

**Recommendations of the SEC (Reproductive) made in its 02<sup>nd</sup>/25 meeting held on 18.02.2025 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>SND Division</b>			
1.	SND/MA/22/000 203  Estradiol Vaginal Inserts USP 4mcg and 10 mcg	M/s West-Coast Pharmaceutical Works Limited	<p>In light of earlier SEC recommendations dated 25.05.2023, firm presented justification for BE and CT waiver for the Proposed dose and proposed indication along with preclinical data before the committee.</p> <p>The Committee noted that Estradiol Vaginal inserts 4 mcg or 10 mcg is already approved in US since long and sufficient clinical data regarding safety and efficacy is available.</p> <p>After detailed deliberation, the Committee opined that the firm should demonstrate in-vitro Bioequivalence/ equivalence study with internationally approved product.</p> <p>Accordingly, firm is required to submit the study results to CDSCO for further review.</p>
2.	SND/MA/22/000 168  Estradiol vaginal cream 0.01%	M/s West-Coast Pharmaceutical Works Limited	<p>In light of earlier SEC recommendations dated 23.12.2022, firm presented justification for BE and CT waiver for the Proposed dose and proposed indication along with preclinical data and nature of applicator used for delivery of the cream before the committee.</p> <p>The Committee noted that Estradiol Vaginal cream 0.01% is already approved in US since long and sufficient clinical data regarding safety and efficacy is available.</p> <p>After detailed deliberation, the Committee opined that the firm should demonstrate in-vitro Bioequivalence/ equivalence study with internationally approved product.</p> <p>Accordingly, firm is required to submit the study results to CDSCO for further review.</p>