

Recommendations of the SEC meeting to examine IND proposals, made in its 10th meeting held on 28.01.2021 at CDSCO, HQ New Delhi, through Webex (Video conference):

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	F. No. IND/CT/20/000075 Manganese (II) chloride tetrahydrate (MnCl ₂ .4H ₂ O; Single oral dose of mangoral (800 mg manganese (II) chloride tetrahydrate, 500 mg L-alanine, and 800 IU vitamin D3)	M/s Lambda Therapeutic Research Limited	The firm presented amendment in the protocol of clinical trial "to incorporate two different fed conditions (i.e. full meal or snacks) to assess food effect on PK and PD before the committee. After detailed deliberation, the committee recommended for approval of the amendment of protocol as proposed subject to the condition that the firm should specify the calories w.r.t. diet & also specify type of milk intake i.e. toned/ full cream.
2.	F. No. IND/MA/20/000001 Cenchaquine citrate Lyophilised Injection 1mg/vial	M/s Pharmazz India Private Limited	The firm presented their proposal to conduct Phase III Clinical Trial in new indication of septic shock before the committee. After detailed deliberation the committee observed that the supportive evidence for use of this drug in clinical trial of septic shock is not adequate. Hence, the committee did not recommend for approval of the study.
3.	F. No. IND/CT/20/000057 ISC 17536	M/s Glenmark Pharmaceuticals Ltd.	The firm presented amendment in the protocol (No. ISC 17536-HV-107, version no 4.0 dt 01.08.2020) of clinical trial before the committee. After detailed deliberation, the committee recommended for approval of the amendment of protocol as proposed.

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4.	F. No. IND/CT/20/000058 HRF10071	M/s Lambda Therapeutic Research Limited	<p>In light of earlier recommendations dated 28.08.2020, the firm presented the report of Single Ascending Dose (SAD) study & requested for proceeding to multiple ascending dose (MAD) study before the committee.</p> <p>After detailed deliberation the committee recommended that the firm may proceed for multiple ascending dose (MAD) study as per protocol already approved.</p>