Recommendations of the SEC meeting to examine IND proposals, made in its 13th meeting held on 11.06.2021 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/21/000001, MKP10241	M/s Mankind Research Center	The firm presented the preclinical data along with Phase I Clinical trial protocol for the drug before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I Clinical trial in first three cohorts with 50mg, 100mg and 200mg dose subject to the following conditions: 1. Thymus toxicity biomarker should be clearly defined and monitored during the clinical trial. 2. Thymus toxicity data at 28 days (repeated dose toxicity data) and at recovery stage should be submitted to CDSCO. 3. The firm should DSMB data to CDSCO.
2.	F. No. IND/CT/19/000021, ZY-19489	M/s Cadila Healthcare Limited	The firm presented the preclinical data along with Phase I Clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the phase I Clinical trial subject to the condition that the Heart rate should be 60-90 bpm and Inclusion criteria should be mentioned accordingly.
3.	F. No. IND/CT/21/000026, ZYIL1	M/s Cadila Healthcare Limited	In light of earlier SEC meeting held on 09.04.2021, the firm presented Phase I Clinical trial protocol for Multiple Dose Study before the committee. After detailed deliberation, the committee recommended for grant of

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
			permission to conduct the Multiple Dose Phase I Clinical trial.
4.	F. No. IND/CT/21/000013, ODM-203	M/s Aurigene Discovery Technologies Limited	The firm presented the Phase II Clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the phase II Clinical trial, subject to the following conditions: 1. Firm should submit stage I clinical trial data to CDSCO. 2. Ophthalmological assessment and follow up should be carried out during the clinical trial.
5.	F. No. IND/CT/21/000028, GRC 17536	M/s Glenmark	The firm presented the Phase II b Clinical trial protocol before the committee. After detailed deliberation, the committee recommend for grant of permission to conduct the Phase II b Clinical trial subject to the following conditions: 1. HbA1c level should be ≤ 8. 2. Trial sites should be geographically distributed across the country. 3. Pharmaceutical equivalence data between 250 mg tablets and 270 mg capsules should be submitted to CDSCO. 4. Justification of B.I.D. in correlation with pharmacokinetic data should be submitted to CDSCO.
6.	F. No. IND/CT/21/000001, AUR101	M/s Aurigene Discovery Technologies Limited	The firm didn't turn up for the presentation.

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7.	F. No. IND/CT/19/000021, PMZ 1620	M/s Pharmazz India Private Limited	The firm presented proposed amendment in the protocol before the committee. After detailed deliberation, the committee recommended for grant approval for the proposed protocol amendment.
8.	F. No. 12-11/17-DC, Arimoclomol	M/s Covance India Pharmaceutical Services Pvt. Ltd	The firm presented proposed amendment in the protocol before the committee. After detailed deliberation, the committee recommended for grant approval for the proposed protocol amendment.
9.	F. No. IND/CT/20/000062 AB1001	M/s Ahammune	In light of earlier SEC meeting held on 30.09.2021, firm presented their revised Clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the phase I Clinical trial.
10.	F. No. IND/MA/21/000001, CPL-2009-0031 35 mg, 70 mg, 140 mg Tablets	M/s Cadila Pharmaceutical Ltd.	In light of earlier SEC meeting held on 09.04.2021, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended that, the firm should submit detailed data regarding metabolic conversion of the drug CPL-2009-0031 to active moiety i.e. sitagliptin.