Protocol CO-161103095739-VCCT

A SINGLE-CENTER, RANDOMIZED, CONTROLLED STUDY TO EVALUATE THE EFFICACY OF TWO INVESTIGATIONAL OTC EYE DROPS IN HEALTHY ADULTS WITH RED EYE

Statistical Analysis Plan (SAP)

Version: Final
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CONTENTS

1 INTRODUCTION

Red eye is a common ophthalmologic condition and can include almost any part of the eye. Conjunctival hyperaemia is caused by vasodilation of the conjunctival blood vessels in response to irritation. This vasodilation causes the red appearance of the normally white appearing sclera, leading to the condition commonly known as "red eye". Red eye is treatable with over-the-counter (OTC) medications.

Preservatives like benzalkonium chloride (BAK) have come under the scrutiny of research studies over the years for their potential to disrupt the protective tear film and ocular surface cells. The medical community has deemed that despite its efficient bactericidal qualities, BAK is more cytotoxic in high quantities than many other preservatives. In order to provide an alternative to BAK, this study will be conducted to test the efficacy of two new investigational products containing [redacted].

[redacted]

[redacted]

1.1 Study Objectives

The objective of this study is to demonstrate the therapeutic equivalence of two investigational, over-the-counter (OTC) redness reliever eye drop formulations to an existing marketed OTC redness reliever eye drop in healthy adults with red eye.

1.2 Study Design

This is a 3-arm, single center, double-blinded, balanced incomplete randomized block design study. Subjects will undergo a 1-day (3 doses over 9 hours total) intervention period where each subject will be randomly assigned to receive 2 of the 3 test products to apply to the left and right eyes. For the duration of the study, subjects will be asked to refrain from using all eye treatments, including contact lenses.

Eligible subjects will complete 2 clinic visits. All subjects will have an ocular health and vision exam for inclusion in the study during clinic Visit 1. Eligible subjects will have

ocular redness assessments using a [redacted] at Baseline (pre-treatment prior to 1st product application), and then 30 seconds, 60 seconds, and 2 minutes following 1st product application. Subjects will also complete Ocular Comfort Assessment for each eye using a scale [redacted] at Baseline and immediately following the Ocular Redness Assessment completed 60 seconds after the 1st product application. The first dose will be instilled by trained study staff at the clinic. Subjects will also complete a questionnaire at Baseline and immediately following the 2- minute Ocular Redness Assessment. Subjects will be provided product and written and verbal instructions to apply the test product at home. Subjects will apply test products at home at 4.5 hours (± 30 minutes) and 9 hours (± 30 minutes) after the 1st product application in the clinic. They will also complete an Ocular Comfort Assessment and questionnaire at 10 hours (+ 15 minutes) and 12 hours (+15 minutes) at home.

Subjects will return in approximately 24 ± 1 hour(s) for a final vision exam.

2 INTERIM ANALYSES

No interim analysis is planned for this trial.

3 ANALYSIS SETS

3.1 Efficacy Analyses Sets

The efficacy analysis set will be based on [redacted].

3.2 Safety Analysis Set

The safety analysis will be based on all randomized subjects who use at least one dose of investigational product.

3.3 Other Analysis Sets

The disposition of the subjects will be summarized for all randomized subjects.

4 ENDPOINTS AND COVARIATES

4.1 Efficacy Endpoint(s)

The efficacy measurements include clinician assessment of ocular redness, subject reported ocular comfort and subject questionnaire.

The clinician assessment of redness will use a [redacted] Redness will be evaluated in each eye at baseline (pre-treatment prior to 1st product application), 30sec, 60sec, and 2 min after the first product application. [redacted]:

The subject reported Ocular Comfort Assessment will be evaluated in each eye using VAS scale [redacted] at baseline, about 60 seconds after product application, and at 10 and 12 hours after the first product application. [redacted]. Subjects will be shown the VAS scale and asked to select the point on the scale that corresponds to their comfort level. The ocular comfort scale is included below:

A subject questionnaire will be administered to evaluate consumer sensory benefits. The questionnaire will be completed at Baseline, after the 2-minute ocular redness assessment in-clinic, and at home at the 10 (+15 minutes) and 12 (+15 minutes) hours after the first product application.

4.1.1 **Primary Efficacy Endpoint**

The primary efficacy endpoint is the change from baseline in redness at 60 seconds after the first application.

4.1.2 **Secondary Efficacy Endpoints**

The secondary efficacy endpoints include:

- Change from baseline in redness at 30 seconds after the first application.
- Change from baseline in redness at 2 minutes after the first application.
- Change from baseline in ocular comfort at approximately 60 seconds after the first application.
- Change from baseline in ocular comfort at approximately 10hr after the first application.
- Change from baseline in ocular comfort at approximately 12hr after the first application.

- Subject questionnaire at each collection time point. The Subject Questionnaire assesses consumer sensory benefits and includes 6 questions at baseline and 7 questions at 2 minutes, 10 hours, and 12 hours after first product application.

Change from baseline in both redness and ocular comfort will be calculated as the baseline score minus the post-baseline score.

4.1.3 Exploratory Efficacy Endpoints

Not applicable.

4.2 Safety Endpoints

The safety endpoints include the Adverse Events. The summarization of adverse events is detailed in section 6.4.4.

4.3 Other Endpoints

Not applicable.

4.3.1 PK Endpoints

Not applicable.

4.3.2 PD Endpoints

Not applicable.

4.3.3 Outcomes Research Endpoints

Not applicable.

4.4 Covariates

For the analysis of ocular redness assessment and ocular comfort assessment, the corresponding baseline measurement will be used as the covariate in the analysis model, detailed information please refer section 6.3.

5 HANDLING OF MISSING VALUES

No missing data will be imputed. The efficacy analysis will be based on the ITT subjects with observed data.

6 STATISTICAL METHODOLOGY AND STATISTICAL ANALYSES

6.1 Statistical Hypotheses

The objective of this study is to demonstrate the equivalence of the test formulation to the control formulation. The statistical hypothesis is stated as

6.2 Statistical Decision Rules

Not applicable.

6.3 Statistical Methods

Summary statistics will be provided for the efficacy endpoints by treatment.

6.3.1 Primary Endpoint

The change from baseline in redness at 60 seconds after the initial eye drop will be analysed using

[redacted]

6.3.1.1 Subgroup analyses

The change from baseline in redness at 60 seconds after the initial eye drop will be summarized by treatment and each of the following [redacted]

6.3.2 Secondary Endpoints

Change from baseline in redness at other time points will be analysed in the same way as for the analysis of the primary endpoint.

[redacted]

6.3.3 Exploratory Endpoint

Not applicable.

6.4 Statistical Analyses

The Quantitative Science Department will be responsible for data management and statistical analyses.

The numbering and titles of summary tables and figures are displayed in Appendix 1. The numbering and titles of data listings are displayed in Appendix 2.

6.4.1 Demographic and Baseline Characteristics

Descriptive statistics (number of subjects, mean, and standard deviation, median, minimum and maximum value for continuous variables; the number and percentage of subjects in each response category for categorical variables) will be provided for demographic and baseline characteristics for all randomized subjects by treatment sequence.

The number and percentage of subjects reporting medical history will be tabulated by condition and treatment group. The number and percentage of subjects receiving each prior medication, concomitant medication and non-drug therapy/procedure will be presented for each category (prior medication, concomitant medication, non-drug therapy/procedure) by treatment sequence. Medications that were stopped before the date of study medication was taken will be considered prior medications. All other medications will be considered concomitant medications.

6.4.2 Primary Efficacy Analysis

See section 6.3.1.

6.4.3 Secondary Efficacy Analysis

See section 6.3.2.

6.4.4 Safety Analyses

The safety analysis will be based on the safety analysis set. The adverse events will be summarized using the MedDRA coding dictionary by the following:

- Number and percentage of subjects experiencing treatment-emergent adverse events
- Most common treatment-emergent adverse events (≥5% in one or more treatment sequence).
- Number and percentage of subjects with treatment-emergent adverse events by severity

Treatment-emergent adverse events are those with a start date and time on or after the date and time of study dose administration.

The number of subjects with treatment-emergent adverse events will also be summarized by sex, age group (18-64 years, ≥ 65 years) and race (white, non-white).

- Number and percentage of subjects who discontinued the trial due to adverse events
- Number and percentage of subjects experiencing a serious adverse event
- Number and percentage of subjects experiencing treatment-related adverse events (relationship to study medication is marked as possible, probable or very likely)

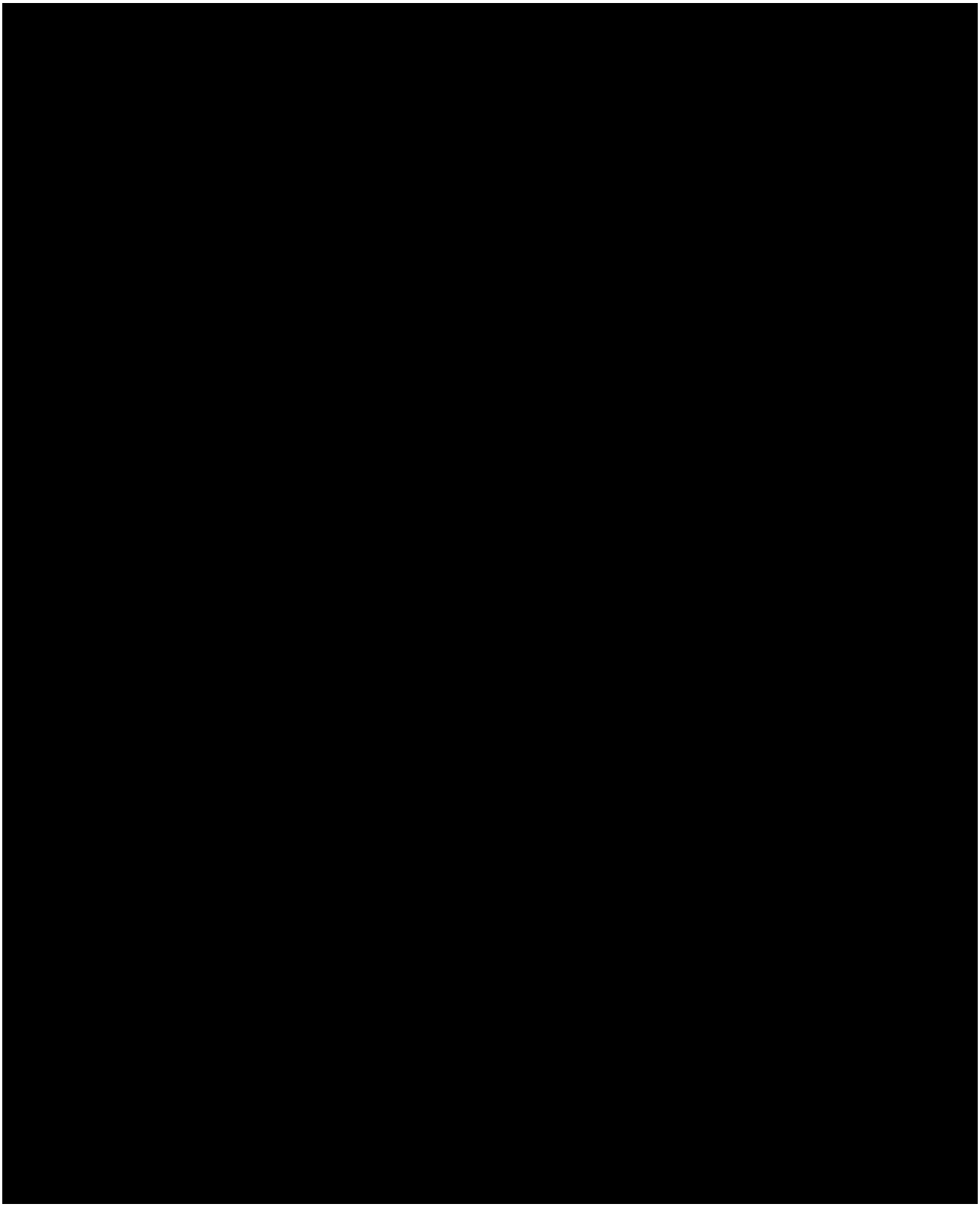
AEs with unknown relationship to treatment will be counted as treatment-related.

- Number and percentage of subjects with treatment-related adverse events by severity.

Subjects will be counted only once for each system organ class and preferred term.

APPENDICES

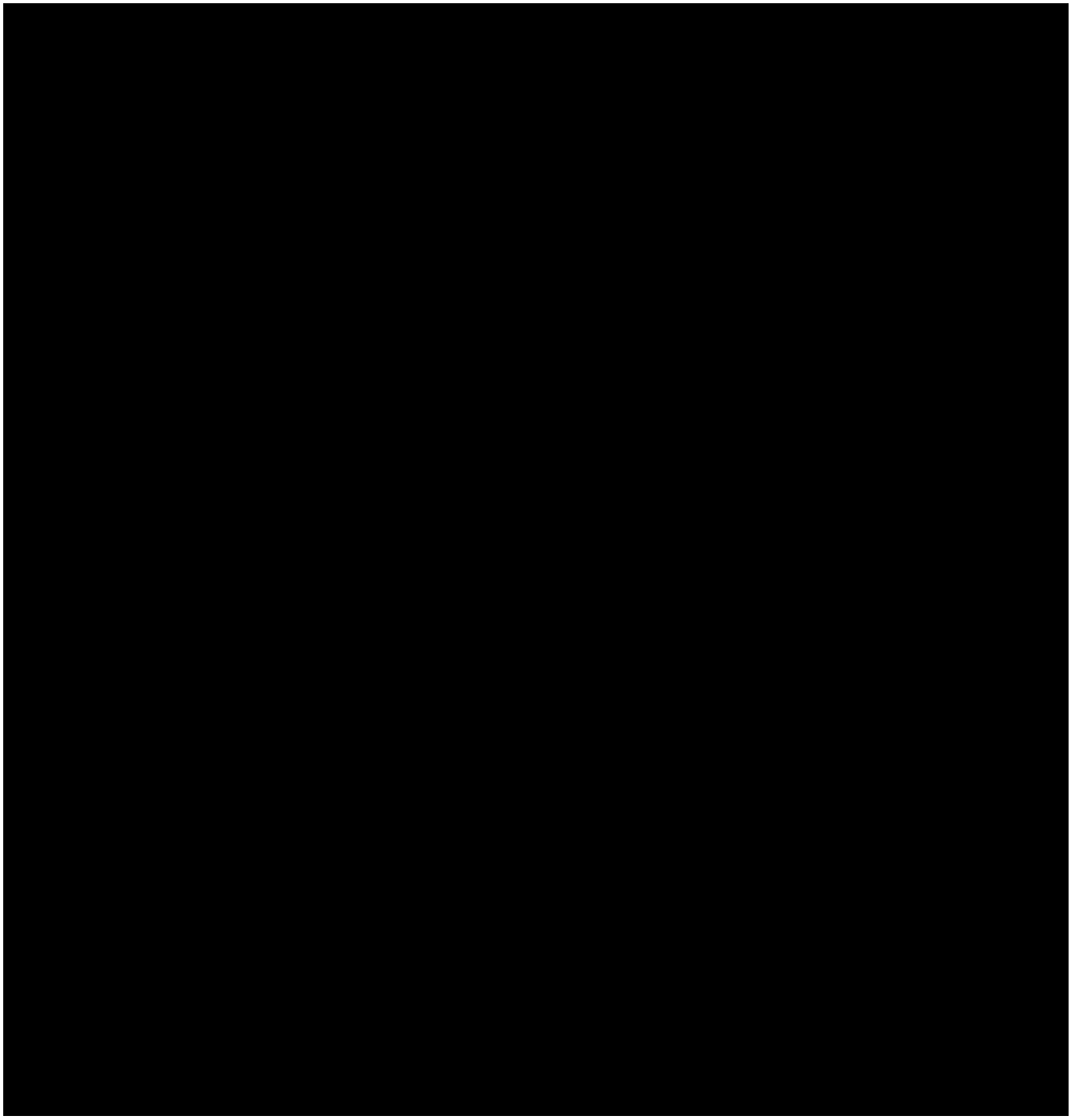
APPENDIX 1: SUMMARY TABLES AND FIGURES



FIGURES:

None.

APPENDIX 2: DATA LISTINGS



14.1 SUBJECT DISPOSITION

14.1.1 Disposition of Subjects and Analysis Sets (All Randomized Subjects)

Table 14.1.1 (Page 1 of 1)
Disposition of Subjects and Analysis Sets
All Randomized Subjects

	A/B (N=xx)	A/C (N=xx)	B/C (N=xx)	Total (N=xx)
	n (%)	n (%)	n (%)	n (%)
Randomized	xx	xx	xx	xx
Completed	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Discontinued	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
Reason for Discontinuation				
Adverse Event	x	x	x	x
Protocol Violation	x	x	x	x
Withdrawal by Subject	x	x	x	x
Lost to Follow-Up	x	x	x	x
Lack of Efficacy	x	x	x	x
Non-Compliance with Study Drug	x	x	x	x
Study Termination by Sponsor	x	x	x	x
Screen Failure	x	x	x	x
Death	x	x	x	x
Pregnancy	x	x	x	x
Other	x	x	x	x
Safety Analysis Population	xx(100%)	xx(100%)	xx(100%)	xx(100%)
Intent-to-Treat Subjects	xx(100%)	xx(100%)	xx(100%)	xx(100%)

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

14.1.2 Summary of Protocol Deviations (All Randomized Subjects)

Table 14.1.2 (Page 1 of 1)
Summary of Protocol Deviations
All Randomized Subjects

Category	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE PROTOCOL DEVIATION	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
CATEGORY 1	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
CATEGORY 2	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
CATEGORY 3	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
CATEGORY 4	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
…				

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Number of deviations is presented for each protocol deviation category.

14.1.3 Demographics and Baseline Characteristics (Intent-to-treat Subjects)

Table 14.1.3 (Page 1 of 1)
Demographic Characteristics
Intent-to-treat Subjects

	A/B (N=xx)	A/C (N=xx)	B/C (N=xx)	Total (N=xx)
Age (Years)				
n	xx	xx	xx	xx
Mean	xx.x	xx.x	xx.x	xx.x
S.D.	xx.xx	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x	xx.x
Min-Max	(xx-xx)	(xx-xx)	(xx-xx)	(xx-xx)
Sex, n (%)				
Male	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Female	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Total	xx(100%)	xx(100%)	xx(100%)	xx(100%)
Race, n (%)				
White	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Black or African American	x(xx.x%)	x(xx.x%)	x(xx.x%)	x(xx.x%)
Asian	x	x	x	x
Native Hawaiian or Other Pacific Islander	x	x	x	x
American Indian or Alaska Native	x	x	x	x
Other	x	x	x	x
Total	xx(100%)	xx(100%)	xx(100%)	xx(100%)
Ethnicity, n (%)				
Hispanic or Latino	x(xx.x%)	x(xx.x%)	x(xx.x%)	x(xx.x%)
Not Hispanic or Latino	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Not Reported	x	x	x	x
Unknown	x	x	x	x
Total	xx(100%)	xx(100%)	xx(100%)	xx(100%)

A: [redacted] Tetrahydrozoline 0.05%
B: 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

14.1.4 Medical History (Intent-to-treat Subjects)

Table 14.1.4 (Page 1 of 1)
Medical History
Intent-to-treat Subjects

Condition	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE MEDICAL HISTORY	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Condition 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Condition 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Condition 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)

…

===
A: [redacted] Tetrahydrozoline 0.05%
B: 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

14.1.5 Prior Medication (Intent-to-treat Subjects)

Table 14.1.5 (Page 1 of 1)
Prior Medication
Intent-to-treat Subjects

Prior Medication	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE PRIOR MEDICATION	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Medication 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Medication 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Medication 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)

…

A: [redacted] Tetrahydrozoline 0.05%
B: 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

14.1.6 Concomitant Medication (Intent-to-treat Subjects)

Table 14.1.6 (Page 1 of 1)
Concomitant Medication
Intent-to-treat Subjects

Concomitant Medication	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE CONCOMITANT MEDICATION	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Medication 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Medication 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Medication 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)

…

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

14.1.7 Prior Non-drug Therapy / Procedure (Intent-to-treat Subjects)

Table 14.1.7 (Page 1 of 1)
Prior Non-drug Therapy / Procedure
Intent-to-treat Subjects

Prior Non-drug Therapy/Procedure	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE PRIOR NON-DRUG THERAPY/PROCEDURE	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Non-drug Therapy / Procedure 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Non-drug Therapy / Procedure 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Non-drug Therapy / Procedure 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
…				

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

14.1.8 Concomitant Non-drug Therapy / Procedure (Intent-to-treat Subjects)

Table 14.1.8 (Page 1 of 1)
Concomitant Non-drug Therapy / Procedure
Intent-to-treat Subjects

Concomitant Non-drug Therapy/Procedure	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE CONCOMITANT NON-DRUG THERAPY/PROCEDURE	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Non-drug Therapy / Procedure 1	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Non-drug Therapy / Procedure 2	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%
Non-drug Therapy / Procedure 3	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
…				

A: [redacted] Tetrahydrozoline 0.05%
B: 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

14.2 EFFICACY VARIABLES

14.2.1.1 Analysis of Change from Baseline in Redness (Intent-to-treat Subjects)

Table 14.2.1.1 (Page 1 of 3)
Analysis of Change from Baseline in Redness
Intent-to-treat Subjects

Visit	Te[redacted]0.05% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.40% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.20% Hypromellose 0.2% Polyethylene glycol 400 1.0% (N=xx)
Baseline			
n	xx	xx	xx
Mean	x.xx	x.xx	x.xx
S.D.	x.xxx	x.xxx	x.xxx
Median	x.xx	x.xx	x.xx
Min,Max	(x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
30 Seconds After First Application			
n	xx	xx	xx
Mean	x.xx	x.xx	x.xx
S.D.	x.xxx	x.xxx	x.xxx
Median	x.xx	x.xx	x.xx
Min,Max	(x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
Change from Baseline			
n	xx	xx	xx
Mean	x.xx	x.xx	x.xx
S.D.	x.xxx	x.xxx	x.xxx
Median	x.xx	x.xx	x.xx
Min,Max	(x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
Adjusted Mean	x.xx	x.xx	x.xx
s.e.	x.xxx	x.xxx	x.xxx
Pairwise Comparison vs [redacted]			
Difference		x.xx	x.xx
s.e.		x.xxx	x.xxx
Between Treatment p-value [1]		0.xxx a	0.xxx a
95% CI		[x.xxx, x.xxxx]	[x.xxx, x.xxxx]

Ocular redness was assessed on a 5-point severity scale with 0.5 increments (0=none, 1=mild, 2=moderate, 3=severe, and 4=extremely severe).
[1] P-values are based on mixed effect analysis of covariance model with treatment as factor, baseline value as a covariate.

Table 14.2.1.1 (Page 2 of 3)
Analysis of Change from Baseline in Redness
Intent-to-treat Subjects

Visit	Te[redacted] 0.05% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.40% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.20% Hypromellose 0.2% Polyethylene glycol 400 1.0% (N=xx)
60 Seconds After First Application			
n	xx	xx	xx
Mean	x.xx	x.xx	x.xx
S.D.	x.xxx	x.xxx	x.xxx
Median	x.xx	x.xx	x.xx
Min,Max	(x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
Change from Baseline			
n	xx	xx	xx
Mean	x.xx	x.xx	x.xx
S.D.	x.xxx	x.xxx	x.xxx
Median	x.xx	x.xx	x.xx
Min,Max	(x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
Adjusted Mean	x.xx	x.xx	x.xx
s.e.	x.xxx	x.xxx	x.xxx
Pairwise Comparison vs [redacted]			
Difference		x.xx	x.xx
s.e.		x.xxx	x.xxx
Between Treatment p-value [1]		0.xxx a	0.xxx a
95% CI		[x.xxx, x.xxxx]	[x.xxx, x.xxxx]

Ocular redness was assessed on a 5-point severity scale with 0.5 increments (0=none, 1=mild, 2=moderate, 3=severe, and 4=extremely severe).
[1] P-values are based on mixed effect analysis of covariance model with treatment as factor, baseline value as a covariate.

Table 14.2.1.1 (Page 3 of 3)
Analysis of Change from Baseline in Redness
Intent-to-treat Subjects

Visit	Te[redacted]0.05% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.40% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.20% Hypromellose 0.2% Polyethylene glycol 400 1.0% (N=xx)
2 Minutes After First Application			
n	xx	xx	xx
Mean	x.xx	x.xx	x.xx
S.D.	x.xxx	x.xxx	x.xxx
Median	x.xx	x.xx	x.xx
Min,Max	(x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
Change from Baseline			
n	xx	xx	xx
Mean	x.xx	x.xx	x.xx
S.D.	x.xxx	x.xxx	x.xxx
Median	x.xx	x.xx	x.xx
Min,Max	(x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
Adjusted Mean	x.xx	x.xx	x.xx
s.e.	x.xxx	x.xxx	x.xxx
Pairwise Comparison vs [redacted]			
Difference		x.xx	x.xx
s.e.		x.xxx	x.xxx
Between Treatment p-value [1]		0.xxx a	0.xxx a
95% CI		[x.xxx, x.xxxx]	[x.xxx, x.xxxx]

Ocular redness was assessed on a 5-point severity scale with 0.5 increments (0=none, 1=mild, 2=moderate, 3=severe, and 4=extremely severe).
[1] P-values are based on mixed effect analysis of covariance model with treatment as factor, baseline value as a covariate.

14.2.1.2 Summary of Change from Baseline in Redness at 60 Seconds Subgroups (Intent-to-treat Subjects)

Table 14.2.1.2 (Page 1 of x)
Summary of Change from Baseline in Redness at 60 Seconds by Subgroups
Intent-to-treat Subjects
Male

Visit		Tet[redacted].05% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.40% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.20% Hypromellose 0.2% Polyethylene glycol 400 1.0% (N=xx)
Baseline				
	n	xx	xx	xx
	Mean	x.xx	x.xx	x.xx
	S.D.	x.xxx	x.xxx	x.xxx
	Median	x.xx	x.xx	x.xx
	Min,Max	x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
60 seconds After First Application				
	n	xx	xx	xx
	Mean	x.xx	x.xx	x.xx
	S.D.	x.xxx	x.xxx	x.xxx
	Median	x.xx	x.xx	x.xx
	Min,Max	x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
Change from Baseline				
	n	xx	xx	xx
	Mean	x.xx	x.xx	x.xx
	S.D.	x.xxx	x.xxx	x.xxx
	Median	x.xx	x.xx	x.xx
	Min,Max	x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)

Ocular redness was assessed on a 5-point severity scale with 0.5 increments (0=none, 1=mild, 2=moderate, 3=severe, and 4=extremely severe).

The tables for other subgroups will be similar as this.

14.2.1.3 Analysis of Responder in Redness (Intent-to-treat Subjects)

Table 14.2.1.3 (Page 1 of 1)
Analysis of Responder [1] in Redness
Intent-to-treat Subjects

Visit	Te[redacted]0.05% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.40% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.20% Hypromellose 0.2% Polyethylene glycol 400 1.0% (N=xx)
60 Seconds After First Application			
Responder	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Non-Responder	xx(xx.xx%)	xx(xx.xx%)	xx(xx.xx%)
Total	xx(100%)	xx(100%)	xx(100%)
Adjusted Responder proportion	xx.x	xx.x	xx.x
Pairwise Comparison vs. [redacted]			
Odds Ratio		x.xx	x.xx
95% CI		[x.xxx, x.xxxx]	[x.xxx, x.xxxx]
Between Treatment p-value [2]		0.xxx a	0.xxx a

[1] The responder is defined as the subject whose assessment score at 60 seconds after the initial eye drop is less than the assessment score at baseline.
[2] P-values are from the GEE model with treatment as factor.

14.2.2 Analysis of Change from Baseline in Ocular Comfort (Intent-to-treat Subjects)

Table 14.2.2(Page 1 of 3)
Analysis of Change from Baseline in Ocular Comfort
Intent-to-treat Subjects

Visit	Te[redacted]0.05% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.40% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.20% Hypromellose 0.2% Polyethylene glycol 400 1.0% (N=xx)
60 Seconds After First Application			
n	xx	xx	xx
Mean	x.xx	x.xx	x.xx
S.D.	x.xxx	x.xxx	x.xxx
Median	x.xx	x.xx	x.xx
Min,Max	(x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
Change from Baseline			
n	xx	xx	xx
Mean	x.xx	x.xx	x.xx
S.D.	x.xxx	x.xxx	x.xxx
Median	x.xx	x.xx	x.xx
Min,Max	(x.xx,x.xx)	(x.xx,x.xx)	(x.xx,x.xx)
Adjusted Mean	x.xx	x.xx	x.xx
s.e.	x.xxx	x.xxx	x.xxx
Pairwise Comparison vs [redacted]			
Difference		x.xx	x.xx
s.e.		x.xxx	x.xxx
Between Treatment p-value [1]		0.xxx a	0.xxx a
95% CI		[x.xxx, x.xxxx]	[x.xxx, x.xxxx]

Ocular comfort was assessed on an 11-point VAS scale (0-10)in which 0 = very uncomfortable and 10 = very comfortable.
[1] P-values are based on mixed effect analysis of covariance model with treatment as factor, baseline value as a covariate.

The tables for 10hr after the first application and 12hr after the first application will be similar as this.

14.2.3 Summary of Subject Questionnaire (Intent-to-treat Subjects)

Table 14.2.3(Page 1 of x)
Summary of Subject Questionnaire
Intent-to-treat Subjects

Baseline	Te[redacted]0.05% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.40% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.20% Hypromellose 0.2% Polyethylene glycol 400 1.0% (N=xx)
Q1: My eye appears healthy			
Strongly agree (1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat agree (2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Neither agree or disagree (3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat disagree (4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly disagree (5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No opinion [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly agree & Somewhat agree	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
S.D.	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min-Max	(xx-xx)	(xx-xx)	(xx-xx)
……			
Q6: My eye xxxxxxxxxxx			
Strongly agree (1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat agree (2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Neither agree or disagree (3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat disagree (4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly disagree (5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No opinion [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly agree & Somewhat agree	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
S.D.	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min-Max	(xx-xx)	(xx-xx)	(xx-xx)

[1] Response of No opinion will not be included in the calculation of mean, S.D., Median, Min and Max.

Table 14.2.3(Page 2 of x)
Summary of Subject Questionnaire
Intent-to-treat Subjects

2 minutes after 1st application	Te[redacted]0.05% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.40% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.20% Hypromellose 0.2% Polyethylene glycol 400 1.0% (N=xx)
Q1: My eye appears healthy			
Strongly agree (1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat agree (2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Neither agree or disagree (3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat disagree (4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly disagree (5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No opinion [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly agree & Somewhat agree	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
S.D.	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min-Max	(xx-xx)	(xx-xx)	(xx-xx)
.....			
Q7: My eye xxxxxxxxxxx			
Strongly agree (1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat agree (2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Neither agree or disagree (3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat disagree (4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly disagree (5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No opinion [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly agree & Somewhat agree	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
S.D.	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min-Max	(xx-xx)	(xx-xx)	(xx-xx)

[1] Response of No opinion will not be included in the calculation of mean, S.D., Median, Min and Max.

Table 14.2.3(Page 3 of x)
Summary of Subject Questionnaire
Intent-to-treat Subjects

10 hrs after 1st application	Te[redacted]0.05% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.40% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.20% Hypromellose 0.2% Polyethylene glycol 400 1.0% (N=xx)
Q1: The product feels gentle on my eye			
Strongly agree (1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat agree (2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Neither agree or disagree (3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat disagree (4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly disagree (5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No opinion [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly agree & Somewhat agree	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
S.D.	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min-Max	(xx-xx)	(xx-xx)	(xx-xx)
.....			
Q7: My eye xxxxxxxxxxx			
Strongly agree (1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat agree (2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Neither agree or disagree (3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat disagree (4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly disagree (5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No opinion [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly agree & Somewhat agree	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
S.D.	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min-Max	(xx-xx)	(xx-xx)	(xx-xx)

[1] Response of No opinion will not be included in the calculation of mean, S.D., Median, Min and Max.

Table 14.2.3(Page 4 of x)
Summary of Subject Questionnaire
Intent-to-treat Subjects

12 hrs after 1st application	Te[redacted]0.05% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.40% (N=xx)	Tetrahydrozoline 0.05% Glycerin 0.20% Hypromellose 0.2% Polyethylene glycol 400 1.0% (N=xx)
Q1: The product feels gentle on my eye			
Strongly agree (1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat agree (2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Neither agree or disagree (3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat disagree (4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly disagree (5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No opinion [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly agree & Somewhat agree	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
S.D.	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min-Max	(xx-xx)	(xx-xx)	(xx-xx)
.....			
Q7: My eye xxxxxxxxxxx			
Strongly agree (1)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat agree (2)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Neither agree or disagree (3)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Somewhat disagree (4)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly disagree (5)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No opinion [1]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Strongly agree & Somewhat agree	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
N	xx	xx	xx
Mean	xx.x	xx.x	xx.x
S.D.	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min-Max	(xx-xx)	(xx-xx)	(xx-xx)

[1] Response of No opinion will not be included in the calculation of mean, S.D., Median, Min and Max.

14.3 SAFETY DATA SUMMARY

14.3.1 Summary of Adverse Events (Safety Analysis Set)

Table 14.3.1 (Page 1 of 1)
Summary of Adverse Events (AEs)
Safety Analysis Set

	A/B (N=xx)		A/C (N=xx)		B/C (N=xx)		Total (N=xx)	
	n	(%)	n	(%)	n	(%)	n	(%)
Subjects with any treatment-emergent AEs	xx	(x.x%)	xx	(x.x%)	xx	(x.x%)	xx	(xx.x%)
Subjects with any serious AEs [1]	x	(x.x%)	x	(x.x%)	x	(x.x%)	xx	(xx.x%)
Subjects who discontinued due to any AEs [1]	x	(x.x%)	x	(x.x%)	x	(x.x%)	xx	(xx.x%)
Deaths [1]	x	(x.x%)	x	(x.x%)	x	(x.x%)	xx	(xx.x%)
Subjects with any treatment-related AEs [2]	x	(x.x%)	x	(x.x%)	x	(x.x%)	xx	(xx.x%)
Subjects with any serious treatment-related AEs	x	(x.x%)	x	(x.x%)	x	(x.x%)	xx	(xx.x%)
Subjects who discontinued due to any treatment-related AEs	x	(x.x%)	x	(x.x%)	x	(x.x%)	xx	(xx.x%)

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%, Hypromellose 0.2%, Polyethylene glycol 400 1.0%
[1] Includes both non-treatment emergent and treatment-emergent adverse events.
[2] Treatment-related adverse events are AEs with relationship to study medication of very likely, probable, possible or unknown.

14.3.2 Subjects with Treatment-Emergent Adverse Events (Safety Analysis Set)

Table 14.3.2 (Page 1 of x)
Subjects with Treatment-Emergent Adverse Events [1]
Safety Analysis Set

System Organ Class Preferred Term	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE AE	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx (xx.x%)
BODY SYSTEM 1	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 1	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 2	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
...				
BODY SYSTEM 2	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 3	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 4	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
...				
...				

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%, Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Note: AEs are coded by MedDRA Dictionary version 16.x.
[1] Subjects were counted only once for each system organ class and preferred term.
System Organ Class and Preferred Terms listed in descending order of frequency reported by all subjects within System Organ Class.

14.3.3 Subjects with Treatment-emergent Adverse Events by Subgroup (Safety Analysis Set)

Table 14.3.3 (Page 1 of 1)
Subjects with Treatment-Emergent Adverse Events by Subgroup
Safety Analysis Set

System Organ Class Preferred Term	A/B (N=xx) n/M (%)	A/C (N=xx) n/M (%)	B/C (N=xx) n/M (%)	Total (N=xx) n/M (%)
Gender, n/M (%) [1]				
Male	x/xx(x.x%)	x/xx(x.x%)	x/xx(x.x%)	x/xx (xx.x%)
Female	x/xx(x.x%)	x/xx(x.x%)	x/xx(x.x%)	x/xx (xx.x%)
Age Group (years), n/M (%) [1]				
<18	x/xx(x.x%)	x/xx(x.x%)	x/xx(x.x%)	x/xx (xx.x%)
>=18	x/xx(x.x%)	x/xx(x.x%)	x/xx(x.x%)	x/xx (xx.x%)
Race, n/M (%) [1]				
White	x/xx(x.x%)	x/xx(x.x%)	x/xx(x.x%)	x/xx (xx.x%)
Non-White	x/xx(x.x%)	x/xx(x.x%)	x/xx(x.x%)	x/xx (xx.x%)

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%, Hypromellose 0.2%, Polyethylene glycol 400 1.0%
[1] n = number of subjects who reported an adverse event; M = total number of subjects in the subgroup.

14.3.4 Most Commonly Reported (>=5% of Subjects in One or More Treatment Groups) Treatment-Emergent Adverse Events (Safety Analysis Set)

Table 14.3.4 (Page 1 of 1)
Most Commonly Reported (>=5% of Subjects in One or More Treatment Groups) Treatment-Emergent Adverse Events
Safety Analysis Set

System Organ Class Preferred Term	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE MOST COMMONLY REPORTED AE	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx (xx.x%)
BODY SYSTEM 1	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 1	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 2	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
...				
BODY SYSTEM 2	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 3	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 4	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
...				

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%, Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Subjects are counted only once for each system organ class and preferred term.
System Organ Class and Preferred Terms listed in descending order of frequency reported by all subjects within System Organ Class.
MedDRA Coding Dictionary version 18.0.

14.3.5 Summary of Treatment-Emergent Adverse Events by Severity (Safety Analysis Set)

Table 14.3.5 (Page 1 of x)
Summary of Treatment-emergent Adverse Events by Severity
Safety Analysis Set

System Organ Class Preferred Term	A/B (N=xx) Mild n (%)	 Moderate n (%)	 Severe n (%)	A/C (N=xx) Mild n (%)	 Moderate n (%)	 Severe n (%)	B/C (N=xx) Mild n (%)	 Moderate n (%)	 Severe n (%)
SUBJECTS WITH AT LEAST ONE AE	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)
BODY SYSTEM 1	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
ADVERSE EVENT 1	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
ADVERSE EVENT 2	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
...									
BODY SYSTEM 2	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
ADVERSE EVENT 3	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
ADVERSE EVENT 4	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
...									
...									

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%, Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Subjects are counted only once for each system organ class and preferred term by selecting the most severe event.
Listed in descending order of frequency reported by all subjects within System Organ Class.
MedDRA Coding Dictionary version 18.0.

14.3.6 Subjects Who Discontinued the Trial Due to Adverse Events (Safety Analysis Set)

Table 14.3.6 (Page 1 of 1)
Subjects Who Discontinued the Trial Due to Adverse Events [1]
Safety Analysis Set

System Organ Class Preferred Term	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE AE	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx (xx.x%)
BODY SYSTEM 1	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 1	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 2	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
...				
BODY SYSTEM 2	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 3	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 4	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
...				
...				

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%, Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Note: AEs are coded by MedDRA Dictionary version 16.x.
[1] Subjects were counted only once for each system organ class and preferred term.
System Organ Class and Preferred Terms listed in descending order of frequency reported by all subjects within System Organ Class.

14.3.7 Subjects with Serious Adverse Events (Analysis Set)

Table 14.3.7 (Page 1 of 1)
Subjects with Serious Adverse Events [1]
Safety Analysis Set

System Organ Class Preferred Term	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE AE	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx (xx.x%)
BODY SYSTEM 1	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 1	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 2	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
...				
BODY SYSTEM 2	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 3	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 4	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
...				
...				

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%, Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Note: AEs are coded by MedDRA Dictionary version 16.x.
[1] Subjects were counted only once for each system organ class and preferred term.
System Organ Class and Preferred Terms listed in descending order of frequency reported by all subjects within System Organ Class.

14.3.8 Subjects with Treatment-related Adverse Events Term (Safety Analysis Set)

Table 14.3.8 (Page 1 of x)
Subjects with Treatment-related* Adverse Events [1]
Safety Analysis Set

System Organ Class Preferred Term	A/B (N=xx) n (%)	A/C (N=xx) n (%)	B/C (N=xx) n (%)	Total (N=xx) n (%)
SUBJECTS WITH AT LEAST ONE TREATMENT-RELATED AE	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx (xx.x%)
BODY SYSTEM 1	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 1	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 2	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
...				
BODY SYSTEM 2	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 3	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
ADVERSE EVENT 4	x(x.x%)	x(x.x%)	x(x.x%)	xx (xx.x%)
...				
...				

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Note: AEs are coded by MedDRA Dictionary version 16.x.
*Treatment-related adverse events are AEs with relationship to study medication of very likely, probable, possible or unknown.
[1] Subjects were counted only once for each system organ class and preferred term.
System Organ Class and Preferred Terms listed in descending order of frequency reported by all subjects within System Organ Class.

14.3.9 Summary of Treatment-related Adverse Events by Severity (Safety Analysis Set)

Table 14.3.9 (Page 1 of x)
Summary of Treatment-related Adverse Events* (TRAE) by Severity
Safety Analysis Set

System Organ Class Preferred Term	A/B (N=xx) Mild n (%)	 Moderate n (%)	 Severe n (%)	A/C (N=xx) Mild n (%)	 Moderate n (%)	 Severe n (%)	B/C (N=xx) Mild n (%)	 Moderate n (%)	 Severe n (%)
SUBJECTS WITH AT LEAST ONE TRAE	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)	xx(x.x%)
BODY SYSTEM 1	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
ADVERSE EVENT 1	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
ADVERSE EVENT 2	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
...									
BODY SYSTEM 2	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
ADVERSE EVENT 3	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
ADVERSE EVENT 4	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)	x(x.x%)
...									
...									

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%, Hypromellose 0.2%, Polyethylene glycol 400 1.0%
*Treatment-related adverse events are AEs with relationship to study medication of very likely, probable, possible or unknown.
Subjects are counted only once for each system organ class and preferred term by selecting the most severe event.
Listed in descending order of frequency reported by all subjects within System Organ Class.
MedDRA Coding Dictionary version 18.0.

16.1.7 Randomization Schedule (All Randomized Subjects)

Listing 16.1.7 (Page 1 of x)
Randomization Schedule
All Randomized Subjects

Randomization Number	Subject ID	Treatment Sequence	Eye	Treatment Code	Treatment Description
001	xxxxxxxx	AB	Left	A	[redacted], Tetrahydrozoline 0.05%
			Right	B	e 0.05%, Glycerin 0.40%
…					

16.2.1.1 Subject Disposition Listing (All randomized Subjects)

Listing 16.2.1.1 (Page 1 of 3)
Subject Disposition Listing
All Randomized Subjects

Treatment Sequence	Subject ID	Intent-to-Treat Subjects	Safety Analysis Set	Date Completed/ Withdrew	Study Completion/ Discontinuation Reason	Treatment: Date First Use	Treatment: Date Last Use
AB	xxxxxxxx	Yes	Yes	14DEC2011	COMPLETED	21SEP2011	04OCT2011
...							

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

16.2.1.2 Discontinued Subjects (All randomized Subjects)

Listing 16.2.1.2 (Page 1 of 1)
Discontinued Subjects
All Randomized Subjects

Treatment Sequence	Subject ID	Intent-to-Treat Subjects	Safety Analysis Set	Date Completed/ Withdrew	Study Completion/ Discontinuation Reason	Treatment: Date First Use	Treatment: Date Last Use
AB	xxxxxxxx	Yes	Yes	14DEC2011	DISCONTINUED	21SEP2011	04OCT2011
...							

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

16.2.2 Subjects with Protocol Deviations (All randomized Subjects)

Listing 16.2.2 (Page 1 of 1)
Subjects with Protocol Deviations
All Randomized Subjects

Treatment Sequence	Subject ID	Code of Deviation	Description of Deviations	Action Taken Code	Comments
AB	xxxxxxxx	xxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxx
	xxxxxxxx	xxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxx
	xxxxxxxx	xxxxx	xxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxx	xxxxxxxxxxxxx

...

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

Protocol Deviation Code List
1. Inclusion/Exclusion; 2. Investigational Product; 3. ConMeds; 4. Lab; 5. Visit Schedule; 6. Procedures/Tests; 7. Randomization; 8. Safety ; 9. Protocol Specific Discontinuation; 10. Non-Compliance; 11. Other

Action Taken Code List:
1. No action taken - minor deviation; 2. Subject discontinued; 3. Subject discontinued and replaced; 4. No action taken - subject completed the study; 5. Site re-trained; 6. Other.

16.2.3 Subjects Excluded from the Primary Analysis (All randomized Subjects)

Listing 16.2.3 (Page 1 of 1)
Subjects Excluded from the Primary Analysis
All Randomized Subjects

Treatment Sequence	Subject ID	Reason for Exclusion	Completed Study?	Intent-to-treat Subjects	Primary Analysis
AB	xxxxxxxx	xxxxxxxxxxxxxxxx	xxx	xxx	xx

...

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

16.2.4.1 Demographic and Baseline Characteristics (All randomized Subjects)

Listing 16.2.4.1 (Page 1 of 3)
Demographic Characteristics
All Randomized Subjects

Treatment Sequence	Subject ID	Date of Birth	Age	Sex	Race	Ethnicity
AB	xxxxxxxx	xxxx-xx-xx	xx	xxx	xxxxx	xxxxxxxxx
	xxxxxxxx	xxxx-xx-xx	xx	xxx	xxxxx	xxxxxxxxx
	xxxxxxxx	xxxx-xx-xx	xx	xxx	xxxxx	xxxxxxxxx
...						

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

16.2.4.2 Medical History (All randomized Subjects)

Listing 16.2.4.2 (Page 1 of 3)
Medical History
All Randomized Subjects

Treatment Sequence	Subject ID	Term for Medical History	Start Date	End Date	Medical History Ongoing
AB	xxxxxxxx	xxxxxxxx	xxxx-xx-xx	xxxx-xx-xx	No
	xxxxxxxx	xxxxxxxx	xxxx-xx-xx	xxxx-xx-xx	No
	xxxxxxxx	xxxxxxxx	xxxx-xx-xx	xxxx-xx-xx	No
...					

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

16.2.4.3 Prior and Concomitant Medications (All randomized Subjects)

Listing 16.2.4.3 (Page 1 of 3)
Prior and Concomitant Medications
All Randomized Subjects

Treatment Sequence	Subject ID	Name of Medication	Indication	Start Date	End Date	Medication Ongoing
AB	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxx-xx-xx	xxxx-xx-xx	No
	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxx-xx-xx	xxxx-xx-xx	No
	xxxxxxxx	xxxxxxxx	xxxxxxxx	xxxx-xx-xx	xxxx-xx-xx	No
...						

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

16.2.4.4 Prior and Concomitant Non-Drug Therapy / Procedure (All randomized Subjects)

Listing 16.2.4.4 (Page 1 of 3)
Prior and Concomitant Non-Drug Therapy / Procedure
All Randomized Subjects

Treatment Sequence	Subject ID	Name of Non-Drug Therapy / Procedure	Start Date	End Date	Medication Ongoing
AB	xxxxxxxx	xxxxxxxx	xxxx-xx-xx	xxxx-xx-xx	No
	xxxxxxxx	xxxxxxxx	xxxx-xx-xx	xxxx-xx-xx	No
	xxxxxxxx	xxxxxxxx	xxxx-xx-xx	xxxx-xx-xx	No
...					

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%

16.2.6.1 Ocular Redness Assessment (All randomized Subjects)

Listing 16.2.6.1 (Page 1 of 3)
Ocular Redness Assessment
All Randomized Subjects

Treatment Sequence	Subject ID	Assessment Time Point	Right Eye	Treatment	Redness Assessment	Reduction from Baseline	Responder?	Start Date	End Date
AB	xxxxxxxx	0s	Right	A	2.5			xxxx-xx-xx	xxxx-xx-xx
	xxxxxxxx	0s	Left	B	2.0			xxxx-xx-xx	xxxx-xx-xx
	xxxxxxxx	30s	Right	A	1.0	1.5	Yes	xxxx-xx-xx	xxxx-xx-xx
	xxxxxxxx	30s	Left	B	1.0	1.0	Yes	xxxx-xx-xx	xxxx-xx-xx

...

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Assessment time point:
0s = Pre-Treatment prior to the first product application (Baseline),
30s = 30 seconds after the first product application,
60s = 60 seconds after the first product application,
120s = 2 minutes after the first product application.
Redness Assessment: 0 = None, 1 = Mild, 2= Moderate, 3 = Severe, 4 = Extremely Severe.

16.2.6.2 Ocular Comfort Assessment (All randomized Subjects)

Listing 16.2.6.2 (Page 1 of 3)
Ocular Comfort Assessment
All Randomized Subjects

Treatment Sequence	Subject ID	Assessment Time Point	Right Eye	Treatment	Comfort Assessment	Reduction from Baseline	Start Date	End Date
AB	xxxxxxxx	0s	Right	A	2.5		xxxx-xx-xx	xxxx-xx-xx
	xxxxxxxx	0s	Left	B	2.0		xxxx-xx-xx	xxxx-xx-xx
	xxxxxxxx	60s	Right	A	1.0	1.5	xxxx-xx-xx	xxxx-xx-xx
	xxxxxxxx	60s	Left	B	1.0	1.0	xxxx-xx-xx	xxxx-xx-xx

...

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Assessment time point:
0s = Pre-Treatment prior to the first product application (Baseline),
60s = Following the 60 second ocular Redness Assessment;
10h = 10 hours after the 1st product application,
12h = 12 hours after the 1st product application.
Comfort Assessment: 0 = Very Uncomfortable, 10 = Very Comfortable.

16.2.6.3 Subject Questionnaire (All randomized Subjects)

Listing 16.2.6.3 (Page 1 of 3)
Subject Questionnaire
All Randomized Subjects

Treatment Sequence	Subject ID	Questions	Assessment Time Point	Right Eye	Treatment	Answer to Question	Start Date	End Date
AB	xxxxxxxx	My eye appears healthy	0s	Right	A	2	xxxx-xx-xx	xxxx-xx-xx
			0s	Left	B	2	xxxx-xx-xx	xxxx-xx-xx
			2m	Right	A	1	xxxx-xx-xx	xxxx-xx-xx
			2m	Left	B	1	xxxx-xx-xx	xxxx-xx-xx

...

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Assessment time point:
0s = Pre-Treatment prior to the first product application (Baseline),
2m = Following the 2-minute ocular Redness Assessment;
10h = 10 hours after the 1st product application,
12h = 12 hours after the 1st product application.
Answer: 1 = Strongly Disagree, 2 = Somewhat Disagree, 3 = Neither Agree or Disagree, 4 = Somewhat Agree, 5 = Strongly Agree, 9 = I don’t have an Opinion.

16.2.7.1 Subjects with Adverse Events (All randomized Subjects)

Listing 16.2.7.1 (Page 1 of 1)
Subjects with Adverse Events
All Randomized Subjects

Treatment Sequence	Subject ID	Age (Yr)	Race	AE TEXT	Preferred Term	Date/Time Started	Date/Time Ended	Freq.	Sev.	Outcm	Rel	Action	Med Given Yes/No	Serious Yes/No
AB	xxxxxx	18	W	xxxxxxxx	xxxxxxxxxx	13NOV2011	18NOV2011	1	1	1	0	1	Yes	No
					xxxxxxxxxx	13NOV2011	18NOV2011	1	2	1	0	1	Yes	No

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Race: W=WHITE, B=BLACK OR AFRICAN AMERICAN, A=ASIAN, N=NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, AI=AMERICAN INDIAN OR ALASKA NATIVE, O=OTHER
Freq. (Frequency): 1=SINGLE EPISODE, 2=INTERMITTENT
Sev. (Severity): 1=MILD, 2=MODERATE, 3=SEVERE
Outcm (Outcome): 1=RECOVERED/RESOLVED, 2=NOT RECOVERED/NOT RESOLVED, 3=FATAL, 4=RECOVERED/RESOLVED WITH SEQUELAE, 5=RECOVERING/RESOLVING, 96=UNKNOWN
Rel. (Relationship to study drug): 0=NOT RELATED, 11=DOUBTFUL, 12=POSSIBLE, 13=PROBABLE, 14=VERY LIKELY
Action (Action taken with investigational product): 1=NOT CHANGED, 2=REDUCED, 3=INTERRUPTED, 4=WITHDRAWN, 5=INCREASED, 96=UNKNOWN, 98=NOT APPLICABLE

16.2.7.2 Subjects with Serious Adverse Events (All randomized Subjects)

Listing 16.2.7.2 (Page 1 of 1)
Subjects with Serious Adverse Events
All Randomized Subjects

Treatment Sequence	Subject ID	Age (Yr)	Race	AE TEXT	Preferred Term	Date/Time Started	Date/Time Ended	Freq.	Sev.	Outcm	Rel	Action	Med Given Yes/No	Serious Yes/No
AB	xxxxxx	18	W	xxxxxxxx	xxxxxxxxxx	13NOV2011	18NOV2011	1	1	1	0	1	Yes	No
					xxxxxxxxxx	13NOV2011	18NOV2011	1	2	1	0	1	Yes	No

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Race: W=WHITE, B=BLACK OR AFRICAN AMERICAN, A=ASIAN, N=NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, AI=AMERICAN INDIAN OR ALASKA NATIVE, O=OTHER
Freq. (Frequency): 1=SINGLE EPISODE, 2=INTERMITTENT
Sev. (Severity): 1=MILD, 2=MODERATE, 3=SEVERE
Outcm (Outcome): 1=RECOVERED/RESOLVED, 2=NOT RECOVERED/NOT RESOLVED, 3=FATAL, 4=RECOVERED/RESOLVED WITH SEQUELAE, 5=RECOVERING/RESOLVING, 96=UNKNOWN
Rel. (Relationship to study drug): 0=NOT RELATED, 11=DOUBTFUL, 12=POSSIBLE, 13=PROBABLE, 14=VERY LIKELY
Action (Action taken with investigational product): 1=NOT CHANGED, 2=REDUCED, 3=INTERRUPTED, 4=WITHDRAWN, 5=INCREASED, 96=UNKNOWN, 98=NOT APPLICABLE

16.2.7.3 Subjects Withdrawn from Investigational Product due to Adverse Events (All randomized Subjects)

Listing 16.2.7.3 (Page 1 of 1)
Subjects Withdrawn from Investigational Product due to Adverse Events
All Randomized Subjects

Treatment Sequence	Subject ID	Age (Yr)	Race	AE TEXT	Preferred Term	Date/Time Started	Date/Time Ended	Freq.	Sev.	Outcm	Rel	Action	Med Given Yes/No	Serious Yes/No
AB	xxxxxx	18	W	xxxxxxxx	xxxxxxxxxx	13NOV2011	18NOV2011	1	1	1	0	1	Yes	No
					xxxxxxxxxx	13NOV2011	18NOV2011	1	2	1	0	1	Yes	No

A: [redacted], Tetrahydrozoline 0.05%
B: [redacted]e 0.05%, Glycerin 0.40%
C: Tetrahydrozoline 0.05%, Glycerin 0.20%. Hypromellose 0.2%, Polyethylene glycol 400 1.0%
Race: W=WHITE, B=BLACK OR AFRICAN AMERICAN, A=ASIAN, N=NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER, AI=AMERICAN INDIAN OR ALASKA NATIVE, O=OTHER
Freq. (Frequency): 1=SINGLE EPISODE, 2=INTERMITTENT
Sev. (Severity): 1=MILD, 2=MODERATE, 3=SEVERE
Outcm (Outcome): 1=RECOVERED/RESOLVED, 2=NOT RECOVERED/NOT RESOLVED, 3=FATAL, 4=RECOVERED/RESOLVED WITH SEQUELAE, 5=RECOVERING/RESOLVING, 96=UNKNOWN
Rel. (Relationship to study drug): 0=NOT RELATED, 11=DOUBTFUL, 12=POSSIBLE, 13=PROBABLE, 14=VERY LIKELY
Action (Action taken with investigational product): 1=NOT CHANGED, 2=REDUCED, 3=INTERRUPTED, 4=WITHDRAWN, 5=INCREASED, 96=UNKNOWN, 98=NOT APPLICABLE

16.2.7.4 Listing of MedDRA Preferred Terms for Adverse Events (All randomized Subjects)

Data Listing 16.2.7.4 (Page 1 of x)
Listing of MedDRA Preferred Terms for Adverse Events
All Randomized Subjects

System Organ Class	Preferred Term	AE Text	Subject ID
SOC1	PT1	xxxxxxx	xxxxxxxx
SOC2	PT2	xxxxxxx	xxxxxxxx
		xxxxxxx	xxxxxxxx
	PT3	xxxxxxx	xxxxxxxx
	PT4	xxxxxxx	xxxxxxxx
		xxxxxxx	xxxxxxxx
		xxxxxxx	xxxxxxxx
			xxxxxxxx
			xxxxxxxx
			xxxxxxxx
			xxxxxxxx