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Efficacy and safety of the PRO-087 Ophthalmic solution versus systane(R) Ultra and Systane(R) Ultra Preservative-free on the tear film dysfunction syndrome from mild to moderate. V.1

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Abstract

The present study was designed to evaluate the efficacy of a sodium hyaluronate/chondroitin sulfate, preservative-free, ophthalmic solution (SH/CS-PF) in normalizing the parameters of the ocular surface, alleviating symptoms and in reducing the squamous metaplasia using the conjunctival impression cytology (CIC) in patients with mild-moderate dry eye disease (DED).

Attachments

PDF

Clinical Protocol_PL...

798KB

Guidelines

This protocol conforms to the Good Clinical Practices (GCP) and principles from the 18th Medical Assembly in Helsinki, Finland in 1964 and the amendments made in Tokyo, Japan 1975, Venice, Italy 1983, Hong Kong 1989 and the 48th General Assembly Somerset West, South Africa in 1996, 59thGeneral Assembly, Seoul, Korea, 2008, 64th General Assembly, Fortaleza, Brazil, 2013, where medical research (clinical research) is contemplated.

Also, according to the specifications of the General Law of Health of Mexico, on research for health, section 17, this study is considered on the subsection III with greater risk to the minimum, by the cell sampling and drug administration. Under this legal framework, the full respect for the person, life and safety is maintained.

Materials

The variables of the study drug PRO-087 tolerability will be evaluated in the visits indicated in the schedule, using the following parameters:

1. Best-corrected visual acuity
2. Corneal epithelization
3. Tear film break-up time
4. Schirmer test
5. OSDI
6. Goblet cells population