Recommendations of the SEC (Investigational New Drugs) made in its 11th/26 meeting held on 10.06.2026 at CDSCO (HQ), New Delhi:

S. No.	File Number & Drug Name, Strength	Name of firm	Recommendations
IND Division			
1.	IND/CT04/FF/2025/49494 Ranpirnase 0.3000 mg/ml + Oxymetazoline Hydrochloride1.0 mg/ml U.S.P.+ Tobramycin 3.0000 mg/ml U.S.P. Eye Drop (OKG-0303)	M/s. CBCC Global Research LLP	In light of earlier SEC recommendation dated 16.04.2026, firm presented the non - clinical data, justification for sample size along with revised Phase I/II clinical trial protocol no. OKO-310 version 4.0 dated 21.05.2026, before the committee. Committee noted the justification/ rationale for the conduct of clinical trial and the revised study design i.e., Phase I - cohort 1 and cohort 2 (healthy and patients) who will be dosed with the FDC and Phase II (patients) who will be randomized in six treatments arm including Ranpirnase 0.03% arm. After detailed deliberation, committee recommended to conduct the Phase I/ II study with the following conditions;- 1) Study design should be updated to incorporate sentinel dosing of the FDC in subjects to be enrolled for the Phase I study. 2) Firm should generate systemic pharmacokinetic data of the proposed combination drug in healthy volunteer's cohort of the Phase I study. 3) Inclusion criteria of Phase I (cohort 2) and Phase II study should be revised to include patients with mixed infection of bacterial and viral conjunctivitis only. 4) The viral as well as bacterial load pre and post dosing i.e., after 07 days must be determined. 5) Firm shall submit the result of Phase I study to CDSCO for further evaluation by the committee before proceeding for Phase II part of the study.

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			Accordingly, firm should submit revised protocol to CDSCO.