Recommendations of the SEC (Investigational New Drugs) made in its 11th meeting held on 13.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2024/43211 NM5072	M/s. Albenio Science private Limited	In light of the earlier SEC (Investigational New Drugs) meeting dated 09.09.2024, the firm presented the revised protocol to conduct Phase-II study titled as "A Phase II, Open Label, Multi-Dose Study of NM5072 in Subjects with Paroxysmal Nocturnal Hemoglobinuria (PNH) vide protocol No. NM5072-PNH-109, Version 2.0 dated 21.10.2024. After detailed deliberation, the committee recommended for approval to conduct the study as per protocol presented by the firm.
2.	BIO/CT04/FF/2024/42825 NM8074	M/s. Albenio Science private Limited	In light of the earlier SEC (Investigational New Drugs) meeting dated 09.09.2024, the firm presented the revised protocol to conduct Phase-II study titled as "A Phase II, Open-Label Study of NM8074 in Patients with Immunoglobulin A Nephropathy (IgAN) vide protocol No. NM8074-IGAN-602, Version 2.0 dated 10.09.2024. After detailed deliberation, the committee recommended for approval to conduct the study as per protocol presented by the firm.
3.	BIO/CT04/FF/2024/43855 NM8074	M/s. Albenio Science private Limited	The firm presented the protocol to conduct "A Phase II, Open-Label Study of Subcutaneously Administered NM8074 in Patients with Paroxysmal Nocturnal Hemoglobinuria(PNH), vide Protocol No. NM8074-PNH-106, Version 1.0 dated 10.06.2024". After detailed deliberation, the committee recommended for approval to conduct the study as per protocol presented by the firm.
IND Division			
4.	IND/CT/24/000068 S007-1500 tablets	M/s. Troikaa Pharmaceuticals Ltd	The firm presented phase I clinical study Protocol no.: CDRI-CLINICAL4/2020, version no. 02 dated 22-07-2024 before the committee. After detailed deliberation, the committee

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			reiterated its earlier decision i.e. grant of permission to conduct the Phase I Clinical trial subject to condition that after completion of 1st three dose level (10, 20 & 50 mg/day), the results of the study should be submitted to CDSCO for further review by the committee to consider the continuation of the single dose study to the higher dose of 100 mg/day & 150 mg/day and the multiple dose part of the study. Further, firm should incorporate responsibility for coding, decoding & SAE management SOP use in the proposed protocol. Accordingly, the firm should submit the revised protocol to CDSCO.
5.	IND/CT/24/000081 SCD-153 Topical Solution	M/s. Sun Pharma Advanced Research Company Limited	The firm presented phase - 1 CSR before the committee and requested permission to conduct Phase - 1b part of the study vide clinical study Protocol no.: SCD-153-24-01, version no. A0 dated 06-09-2024 After detailed deliberation, the committee noted the phase-1 CSR presented by the firm & recommended that the firm should submit the Cmax data of individual subject with justification of variation to CDSCO. For the Phase 1b study protocol presented by the firm, the committee recommended that the Firm should revise the protocol as follows: • To constitute DSMB • Eligibility criteria for female patients should be revised as 18-45 years instead of 18-65 years • To include acceptable dropouts rates & its analysis and variability Accordingly, the firm should submit the revised protocol to COSCO. The committee further recommended the firm to conduct the Phase - 1b part of the study with the condition that before initiation of second dose cohort, the firm

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			should submit the first dose cohort data to CDSCO for further review by the committee.
6.	IND/CT/23/000048 ZYIL1	M/s. Zydus Life Sciences Ltd	The firm presented phase II clinical study report for the Protocol no.: ZYIL1.23.003, version no. 01 dated 27.05.2023 before the committee, After detailed deliberation, the committee noted the submitted CSR. 1. The protocol was approved by earlier SEC with sample size 24, accordingly firm has conducted study. Firm has recruited 34 subjects covering dropout and conducted study in 24 patients. 2. The matter has been discussed with biostatistician & biostatistician opined that there is no issue with the sample size, however justification may be sought for applying two methods ANOVA & ANCOVA.
7.	IND/CT/20/000087 Diperoxochloric Acid [DPOCL] topical solution	M/s. Centaur Pharmaceuticals Pvt. Ltd.	The firm presented the Interim Active PMS study report before the committee & mentioned that study is ongoing. After detailed deliberation, the committee noted that, the generated data are not adequate in recommended sample size for review at present & recommended to continue the study and to submit the final clinical study report (CSR) after completion of study to CDSCO for further review by the committee.
8.	IND/CT/24/000091 GRC 65327	M/s. Glenmark Pharmaceuticals Ltd.	The firm presented Pre-Clinical study data & phase I clinical study Protocol no.: GRC 65327-101, version no. 1.0 dated 25-10-2024 before the committee. After detailed deliberation, the committee recommended the following: • To submit the reason for not performing Single dose toxicity studies in preclinical. • To submit name of the laboratories with their GLP compliance/GLP certificate for

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			pre clinical/ non-clinical studies conducted at various places like India, China, France and other countries/sites. • To constitute DSMB • Firm to revise protocol to include three subjects for each 10 mg & 30 mg dose. Accordingly, the revised protocol should be submitted to CDSCO. Committee recommended for approval of the Phase I protocol with the condition to initiate the study with 10 mg dose cohort and submit the data of first subject of the same cohort before initiation into the second subject to CDSCO for further deliberation by the committee.
9.	IND/CT/24/000083 MKP-11093	M/s. Mankind Pharma Ltd.	The proposal may be deliberated in presence of orthopedican.