

**Recommendations of the SEC (Ophthalmology) made in its 02<sup>nd</sup>/24 meeting held on 22.02.2024 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/11/24 Online Submission (41550)  Dexamethasone (1.5% w/v)	M/s. Pharmaceutical Research Associates India Private Limited	The firm presented Phase III clinical trial protocol No. DX221, version 2.0 dated 10 Jan 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that:  <ol style="list-style-type: none"> <li>1. ICF shall be amended mentioning information above redness of eyes, any infection etc.</li> <li>2. Patients with increased IOP shall be followed more frequently.</li> <li>3. Safety data shall be submitted for review of the committee every six month.</li> </ol>
2.	CT/15/24 Online Submission (41602)  Dexamethasone (1.5% w/v)	M/s. Pharmaceutical Research Associates India Private Limited	The firm presented Phase 2/3 clinical trial protocol No. DX219, version 5.0 dated 10 Jan 2024.  After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that:  <ol style="list-style-type: none"> <li>1. ICF shall be amended mentioning information above redness of eyes, any infection etc.</li> <li>2. Patients with increased IOP shall be followed more frequently.</li> <li>3. Safety data shall be submitted for review of the committee every six month.</li> </ol>
<b>FDC Division</b>			
3.	FDC/MA/23/000377  Moxifloxacin Hydrochloride IP Equivalent to Moxifloxacin 0.5 % w/v + Nepafenac	M/s. Ajanta Pharma Limited	The firm presented the proposal along with Phase III clinical trial protocol before the committee.  After detailed deliberation, the committee recommended that the inclusion criteria of CT protocol should

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	0.1 % w/v + Benzalkonium Chloride IP 0.01 % w/v (as preservative) Ophthalmic solution		<p>be changed from “Subjects who will undergone uncomplicated cataract surgery” to “uncomplicated Phacoemulsification surgery”.</p> <p>Accordingly, the revised Phase III clinical trial protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit Phase III clinical trial report for further review by the committee.</p>