

Recommendations of the SEC meeting to examine IND proposals, made in its 32nd meeting held on 02.02.2023, 12:00 Noon at CDSCO, HQ New Delhi, through Webex (Video Conference):

Sr.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	F. No. IND/CT/23/000002 HRF-10071 Tablet 120 mg	M/s Synapse Labs Pvt. Ltd.	The firm presented its proposal to conduct Phase I clinical trial alongwith preclinical data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol.
2.	F. No. ND/CT/22/000064 AKP-11 Ointment	M/s ICBio Clinical Research Pvt. Ltd	In light of SEC committee recommendation dated 19.12.2022, the firm presented its proposal to conduct Phase II clinical trial along with the preclinical and clinical study data and justification before the committee. After detailed deliberation, the committee recommended that the firm should submit following: 1. Proof of concept for the proposed drug. 2. Details of Phase I clinical trial conducted in patients and healthy volunteers in Australia. 3. Toxicity profile of Propylene glycol used in the composition of the proposed ointment. 4. The justification for denying standard of care to the control arm having patients diagnosed with atopic dermatitis of the proposed study. The firm should submit the Phase I clinical trial protocol alongwith ethical justification and proper study design and documents as above for further consideration by the committee.

Sr.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
3.	F. No. IND/CT/22/000013 GRC 54276	M/s Glenmark Pharmaceuticals Ltd.	The firm presented the Phase I protocol amendment before the committee. After detailed deliberation, the committee recommended for the amendment in Phase I clinical trial protocol vide Protocol No. GRC 54276-101, Version 04 dated 16.01.2023. Further, committee also opined that the comments of Oncologist should be obtained by CDSCO before approving the protocol amendment to the firm.
4.	F. No. IND/CT/22/000082 AUR106 Tablets	M/s Aurigene Discovery Technologies Limited	In light of earlier SEC recommendation dated 13.01.2023, the firm presented its proposal to conduct Phase I clinical trial along with justification before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to the condition that the firm should mention in the study protocol under the inclusion criteria that "Standard treatment options provided to the patients are exhausted". Further, committee also opined that the comments of Oncologist on the study protocol should be obtained by CDSCO before granting permission to the firm.
Biological Division			
5.	F. No. BIO/CT04/FF/2022/3 4269 NM8074	M/s Ablenio Sciences Private Limited	The proposal of the firm was deferred to next meeting as per firm's request.