

Recommendations of the SEC (Ophthalmology) made in its 65th meeting held on 26.04.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000156 Lifitegrast Oph. Solution 5% w/v preservative free	M/s. Ajanta Pharma	<p>The firm has presented the proposal for manufacturing and marketing of Lifitegrast Oph. Solution 5% w/v preservative free along with Phase-III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-III clinical trial as per the protocol presented by the firm subject to the condition that the firm should define the volume of the solution i.e. one drop per eye in the protocol and revised protocol should be submitted to CDSCO for grant of the clinical trial permission.</p>
2.	ND/MA/20/000176 Lifitegrast 5% Eye drops	M/s. Micro Labs Limited	<p>The firm presented Phase-III clinical trial report before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market Lifitegrast 5% eye drops with condition that the drug should be sold by retail under prescription of Ophthalmologist only.</p>