

**Recommendations of the SEC (Reproductive & Urology) made in its 80<sup>th</sup> meeting held on 23.03.2023 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>New Drug Division</b>			
1.	ND/MA/22/000171  Relugolix Film Coated Tablets 40mg	M/s. Synokem Pharmaceutical Ltd.	<p>The firm presented the proposal for manufacture and marketing of drug Relugolix film coated tablet 40mg along with Bioequivalence study protocol and justification for waiver of Phase III clinical trial before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the bioequivalence study as per the protocol presented.</p> <p>Committee also opined that Local clinical trial waiver will be considered after submission of the results of the Bioequivalence study.</p>
<b>SND Division</b>			
2.	SND/MA/23/000008  Solifenacin Succinate oral solution 1mg/ml	M/s. Pure & Cure Pvt. Ltd.	<p>The firm presented the proposal for manufacture and marketing of Solifenacin Succinate oral solution 1 mg/ml along with the justification for waiver of BE study and clinical trial.</p> <p>After detailed deliberation, the committee recommended that firm should conduct bioequivalence study with already approved product. Accordingly firm should submit the protocol for bioequivalence study further review by the committee.</p> <p>Committee also opined that clinical trial waiver will be consider after submission of the results of the bioequivalence study.</p>
3.	SND/MA/22/000299  Dydrogesterone Sustained Release Tablet 20mg	M/s. Synokem Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
4.	SND/MA/22/000353  Dydrogesterone Film Coated SR Tablet 30mg	M/s. Ravenbhel Healthcare (P) Limited	<p>The firm presented the proposal of amendment in Form CT-07 issued for bioequivalence study of Dydrogesterone sustained release tablets 30mg along with details of changes in tabular form before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of proposed</p>

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			amendment for bioequivalence study of Dydrogesterone sustained release tablets 30mg.
5.	SND/MA/23/000051  Dydrogestrone Extended Release Tablet 30mg	M/s. Zydus Healthcare Ltd.	The proposal was deferred for next meeting.
<b>FDC Division</b>			
6.	FDC/MA/18/000074  L-Methylfolate 1mg + Dehydroepiandrosterone 75 mg + Vitamin D3 2000IU tablets	M/s. Synokem Pharmaceuticals	The proposal was deferred for next meeting.
7.	FDC/MA/22/000366  Pyridoxine HCL IP (ER) 20mg + Doxylamine succinate (ER) 20 mg tablets	M/s. Akums	The proposal was deferred for next meeting.
<b>Medical Device Division</b>			
8.	MFG/MD/2023/7979 3  Cervicheck™ Self sampling Kit	M/s Pragmatech Healthcare Solutions Pvt. Ltd.	The firm presented the proposal before the committee After detailed deliberation, the committee recommended for grant of permission to manufacture for sale or distribution of the proposed product 'Cervicheck™ Self sampling Kit' in the country.