

**Recommendations of the SEC (Reproductive) made in its 07<sup>th</sup>/25 meeting held on 21.08.2025 at CDSCO HQ New Delhi:**

<b>S. No</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendations</b>
<b>GCT Division</b>			
1.	CT/107/24 Online Submission (40603)  Carbetocin RTS	M/s Jawaharlal Nehru Medical College	The firm presented protocol amendment version 4.0 dated 17 Jan 2025 protocol no. A66045.  After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
<b>FDC Division</b>			
2.	FDC/MA/23/000319  Tamsulosin Hydrochloride IP (ER tablet) 0.4 mg/0.4 mg + Dutasteride IP (as film coated tablet) 0.5 mg/0.5 mg + Tadalafil IP (as film coated tablet) 2.5 mg/5 mg hard gelatin capsule	M/s Malik Lifesciences Pvt. Ltd.	The proposal of the said FDC was briefed before the committee.  The committee noted that the proposed indication of the FDC should be discussed in the presence of one Urologist & one Andrologist in the next SEC meeting.