Recommendations of the SEC (Ophthalmology) made in its 11th/25 meeting held on 12.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/150/25 Online Submission (52625) Aflibercept	M/s Syneos Health India Private Limited	The firm presented phase III clinical study protocol number: AVT29 -GL - C01, Version 2.0, Amendment 1.0, dated 17 -Sep -2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/101/25 Online Submission (50891) T1695 (Tacrolimus)	M/s Syneos Health India Private Limited	In light of earlier SEC recommendation dated 26.08.2025, the firm presented phase II clinical study protocol no. LT1695-201 version no.3.0 dated 15 May 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
FDC Division			
3.	FDC/MA/21/000132 Netarsudil Mesylate eq. to Netarsudil 0.2 mg + Latanoprost IP 0.05 mg + Benzalkonium Chloride IP 0.2 mg (as preservative) per ml Ophthalmic Solution	M/s. Pure & Cure Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 22.09.2022, the firm presented Phase III clinical trial report before the committee. After detailed deliberation the committee opined that the firm needs to present the following information/documents: 1. Stratification of patients in open angle glaucoma and ocular hypertension groups. 2. Stratification of subjects across severity and stages of open angle glaucoma. 3. Distribution of subjects across sites. 4. How was the causality of AEs with treatment arms ruled out? 5. Baseline IOP measurement and its titration based on CCT needs to be mentioned. 6. Those patients uncontrolled by a single arm drug what was the strategy planned for such patients. 7. Baseline visual field comparison with the post treatment changes. 8. Optic disc changes at baseline and after treatment.

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			9. Whether the patients were using treatment for dry eyes simultaneously. Accordingly, the firm should submit above data for further review by the committee.
4.	FDC/CT/25/000024 Phenylephrine 1% + Ketorolac 0.3% intraocular solution	M/s COD Research Pvt. Ltd.	In light of the earlier SEC recommendation dated 16.07.2025, the firm presented the proposal along with revised Phase III CT protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial. Accordingly, the firm should submit the Phase III CT report to CDSCO for further review by the committee.