

Recommendations of the SEC (Ophthalmology) made in its 05th/26 meeting held on 13.05.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/26/000035 Losartan Ophthalmic Solution 0.8 mg/ml	M/s. Entod Pharmaceuticals Ltd.	<p>The firm presented the proposal for grant of permission to manufacture and marketing of Losartan Ophthalmic Solution 0.8 mg/ml along with the proposed Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee observed that adequate dose-finding study data and safety data for the proposed ophthalmic formulation have not been established and also noted that, although the firm had initially submitted Phase II/III clinical trial protocol as part of the application while the firm presented a standalone Phase III clinical trial protocol before the committee.</p> <p>The committee recommended that the firm should first present the dose-finding study results before the committee for further evaluation.</p> <p>Therefore, the firm shall submit revised Phase II clinical trial protocol incorporating detailed dose-finding studies, safety assessment plan, and clearly defined endpoints to CDSCO for further review by the committee.</p>