

CLINICAL STUDY PROTOCOL
IND 116542

A Double-Masked, Randomized, Multicenter, Placebo-Controlled, Parallel-Group Study of SJP-0035 Ophthalmic Solution Compared with Placebo to Assess Safety and Efficacy of Two Dose Concentrations of SJP-0035 Ophthalmic Solution for Corneal Epithelial Wound Healing in Patients with Moderate to Severe Corneal Epithelial Disorders

PROTOCOL NO.: SJP-0035/2-02

Sponsor: Senju Phannaceutical Co., Ltd.
2-5-8, Hiranomachi, Chuo-Ku
Osaka 541-0046, Japan

Sponsor Contact:



Version of Protocol: 1.0

Date of Protocol: 27 April2016

CONFIDENTIAL

All financial and nonfinancial suppolt for this study will be provided by Senju Pharmaceutical Co., Ltd. The concepts and info1mation contained in this document or generated during the study are considered proprietary and may not be disclosed in whole or in part without the expressed, written consent of Senju Pharmaceutical Co., Ltd.

The sn1dy will be conducted according to the Intemational Council on Harmonisation harmonised tripaltite guideline E6(R1): Good Clinical Practice.

A redacted version of the Protocol, containing the Statistical Analysis Plan (SAP) is being prepared and will be uploaded in due course.