

Recommendations of the SEC meeting to examine IND proposals, made in its 7th meeting held on 28.10.2020 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 Therapeutics Research Ltd	The firm presented their proposal to conduct the PK-PD study of the product in healthy adult human volunteers before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the PK- PD study.
2.	F. No. IND/CT/20/000076 Nafithromycin (WCK4873) Tablets 400 mg and Nafithromycin (WCK4873) Oral suspension, 200mg/5 ml	M/s Wockhardt Ltd	The firm presented their proposal to conduct the comparative bio-availability/ bio- equivalence study of Nafithromycin (WCK4873) Tablets 400 mg and Nafithromycin (WCK4873) Oral suspension, 200mg/5ml before the committee. After detailed deliberation the committee recommended for grant of permission to conduct the proposed study.