

Recommendations of the SEC (Ophthalmology) made in its 54th meeting held on 22.02.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/CT/22/000001 Atropine Sulfate Ophthalmic Solution 0.05% w/v with Stabilized Oxychloro Complex as preservative.	M/s. Entod Pharmaceuticals	The firm presented the proposal to conduct Phase III clinical trial of Atropine Sulfate Ophthalmic Solution 0.05% w/v before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented. Dr. Rohit Saxena did not participate in the deliberation.
2.	SND/CT/22/000002 Cyclosporine Ophthalmic Solution 0.09% w/v	M/s. Sun Pharma	The firm presented the proposal to conduct Phase IV clinical trial of Cyclosporine Ophthalmic Solution 0.09% w/v as per the condition of the import and marketing permission of the product before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented and the result of the Phase IV study should be submitted for further review by the committee.
FDC Division			
3.	FDC/MA/21/000021 Ketorolac TromethamineIP + Phenylephrine Hydrochloride IP(0.3% w/v+1.0% w/v) Ophthalmic solution	M/s. Akums Drugs and Pharmaceutical Limited	In light of earlier SEC recommendations dated 08.04.2021, the firm presented their proposal before the committee along with ocular toxicity studies and Phase III CT protocol before the committee. After detailed deliberation, the committee opined that: 1. The firm should take innovator product as the comparator and accordingly, sample size should be recalculated. 2. Pre-operative procedure should be clearly defined in the Phase III CT protocol. 3. Procedure for measurement of intra-operative pupillary diameter should be clearly prescribed. In view of above, the committee recommended that the firm should present the revised Phase III CT protocol

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			for further review by the committee.
4.	4-64/2018-DC Ripasudil 0.4% w/v + Timolol 0.5% w/v eye drops	M/s. Ajanta	In light of earlier SEC recommendations dated 28.01.2022, the firm presented their proposal along with justification. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.