Recommendations of the SEC (Ophthalmology) made in its 08th/25 meeting held on 26.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/101/25 Online Submission (50891) T1695 (Tacrolimus)	M/s Syneos Health India Private Limited	The firm presented phase II clinical study protocol no. LT1695-201 version no.3.0 dated 15 May 2025. After detailed deliberation, the committee opined that the firm shall submit justification for following technical issue raised by SEC member for further deliberation and review. 1. The treatment for the non-responders must be taken care of by the Sponsors. 2. The quantification of the grading of staining must be mentioned elaborately. 3. In cases of concomitant moderate to severe dry eyes what will be the strategy and modifications in the study protocol. 4. The blood levels in ng/ml of these drugs will be measured by which specific equipment at all the study multi centers. 5. What will be the strategy of various examinations among the uncooperative children? 6. Artificial tears permitted during the washout period maybe specified. 7. During the washout period, in - person safety assessment visits and additional telephonic safety assessment calls should be scheduled in the study design. 8. The term 'Investigator masked' follow-up should be rephrased for clarity. 9. The assessment for non-responder patients and need for standard of care should not only be at visit 6 but specified from randomisation till end of study. 10. Presence of Shield's ulcer should be added in exclusion criteria. 11. The term 'corticosteroid responders' in inclusion criteria needs to be defined.