

Recommendations of the SEC (Reproductive & Urology) made in its 83rd meeting held on 21.06.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000065 Elagolix sodium 150mg/200mg tablets	M/s. Hetero Labs Ltd.	The firm presented the proposal for grant of permission to manufacture and market the drug Elagolix tablets 150mg and 200mg along with bioequivalence study waiver and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee opined that the firm should conduct BE study. Accordingly, the firm should submit BE study protocol for review by the SEC.
SND Division			
2.	SND/MA/22/000109 Dydrogesterone film coated Sustained Release Tablet 20 mg /30 mg	M/s. Macmillon Pharmaceuticals Pvt. Ltd.	The firm did not turn up for presentation.
3.	SND/MA/21/000034 Letrozole Tablets 5mg (Additional Strength Indication)	M/s. Akums Drugs and Pharmaceuticals Ltd.	The firm presented the proposal for amendment of clinical trial protocol version no 2.1. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per protocol presented. Committee also recommended that more clinical trial sites should be included to have geographically distributed sites across India.
4.	SND/MA/23/000076 Carbetocin Injection 100mcg/ml in prefilled syringes	M/s. Ferring Pharmaceuticals Pvt. Ltd.	The firm presented the proposal for manufacturing and marketing of Carbetocin injection 100mcg/ml in prefilled syringes. The committee noted that Carbetocin Injection 100mcg/ml in prefilled syringes is already approved by CDSCO. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Carbetocin Injection 100mcg/ml in prefilled syringes for already approved indication.

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5.	SND/MA/22/000276 Tadalafil Oral jelly 20mg (Orange flavor)	M/s. Ajanta Pharma Limited	<p>The firm presented the proposal for manufacturing and marketing of Tadalafil oral jelly 20mg. The firm presented the results of the Bioequivalence study report along with the justification for clinical trial waiver.</p> <p>The committee noted that the Tadalafil oral jelly 20mg is found bioequivalent with the reference product i.e Tadalafil tablets 20 mg.</p> <p>After detailed deliberation, the committee considered the request of firm for waiver of clinical trial and recommended for grant of manufacturing permission for Tadalafil oral jelly 20mg for the indication “for the treatment of erectile dysfunction in adult men.</p>
6.	SND/MA/23/000157 Dydrogesterone Sustained Release Tablet 30 mg	M/s Acme Formulation Pvt. Ltd.	<p>The firm presented the proposal for manufacturing and marketing for Dydrogesterone sustained release tablet 30mg for treatment of endometriosis along with the Bioequivalence study protocol and Phase III clinical trial protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of the Bioequivalence study.</p> <p>The committee recommended that the clinical trial protocol is deficient with respect to inclusion criteria and study endpoints.</p> <p>Accordingly, revised Phase III clinical trial protocol should be submitted for further review by the committee along with BE study report.</p>
FDC Division			
7.	FDC/MA/23/000088 Estradiol 1mg U.S.P. + Relugolix 40mg + Norethisterone 0.5mg Film Coated Tablet	M/s. Synokem Pharmaceuticals	<p>The firm presented their proposal before the committee along with BE study protocol as well as clinical trial study protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conducting the BE study.</p> <p>The result of the study should be presented before the committee for further review, alongwith more evidence of scientific literature available from peer reviewed journal in support for use of the</p>

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			combination in proposed indication for long term use.
8.	FDC/MA/22/000343 Tamsulosin HCL I.P 0.4mg (As Extended Release Form) + Tadalafil I.P. 2.5mg (Film Coated) Tablet	M/s. Akums drugs & Pharmaceuticals Ltd.	In light of earlier, SEC recommendations dated 23.12.2022, the firm presented their proposal before the committee along with BE study report for higher strength and Phase IV clinical trial protocol. After detailed deliberation, the committee recommended for grant of manufacturing and marketing permission for the said FDC subject to condition that the firm should conduct Phase IV clinical trial with increased sample size (approx. 300) and study centers geographically distributed in the country.
Medical Device Division			
9.	MD/PostAppr/2023/14522 HepaSphere Embolization MicroSpheres Embosphere Microspheres in vial	M/s. Merit Medical System India Pvt. Ltd.	The firm did not turn up for presentation.