

Recommendations of the SEC (Ophthalmology) made in its 51st meeting held on 25.11.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/IMP/19/000057 Brolucizumab	M/s. Novartis	The firm presented their proposal for conduct of observational/non interventional study vide protocol number CRTH258IN02. After detailed deliberation, the committee recommended for grant of permission to conduct the study as per the protocol presented.
FDC Division			
2.	FDC/MA/20/000186 Brinzolamide IP 10mg +Timolol Maleate IP eq. to Timolol 5mg + Potassium Sorbate IP 0.47%w/v (as preservative) ophthalmic suspension	M/s. Sun Pharma Laboratories Ltd	In light of the earlier recommendations of the SEC dated 27.08.2021, the firm presented their proposal along with the request for waiver of conducting Phase III clinical trial. The committee noted that the FDC is already approved and the firm is changing the preservative from BKC to Potassium sorbate. The committee also noted that the frequency of administration as well as dose remain same as that of the already approved FDC. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC with the condition that the firm should conduct Phase IV clinical trial. The phase IV clinical trial protocol should be submitted within 3 months of approval of the product.
GCT Division			
3.	CT/21/19 Online Submission (11919) QL1205/Ranibizumab Biosimilar	M/s. Kendle	The firm didn't turn up for presentation.
Medical Device Division			
4.	4-MD/CT-192/2017- DC Endoart	M/s. Hyderabad Eye research Foundation	In light of the earlier recommendations of the SEC dated 23.02.2021, the firm presented their proposal. However, it was noted by the committee

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			<p>that the firm was not ready for complete presentation of their proposal.</p> <p>Therefore, the committee recommended that the firm should present the complete technical and clinical details in next meeting for further consideration.</p>