

Recommendations of the SEC (Reproductive & Urology) made in its 63th meeting held on 28.09.2021 at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/21/000383 Solifenacin Succinate Oro-Dispersible Granules 5/10 mg	M/s Ferring Pharmaceuticals	<p>The firm presented the proposal of Solifenacin Succinate Oro-Dispersible Granules 5/10 mg along with BE study protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission for conduct of the BE study as per the protocol presented.</p> <p>However, in light of issues of oral side effects that may be associated with use of the product and overall safety and efficacy profile, the committee recommended that the firm should also conduct Phase III clinical trial. Accordingly, the firm should submit the Phase III CT study protocol along with the BE study report for review by the committee.</p>
Medical Device Division			
2.	CI/MD/2021/40284 CERVICH ECK self Sampling Kit	M/s. Pragmatech Healthcare solutions Pvt. Ltd.	<p>The firm presented their proposal to conduct pivotal clinical investigation of the product before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to the conduct pivotal clinical investigation subject to condition that the proposed study should be carried out in atleast two sites and one of the sites should be from Government institute.</p>

