Recommendations of the SEC meeting to examine IND proposals, made in its 22nd meeting held on 29.04.2022, 12:00 noon at CDSCO, HQ New Delhi, through Webex (Videoconference):

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
1.	F. No. IND/CT/22/000018 HRF-10071	M/s Veeda Clinical Research Ltd	The firm presented their proposal to conduct Phase I clinical trial to study the pharmacokinetic interactions between HRF-10071 and Tenofovir alafenamide and Lamivudine along with the protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol with the following conditions: 1. Subjects of either sex should be included of which at least 1/3rd should be women. 2. Additional sampling point at 7 hrs should be added. 3. Reserve sample for reanalysis should be mentioned in the protocol. Accordingly, the firm should submit the revised protocol to CDSCO.
2.	F. No. IND/CT/22/000019 HRF-10071	M/s Veeda Clinical Research Ltd	The firm presented their proposal to conduct Phase I clinical trial to study the pharmacokinetic interactions between HRF-10071 and Tenofovir alafenamide and Emtricitabine along with the protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol with the following conditions: 1. Subjects of either sex should be included of which at least 1/3rd should be women. 2. Additional sampling point at 7 hrs should be added. 3. Reserve sample for reanalysis should be mentioned in the protocol. Accordingly, the firm should submit the revised protocol to CDSCO.
3.	F.No. IND/CT/22/000024 HRF-10071	M/s Lambda Therapeutic Research	The firm presented their proposal to conduct Phase I clinical trial to study the Pharmacokinetic Interactions between HRF-10071 and Tenofovir alafenamide and Dolutegravir along with the protocol before the

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		Ltd	committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol with the following conditions: 1. Subjects of either sex should be included of which at least 1/3rd should be women. 2. Additional sampling point at 7 hrs should be added. 3. Reserve sample for reanalysis should be mentioned in the protocol. Accordingly, the firm should submit the revised protocol to CDSCO.
4.	**F.No. IND/CT/22/000025** **HRF-10071**	**M/s Lambda Therapeutic Research Ltd**	The firm presented their proposal to conduct Phase I clinical trial to study the Pharmacokinetic Interactions between HRF-10071 and Rilpivirine along with the protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol with the following conditions: 1. Subjects of either sex should be included of which at least 1/3rd should be women. 2. Additional sampling point at 7 hrs should be added. 3. Reserve sample for reanalysis should be mentioned in the protocol. Accordingly, the firm should submit the revised protocol to CDSCO.
5.	**F.No. IND/CT/22/000026** **HRF-10071**	**M/s Lambda Therapeutic Research Ltd**	The firm presented their proposal to conduct Phase I clinical trial to study the Pharmacokinetic Interactions between HRF-10071 and Tenofovir alafenamide and Rilpivirine along with the protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the presented protocol with the following conditions: 1. Subjects of either sex should be included of which at least 1/3rd should be women. 2. Additional sampling point at 7 hrs should be added. 3. Reserve sample for reanalysis should be

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			mentioned in the protocol. Accordingly, the firm should submit the revised protocol to CDSCO.
6.	F.No. ND/CT/22/000021 PNB001	M/s Biosphere Clinical Research Pvt. Ltd	The firm presented their Phase II clinical trial protocol before the committee. After detailed deliberation, the committee recommended that the firm should submit the preclinical data including animal toxicity data in support of use of PNB001 in Inflammatory Bowel Disease for further deliberation by the committee.
7.	F.No. IND/CT/22/000023 NRC-1111	M/s Natco Pharma Limited	The firm did not turn up for the meeting.
8.	F. No. IND/CT/22/000020 Nor-ursodeoxycholic acid tablets 500 mg	M/s Shilpa Medicare Limited	The firm presented their proposal to conduct Phase I clinical trial, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I Clinical trial, subject to the following conditions: 1. The firm should revise the title of the clinical trial protocol as Phase I, open label study for safety and tolerability. 2. Subjects of either sex should be included of which at least 1/3rd should be women. 3. The firm should revise sample size as per justification in the clinical trial protocol. Accordingly, the firm should submit the revised protocol to CDSCO.
9.	F. No. IND/CT/22/000027 AUR103 Calcium	M/s Aurigene Discovery Technologies Limited	The firm presented their proposal to conduct Phase I clinical trial protocol along with nonclinical, toxicological and pharmacokinetics data before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Part I of the protocol with first three cohorts i.e. 25 mg, 50 mg & 100 mg of Phase-I clinical trial and present the clinical trial results before the committee, before proceeding to the next cohorts.

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10.	**F. No. IND/CT/22/000003** **Intravesical SN-38 Lipid Suspension**	**M/s Intas Pharma**	The firm presented the protocol amendment before the committee. After detailed deliberation, the committee recommended that the Inclusion criteria should be modified clearly to include the patients who have already been treated with radiotherapy, chemotherapy and surgery as recommended by the committee in meeting dt 28.03.2022. Mentioning that "patients who have already been treated with radiotherapy / chemotherapy/ surgery can be enrolled in the above cohorts" does not serve the purpose. Accordingly revised protocol should be submitted to CDSCO.
11.	**F. No. IND/CT/21/000014** **MKP 10241 Suspension**	**M/s Mankind Research Centre**	The firm presented the Phase I clinical trial results of first two cohort data (50 mg & 100 mg doses) before the committee in line with the conditions of CT NOC dt 18.06.2021 . After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I clinical trial for the next cohorts of 200 mg, 300 mg & 400 mg dose.
12.	**F. No. IND/CT/22/000020** **(+)- -DHTBZ 5 mg, 7.5 mg, 10 mg, 15 mg and 22.5 mg**	**M/s Synapse Labs Pvt. Ltd**	The firm presented their proposal to conduct Phase I clinical trial protocol before the committee. After detailed deliberation, the committee recommended that the firm should present the detailed justification and supporting data including nonclinical, toxicological and pharmacokinetics data etc for conduct of Phase-I Clinical trial for further deliberation by the committee.