Study Designs for CEQUA® (cyclosporine ophthalmic solution) 0.09% CEQUA FY2025 ASCRS Flashcard

Study design: Single-arm, open-label study evaluating 60 (46 assessable) patients at 7, 14, and 28 days. The primary endpoint was corneal higher-order aberrations. Exclusion criteria were similar to past studies with the exception that patients switching from another dry eye medication were not excluded.[2]

Study design: In two 12-week double-masked studies, a Phase 2/3 (Study 1; N=455) and a Phase 3 (Study 2; N=744), patients were randomized 1:1:1 to receive CEQUA® (0.05% or 0.09%) or vehicle control. Study 1 co-primary endpoints were change from baseline in conjunctival staining and global symptom score at Day 84. Study 2 primary endpoint was improvement of ≥10 mm in Schirmer score at day 84. Conjunctival staining was a secondary endpoint in both studies.[3-5]

References

1. Starr CE, Gupta PK, Farid M, et al. An algorithm for the preoperative diagnosis and treatment of ocular surface disorders. *J Cataract Refract Surg*. 2019;45(5):669-684.

2. Data on file. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.

3. Goldberg DF, Malhotra RP, Schechter BA, Justice A, Weiss SL, Sheppard JD. A phase 3, randomized, double-masked study of OTX-101 ophthalmic solution 0.09% in the treatment of dry eye disease. *Ophthalmology*. 2019;126(9):1230-1237.

4. CEQUA [package insert]. Cranbury, NJ: Sun Pharmaceutical Industries, Inc.; 2022.

5. Tauber J, Schechter BA, Bacharach J, et al. A phase II/III, randomized, double-masked, vehicle-controlled, dose-ranging study of the safety and efficacy of OTX-101 in the treatment of dry eye disease. *Clin Ophthalmol*. 2018;12:1921-1929.

Current as of July 25, 2025

PM-US-CQA-1971 07/2025