applied indication falls under the domain of Urology.</p> <p>Accordingly, the matter is deferred for deliberation before the SEC (Nephrology &amp; Urology).</p>