

**Recommendations of the SEC (Ophthalmology) made in its 02<sup>nd</sup>/26 meeting held on 17.02.2026 at CDSCO HQ New Delhi:**

<b>S. No.</b>	<b>File Name &amp; Drug Name, Strength</b>	<b>Firm Name</b>	<b>Recommendations</b>
<b>Medical Devices Division</b>			
1.	IMP/MD/2025/138751 (Form MD-26)  Sodium hyaluronate 0.2 % eye drop + Carbomer 980 0.2 % w/v Eye Drops	M/s. Medicom International Eyetech Private Limited	<p>The firm presented the proposal for grant of permission to import investigational medical device viz. Sodium hyaluronate 0.2% eye drop + Carbomer 980 0.2% w/v Eye Drops, manufactured by M/s. Medicom Healthcare Limited, United Kingdom. The proposed product is approved for marketing in UK, Canada, etc.</p> <p>The firm has presented the Clinical evidence along with Post market surveillance data demonstrating safety and performance of the said device.</p> <p>After detailed deliberation, the experts recommended for grant of permission to import the said device with the condition that the firm shall may generate Clinical study data on Indian population and accordingly they shall submit the detailed Post market Clinical Investigation protocol within 03 months from the date of launch of the product in India.</p>
2.	CI/MD/2025/149962 (Form MD-22)  Trabecular Micro-Bypass System	M/s. Tech Observer India Private Limited	<p>The firm has presented study protocol to conduct Post marketing clinical investigation on the device “Trabecular Micro-Bypass System” intended to reduce intraocular pressure safely and effectively in patients diagnosed with primary open-angle glaucoma, pseudo-exfoliative glaucoma or pigmentary glaucoma manufactured by M/s. Glaukos Corporation, USA.</p> <p>After detailed deliberation, the committee recommended for consideration of the proposed study with the condition, that the proposed study shall include 12 months patient follow-up after implantation of the Medical Device.</p>
<b>FDC Division</b>			
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	M/s. Pure & Cure Healthcare Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 12.11.2025, the firm presented data/justification for Phase III CT report before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for</p>

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	preservative) per ml Ophthalmic Solution		<p>manufacturing and marketing of the proposed FDC with the condition to conduct Active PMS study.</p> <p>Accordingly, the firm should submit Active PMS protocol to CDSCO within 3 months of approval of the FDC for review by the committee.</p>
4.	<p>FDC/MA/25/000114</p> <p>Carboxymethylcellulose Sodium IP 5 mg + Glycerin IP 10 mg + Sodium Perborate BP 0.028 % w/v (As preservative) per ml eye drops</p>	M/s Sun Pharmaceutical Industries Ltd.	<p>In light of the earlier SEC recommendation dated 24.06.2025, the firm presented their proposal along with the Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> <li>1. Tear film height should be measured during screening and follow-up.</li> <li>2. The class of drug used in systemic medication to be elaborated.</li> <li>3. Inclusion criteria should mention that this combination therapy will be instilled, who didn't respond to the previous dry eye treatment.</li> <li>4. The firm must pay for the investigations and any adverse event management for all the study participants.</li> <li>5. The topical and systemic drugs like atropine, AGM, anti-histaminic, diuretics, anti-depressants, decongestants, beta blockers, hormonal therapy, NSAIDs and isotretinoin history must be asked from all the study participants and properly included and excluded from the RCT.</li> <li>6. Cases of MGD associated dry eye must be excluded.</li> <li>7. Follow-up period should be doubled.</li> </ol> <p>Accordingly, the revised Phase III CT Protocol should be submitted to CDSCO for review. Further, after approval from CDSCO, the firm should submit the Phase III CT report for review by the committee.</p>