Recommendations of the SEC meeting to examine IND proposals, made in its 18th meeting held on 30.11.2021, 12:00 noon at CDSCO, HQ New Delhi, through Webex (Videoconference):

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	F. No. IND/CT/21/000070, HRF 10071	M/s Veeda Clinical Research Private Limited	The firm presented their Phase I clinical trial report before the committee along with the Phase II protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II trial with following modifications- 1. Patients with the Tuberculosis should be excluded from the study. 2. Inclusion age criteria should be lowered from 65 to 45 years. 3. Additional cohort of 30 mg should be included and not the120 mg cohort. 4. Additional PK sampling timepoints at 7hrs should be added. 5. Justification for inter individual variability in the C_{max} should be submitted. Accordingly, revised protocol should be submitted to CDSCO before initiation of the study.
2.	F.No. IND/CT/20/000076, Nafithromycin (WCK4873)	M/s Wockhardt Limited	The firm presented their bioequivalence (BE) report before the committee. After detailed deliberation, the committee noted the results of the BE study as presented by the firm.
3.	F.No. IND/CT/19/000042, AUR101	M/s Aurigene Discovery Technologies Limited	The firm presented their Phase II clinical trial report before the committee. After detailed deliberation, the committee noted the results of the clinical trial as presented by the firm.
4.	F.No. IND/CT/20/000057,ISC 17536	M/s Glenmark Pharmaceuticals Ltd.	The firm presented their bioequivalence (BE) report before the committee. After detailed deliberation, the committee noted the results of the BE study as

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5.	F. No. 12-02/21-DC, PDP-117 Tablets	M/s Norwich Clinical Services Pvt. Ltd.	The firm presented the proposed amendment in Phase-I clinical trial protocol, before the Committee. After detailed deliberation the committee recommended for grant of approval of the protocol amendment of study No. NCS-769-21-CS, amendment version 2.0 dated 21.10.2021 presented by the firm.
6.	F. No. 4-387/ICMR-Hcg/16-BD, Recombinant Vaccine against Human Chorionic Gonadotropin (hCG)	ICMR	The applicant presented progress report of the ongoing Phase I/II clinical trial of Recombinant Vaccine against Human Chorionic Gonadotropin (hCG) before the committee. The committee noted that the Data Safety Monitoring Board (DSMB) has recommended conducting more detailed animal toxicity studies including antibody titers, Mantoux test, etc. After detailed deliberation the committee recommended that following data should be submitted before resuming the trial: 1. The updated status on the safety data of the enrolled subjects. 2. Detailed causality assessment reports for the reported adverse events. 3. Additional animal experimentation should be conducted separately for DNA, protein & adjuvant and in combination of all as recommended by the DSMB and data should be submitted for further evaluation.