

Recommendations of the SEC meeting to examine IND proposals, made in its 24th meeting held on 28.06.2022, 02:00PM at CDSCO, HQ New Delhi, through Webex (Videoconference):

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
1.	F. No. IND/CT/22/000023 NRC-1111	M/s Natco Pharma Limited	<p>The firm presented their proposal to conduct Phase I clinical trial alongwith <i>In-Vitro/In-Vivo</i> preclinical data before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol with the following conditions:</p> <ol style="list-style-type: none"> 1. The starting dose should be 5 mg/per day instead of 10 mg. 2. To include patients of four types of solid tumors in the proposed trial. <p>Accordingly, the firm should submit revised protocol to CDSCO.</p>
2.	F. No. IND/MA/22/000027 SOVATELTIDE INJECTION (PMZ-1620)	M/s Pharmazz India Private Limited	<p>The firm presented Phase I, II & III Clinical trial reports along with permission for manufacturing and marketing before the committee.</p> <p>Based on the clinical trial data presented by the firm, after detailed deliberation, the committee recommended that the firm should submit following justification:</p> <ol style="list-style-type: none"> 1. The firm should submit the details of strokes sub-types in the present study. 2. Details of scoring System regarding efficacy, safety and mortality data. 3. Statistical justification for the sample size and number needed to treat to be provided. <p>Accordingly, the firm should submit documents to CDSCO to consider the matter further for deliberation in the committee.</p>

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
3.	F. No. IND/CT/22/000043 Pharmacokinetic Interactions Between HRF-10071, Darunavir and Ritonavir	M/s Veeda Clinical Research Limited	<p>The firm presented their proposal to conduct Phase-I clinical trial to study the pharmacokinetic drug-drug interactions between HRF-10071, Darunavir and Ritonavir along with the protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol.</p>