Recommendations of the SEC (Reproductive & Urology) made in its 69th meeting held on 27.04.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000063 Sodium phenyl butyrate oral powder 940mg	M/s. Laurus	The firm presented their proposal for manufacturing and marketing of Sodium phenyl butyrate oral powder 940 mg along with their justification for waiver of local clinical trial before the committee. After detailed deliberation, the committee opined that the firm should submit published literature, adequate safety & efficacy data from other countries for the proposed drug, advantage & disadvantage of the proposed drug over the available drugs for the proposed indication, regulatory status in other countries and justification of clinical trial waiver as per the provisions of New Drugs and Clinical Trials Rules, 2019 to CDSCO for further review by the committee. Further, the committee opined that the proposal may be deliberated in presence of Nephrologist and Pediatrician.
2.	ND/MA/21/000151 Topiroxostat tablets 20mg, 40mg and 60mg	M/s. Synokem Pharmaceuticals Limited	The firm presented the proposal of CT waiver along with the BE study protocol before the committee. After detailed deliberation, the committee noted that Topiroxostat tablets 20mg, 40mg and 60mg are already approved in the country and agreed with the justification submitted for CT waiver and recommended for grant of permission to conduct the BE study as per the protocol presented subject to the condition that reference arm of bioequivalence study should be Topiroxostat 60mg tablets only.
SND Division			
3.	SND/MA/22/000088 Tamsilosin HCI MR Tablets 400 mg	M/s Dr. Reddy's Laboratories	The firm presented the BE study protocol before the committee for approval. After detailed deliberation, the committee recommended for grant of permission to conduct the BE study as per the protocol presented.

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4.	SND/MA/22/000108 Carbetocin Injection 100mcg/ml (Room temperature stable formulation) in Prefilled syringes (PFS)	M/s Precise Biopharma	The firm presented the proposal of Carbetocin Injection 100mcg/ml (room temperature stable formulation) in prefilled syringes (PFS). After detailed deliberation the committee recommended for grant of permission to manufacture and market Carbetocin Injection 100mcg/ml (room temperature stable formulation) in prefilled syringes (PFS) with the condition that the firm should submit the Phase IV clinical trial protocol within 3 months of approval of the product.
5.	SND/MA/21/0000477 Vardenafil Oral Jelly 20mg/5mg	M/s. Ajanta Pharma	The firm presented the proposal along with BE study report. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Vardenafil Oral Jelly 20mg/5mg.
6.	SND/MA/21/000383 Solifenacin Succinate Oro-dispersible Granules 5mg and 10mg	M/s. Ferring Pharma	The firm presented their proposal alongwith BE study report and justification for Phase III CT waiver. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Solifenacin Succinate Oro-dispersible Granules 5mg and 10mg for proposed indication.
7.	SND/MA/22/000119 Clotrimazole Vaginal Film 50 mg	M/s. Hetero Drugs	The firm presented the proposal along with clinical trial protocol. After detailed deliberation, the committee opined that the firm should revise the study design of the clinical trial as a randomized, comparative study with already available approved product with same route of administration in statistically significant number of patients. Accordingly, the firm should submit the revised CT protocol for review by the committee.
FDC Division			
8.	FDC/MA/22/000081 Dutasteride 0.5mg + Silodosin 4mg tablets	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm presented their proposal along with BE study protocol and requested for Phase III CT waiver. The committee noted that both the

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			proposed strengths are approved in capsule dosage form. The committee also noted that the firm is conducting active PMS study on approved capsule dosage form. After detailed deliberation, the committee recommended for conducting proposed bioequivalence study with the following conditions: 1. The firm should revise the indication as per the approved indication i.e. for the treatment of the signs and symptoms of BPH in men with an enlarged prostate. 2. The firm should present results of active PMS study conducted on approved dosage form. The firm should present the results of the studies before the committee for further examination.
9.	FDC/MA/22/000068 Silodosin + Solifenacin Succinate (8mg + 5mg) tablets	M/s. SAVI HEALTH	The firm presented their proposal along with Phase III CT study protocol as well as justification for BE study waiver. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical study with condition that the firm should conduct the study in geographically distributed sites and few sites should be government sites. Details should be submitted to CDSCO.
BA/BE Division			
10.	12-09/2022/BA-BE/MISC-08/DC Etonogestral + Ethinylestradiol Vaginal Ring 0.12 mg/0.010 mg per day	M/s. Raptim Research Pvt. Ltd	The firm presented their proposal along with study protocol for Etonogestral + Ethinylestradiol Vaginal Ring 0.12 mg/0.010 mg per day. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed study as per study protocol no. CVR-WH-202.