

Recommendations of the SEC (Ophthalmology) made in its 06th/25 meeting held on 24.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/32/21 Online Submission (39233) Ranibizumab 10 mg/ mL solution for injection	M/s CuraTeQ Biologics Private Limited	The firm presented protocol amendment 01 version 1.0 dated 30 April 2025 protocol no. CR213-20. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/156/24 Online Submission (39537) Vorolanib	M/s Syneos Health India Pvt. Ltd	The firm presented protocol amendment 2.0 dated 18 December 2024 and protocol amendment 3.0 dated 17 April 2025 protocol no. EYP-1901-302. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Medical Devices Division			
3.	CI/MD/2024/130793 Intraocular pressure monitoring device for Tonometry (Accuway)	M/s. OKO iCare Solutions Private Limited	The firm presented their proposal for a grant of permission to conduct a clinical investigation on the proposed medical device, i.e., the intraocular pressure monitoring device for tonometry, in the country before the committee. After detailed deliberation, the expert committee opined that the applicant should submit a revised Clinical study protocol addressing the concerns raised by experts with respect to the intended users, intended population, inclusion and exclusion criteria, terminologies used, etc., during the meeting. Accordingly, the firm shall present the revised clinical study protocol for further deliberation, along with the presence of at least one of their principal investigators.
4.	CI/MD/2024/134358 Collagen Ophthalmic Matrix (ABCcolla Collagen Ophthalmic Matrix)	M/s. Raptim Research Pvt. Ltd.	The firm presented their proposal for the grant of permission to conduct pivotal Clinical Investigation (Protocol number: CT/24/002, final 00, and version date: 21/08/24) on the proposed medical device, i.e., Collagen Ophthalmic Matrix, before the expert committee along with clinical evidence and safety evaluation data generated on the device in the country of origin, i.e., Taiwan. After detailed deliberation, the expert

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			<p>committee recommended granting permission to conduct the said study in the country with the following amendment in the clinical study protocol, and the revised protocol shall be submitted to this office prior to initiation of the Clinical Investigation:</p> <ol style="list-style-type: none"> 1. Inclusion criteria to be rephrased as patients who are not responsive to treatment. 2. The instrument used for IOP measurement should be specified. 3. Best corrected vision acuity (BCVA) < 0.05 should also be mentioned in Snellen notation. 4. The grade of chemical burns and stage (acute/chronic/range) to initiate this treatment in the inclusion criteria needs to be specified. 5. Methods for dry eye assessment should be specified. 6. Optometry details to be clarified.
SND Division			
5.	SND/MA/20/000103 cetirizine ophthalmic solution 0.24% W/V	M/s Akums Drugs & Pharmaceuticals Limited	<p>In light of earlier recommendations dated 20.09.2023, the firm presented Phase III clinical trial report for the grant of permission to manufacture and market Cetirizine Ophthalmic solution 0.24% w/v for proposed indication before the Committee.</p> <p>After detailed deliberation, the Committee recommended the grant of permission to manufacture and market Cetirizine Ophthalmic Solution 0.24% w/v for the proposed indication, subject to the conduct of a Post-Marketing Surveillance (PMS) study.</p> <p>Accordingly, the firm should submit PMS protocol to CDSCO within 03 months from date of approval of the drug product for review by the Committee.</p>
6.	SND-16011(11)/49/2025-eoffice Moxifloxacin Hydrochloride Ophthalmic Solution 0.5 % w/v	M/s Novartis Healthcare Pvt. Ltd	<p>The firm has presented the study report of active PMS study for the drug Moxifloxacin Hydrochloride Ophthalmic Solution 0.5% w/v for the indication Perioperative Sterilization in Patients Undergoing Ophthalmic Surgery, before the committee.</p>

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			After detailed deliberation, the committee recommended to accept the result of active PMS study presented by the firm.
FDC Division			
7.	FDC/MA/20/000095 Brimonidine Tartrate 2.0 mg + Brinzolamide IP 10.0 mg + Timolol Maleate IP eq. to Timolol 5 mg + Benzalkonium Chloride Solution IP 0.2 mg (as preservative) + Water for injection IP q.s. per ml ophthalmic suspension	M/s Micro Labs Limited	As per the condition mentioned in Form CT-23 dated 13.07.2023, the firm presented Active PMS protocol before the committee. After detailed deliberation, the committee recommended for conducting the Active PMS study with the condition that: <ol style="list-style-type: none"> 1. Visit 3 at week 2 should be in-person visit and not just telephonic visit. 2. Pachymetry, dilated fundus examination, fundus image and visual field analysis should be done at screening. 3. In exclusion criteria the term "Blind" to be defined as per WHO/NPCB classification. 4. The dry eyes assessment should be done at screening and all follow-up visits. Further, the ocular surface disorder assessment should be done at all follow-up visits. Accordingly, the revised Active PMS protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Active PMS report for further review by the committee.
8.	FDC/CT/25/000029 Brimonidine Tartrate 2 mg + Brinzolamide 10 mg +Timolol 5 mg Ophthalmic Suspension	M/s Ajanta Pharma Limited	As per the condition mentioned in Form CT-23 dated 14.01.2025, the firm presented Active PMS protocol before the committee. After detailed deliberation, the committee recommended for conducting the Active PMS study with the condition that Visual field analysis, fundus examination and fundus images should be done at screening. The dry eyes assessment should be done at screening and all follow-up visits. Further, the ocular surface disorder assessment should be done at all follow-up visits.

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			Accordingly, the revised Active PMS protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Active PMS report for further review by the committee.
9.	FDC/MA/25/000114 Carboxymethylcellulose Sodium IP 5 mg + Glycerin IP 10 mg + Sodium Perborate BP 0.028 % w/v (As preservative) per ml eye drops	M/s Sun Pharmaceutical Industries Limited	The firm presented the proposal along with justification for Phase III CT waiver before the committee. After detailed deliberation, the committee did not consider the request for Phase III CT waiver and recommended to conduct Phase III CT study with the proposed FDC. Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for further review by the committee.