

Recommendations of the SEC (Reproductive) made in its 08th/24 meeting held on 18.09.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/107/24 Online Submission (44749) Carbetocin RTS (HSC)	M/s. Jawaharlal Nehru Medical College	<p>The firm presented phase 3 clinical study protocol no. A66045, version 3.0, dated 03 September 2023.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with the condition that</p> <ol style="list-style-type: none"> (1) Uterine massaging shall be given routinely to all the subjects to maintain uterine tone. (2) Measurement of blood loss at 3rd stage shall be done separately to minimize calculation errors. (3) The internal safety sub-study conducted in 250 subjects in Argentina, South Africa, and United Kingdom shall be submitted to CDSCO before the trial is initiated in India.
Biological Division			
2.	BIO/CT04/FF/2024/43762 Follicle Stimulating Hormone Solution for Injection, 300 IU	M/s. Intas Pharmaceuticals Ltd.	<p>The firm presented the protocol to conduct Phase I clinical study of Recombinant Human Follicle Stimulating Hormone 300 IU Solution for Injection titled " An open label, Phase-I, balanced, randomized, two-treatment, two-period, two-sequence, single subcutaneous dose administration, crossover, bioequivalence study of r-h-FSH (recombinant human follicle stimulating hormone injection), solution for injection of Intas pharmaceuticals limited, India with Gonal-f, recombinant human follicle stimulating hormone (r-hFSH) follitropin alfa, solution for injection of Merck serono Ltd. in pituitary down-regulated normal, healthy, adult, human female subjects under fasting conditions." vide Protocol no. 0501-23, Version: 2.0 dated</p>

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			<p>27-May-2024.</p> <p>After detailed deliberation, the committee recommended for conduct of proposed Phase I study with a condition that firm should have tie up with an IVF centre in case of any emergency.</p> <p>Accordingly, firm should submit revised protocol to CDSCO for further evaluation.</p>