STATISTICAL ANALYSIS PLAN

Study CRO-23-153 - Sponsor code CHL.3-01-2021-M

A prospective, observer-blind, randomized clinical trial to investigate and compare the clinical efficacy of Chloroprocaine 3% gel and Oxybuprocaine 0.4% eye drops anesthesia for clinical practice in pediatric population

EU Trial Number: 2023-504477-21-01

Prospective, multicenter, randomized, active-controlled, parallel-group, observer-blind, Phase III pediatric non-inferiority study

Test product:	Chloroprocaine 3% gel, Sintetica S.A., Switzerland
Reference product	Benoxinato Cloridrato 4 mg/mL eye drops (oxybuprocaine chlorhydrate 0.4%), ALFA INTES, Italy
Sponsor:	Sintetica S.A., Via Penate 5, CH-6850 Mendrisio, Switzerland Phone: +41.91.640.42.50 Fax: +41.91.646.85.61
Coordinating Investigator:	Prof. E. Pedrotti, Clinica Oculistica dell'Azienda Ospedaliera Integrata di Verona, Policlinico di Borgo Roma (Verona), Italy
Development phase:	Phase III
Version and date:	Final version 2.0, 06JUN2025

This study will be conducted in compliance with the protocol, the principles of Good Clinical Practice (GCP), ICH topic E6 (R2), and with the applicable local regulatory requirements

This document comprises 29 pages plus appendices

VERSIONS' HISTORY

Version	Date of Issue	Reason for change
Draft version 0.1	10OCT2024	Giacomo Pellegrini issued the first draft
Draft version 0.2	19NOV2024	Giacomo Pellegrini issued the second draft after MW's review
Final version 1.0	28NOV2024	Giacomo Pellegrini issued the final version
Final version 2.0	06JUN2025	Francesca Morano issued the final version 2.0 after the Blind Review Meeting to update the analysis set definition section

APPROVAL AND ACKNOWLEDGEMENT

SPONSOR
Sintetica S.A., Switzerland

Clinical Operations Coordinator (for approval)
Anna Guaita

Anna Guaita Firmato digitalmente da Anna Guaita
Data: 2025.06.10 09:51:45 +02'00'

Date	Signature

CRO
CROSS Research S.A.

Author of Statistical Analysis Plan (for approval and acknowledgement)
Francesca Morano, Biostatistician and Senior Data Manager, DM team coordinator

Date | Signature

Medical Writer Team Representative (for approval and acknowledgement)
Chiara Leuratti, Clinical Project Unit Head and Sr. Medical Writer

Date | Signature

STUDY SCHEDULE

Study procedures	**Visit 1 Inclusion visit D-7/D1***	**Visit 2 Follow-up visit D2 (phone visit)**	**Visit 3 Final visit D8 (+/-3 days)**	**Unscheduled visit (Visit 4) up to D15 (if needed as per investigator's judgement)**
Information on the study and Informed consent/assent signature (as applicable)	X			
Demography*****	X			
Ocular medical and surgical history*****	X			
Systemic medical and surgical history*****	X			
Previous and concomitant ocular and non-ocular treatments	X	X	X	X
Pregnancy test (postmenarchal girls only)*****	X			
Slit lamp examination/Binocular indirect ophthalmoscopy	X**		X	X***
Adverse events	X	X	X	X
Verification of inclusion and exclusion criteria / Status of the patient	X			
Allocated treatment group	X			
IMP administration (2 drops in each eye)	X			
Vital signs*****	X			
Efficacy assessment (conjunctival anaesthesia)****	X			
Product global tolerance	X (Day 1, post-dose)			

**Informed consent form and assent form can be signed, as applicable, within 7 days before inclusion visit as per local practice. All other procedures must be done at D1.*

***Before (0 min) and after (60 min) the instillation (Before instillation to check patient's eligibility and after instillation to assess the safety)*

****Only if the visit is on-site*

*****Both eyes. Five (5) min after study product administration, i.e., right before the ocular examination (Day 1). WBFPS for patients ≥ 3 years or FLACC scale for patients <3*

******At screening only*

******* At screening and post-dose*

TABLES OF CONTENTS

TABLES AND FIGURES

ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Event
BP	Blood Pressure
BSS	Balanced Salt Solution
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CRO	Contract Research Organization
CSP	Clinical Study Protocol
CTFG	Clinical Trials Facilitation and Coordination Group
CRS	Clinical Study Report
CV	Coefficient of Variation
D	Day
DBP	Diastolic Blood Pressure
EC	Ethics Committee
eCRF	Electronic Case Report Form
ETV	Early Termination Visit
FLACC	Face, Legs, Activity, Crying and Consolability scale
FPFV	First Patient First Visit
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HR	Heart Rate
IB	Investigator's Brochure
ICH	International Conference on Harmonization
IRB/IEC	Institutional Review Board/Independent Ethics Committee
IMP	Investigational Medicinal Product
ITT	Intention To Treat
IV	Intravenous
LPLV	Last Patient Last Visit
LA	Local Anaesthesia
MedDRA	Medical Dictionary for Regulatory Activities
MF	Missing as Failure
NA	Not Applicable
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
PP	Per Protocol
PT	Preferred Term
PTAE	Pre-Treatment Adverse Event
SAE	Serious Adverse Event
SD	Standard Deviation
SOC	System Organ Class
SOP	Standard Operating Procedure
SDTM	Study Data Tabulation Model
TEAE	Treatment-Emergent Adverse Event
T	Time
WBPS	Wong-Baker faces pain rating scale
WC	Worst Case
WHODDE	World Health Organization Drug Dictionary Enhanced

1 INTRODUCTION

Statistical analysis will be performed by the CROSS Research Biometry Unit. The end-points and methods of analysis specified in this SAP are consistent with ICH E6 (R2) and E9 guidelines (1, 2). The SAP has been compiled by the Contract Research Organisation (CRO) Biometry Unit on the basis of the final version 5.0 of the clinical study protocol (3), reviewed by the Sponsor and finalized before the database lock and the treatment unblinding.

1.1 Changes with respect to the study protocol

No change with respect to the study protocol (3) was introduced in this SAP.

2 STUDY OBJECTIVES

2.1 Primary objective

The primary objective of the study is to evaluate the efficacy of Chloroprocaine 3% ophthalmic gel as compared to Oxybuprocaine chlorhydrate 0.4% eye drops anesthesia for clinical practice in pediatric population.

2.2 Secondary objectives

The secondary objective of the study is to evaluate the safety of Chloroprocaine 3% ophthalmic gel as compared to Oxybuprocaine chlorhydrate 0.4% eye drops anesthesia for clinical practice in pediatric population.

3 INVESTIGATIONAL PLAN

3.1 Overall study design

This will be a prospective, multicenter, randomized, active-controlled, parallel-group, observer blind, Phase III non-inferiority study.

3.2 Discussion of design

The study has been designed to assess the non-inferiority of chloroprocaine 3% ophthalmic gel (Test) versus Benoxinato Cloridrato 4 mg/mL (oxybuprocaine chlorhydrate 0.4%) eye drop solution (Reference) in eye surface anesthesia in children undergoing ocular exams.

The study was designed in line with a request from FDA and following a scientific advice with the Authority.

In designing the study, the following guidelines were taken into consideration: ICH E9 and ICH E9(R1) Guideline on Statistical principles for clinical trials (2, 4); the Guideline on the choice of the non-inferiority margin (CPMP/EWP/2158/99; 5); and the Points to consider on switching between superiority and non-inferiority guideline (CPMP/EWP/482/99; 6).

See section § 9.3 of the study protocol (3) for details.

4 STUDY POPULATION

4.1 Target population

The study population will consist of approximately 74 evaluable pediatric patients (0-17 years [18 years not completed at screening and during the study period]) who will undergo ocular exams with a need for ocular surface anaesthesia.

4.2 Inclusion criteria

To be enrolled in this study, patients must fulfil all these inclusion criteria:

1. Age ≥ one day of life (newborn, infant, child) and 17 years included (not anticipated to turn 18 during the study).
2. Female subjects currently either of:
   - Non-childbearing potential (i.e., premenarchal or physiologically incapable of becoming pregnant, including any female who is surgically sterilized via documented hysterectomy or bilateral tubal ligation),

   or
   - Childbearing potential (i.e., postmenarchal girls): the subject is eligible to enter and participate in this study if she is not lactating, has a negative pregnancy test and agrees to abstain from intercourses or uses, until study completion, a valid contraceptive method according to CTFG recommendation on Contraception and pregnancy, v 1.2-2020, i.e.:
     - Hormonal oral, implantable, transdermal or injectable contraceptives for at least 2 months before the screening visit
     - A non-hormonal intrauterine device or female condom with spermicide or contraceptive sponge with spermicide or diaphragm with spermicide or cervical cap with spermicide for at least 2 months before the screening visit
     - A male sexual partner who agrees to use a male condom with spermicide
     - A sterile sexual partner
3. Signed written informed consent by both parents or legal representative(s) (unless only one has legal authority). Written informed assent for adolescents aged 12-17 years included and, whenever possible, informed assent for children aged 6 to 11 years included. Ability of the subjects and their parents/legal representative(s) to understand and comply with the protocol requirements, study-specified visit schedule and procedures.
4. Scheduled to undergo a routine clinical procedure which needs local ocular surface anesthesia, including but not limited to applanation tonometry, gonioscopy, Ultrasound Biomicroscopy (UBM), ocular ultrasonography, retinal peripheral examination with blepharostat and scleral indentation.

4.3 Exclusion criteria

Subjects meeting any of these criteria will not be enrolled in the study:

Ophthalmic exclusion criteria

1. Previous ocular surgery less than 6 months before screening

2. Eye movement disorder (nystagmus)
3. History of herpetic keratitis
4. Corneal, epithelial, stromal or endothelial, residual or evolutionary disease (including corneal ulceration, corneal damage and superficial punctuate keratitis)
5. History of ocular traumatism, infection or inflammation within the last 3 months

Systemic/non ophthalmic exclusion criteria

- General history:

6. Any other medical or surgical history, disorder or disease such as acute or chronic severe organic disease: hepatic, endocrine neoplasia, hematological diseases, severe psychiatric illness, cardiac rhythm disorders and/or any complicating factor or structural abnormality judged by the investigator to be incompatible with the study

- Allergic history:

7. Known hypersensitivity to one of the components of the investigational products

Exclusion criteria related to general conditions

8. Non-compliant patient and/or parent(s)/legal representative(s) (e.g., not willing to attend the follow-up visits, way of life interfering with compliance)
9. Participation in another clinical study in the last three months before this study. The 3-month interval is calculated as the time between the first calendar day of the month that follows the last visit of the previous study and the first day of the present study
10. Already included once in this study

Exclusion criteria related to previous and concomitant medications / non-product therapies

11. Patient using any of the following previous and concomitant medication / treatment (according to the described periods) will not be included in the study:

<table>
<tr><td colspan="4">NOT ALLOWED CONCOMITANT MEDICATIONS (washout times)</td></tr>
<tr><td colspan="3">Before Inclusion</td><td>Inclusion</td></tr>
<tr><td>30 days</td><td>15 days</td><td>7 days</td><td>Day 1</td></tr>
<tr><td colspan="4">Any change in concomitant anti-depressant medication ……..</td></tr>
<tr><td colspan="4">Any topical ocular treatment ……</td></tr>
<tr><td></td><td colspan="3">Systemic opioids and morphinic drugs .....</td></tr>
<tr><td></td><td colspan="3">Sulphonamides</td></tr>
<tr><td></td><td colspan="3">Anticholinesterase drugs</td></tr>
<tr><td colspan="2"></td><td colspan="2">Any change in other systemic medication already ongoing before inclusion visit</td></tr>
<tr><td colspan="3"></td><td>Others systemic antalgics drugs (except paracetamol)</td></tr>
<tr><td colspan="3"></td><td>Silver nitrate (bactericides), Mercury salts (some disinfectants), Alkaline substances (e.g. detergents)</td></tr>
</table>

** Paracetamol after primary endpoint assessment and oral, implantable, transdermal, or injectable contraceptives for child-bearing potential girls during the entire study will be allowed*

5 STUDY SCHEDULE

The schedule of the study is summarised at page 5.

5.1 Study visits and procedures

Each patient will receive one study product, either Test or Reference, according to the study protocol. Maximum study duration will be 8±3 days (from D1 to D8) plus the screening phase (Inclusion visit) and the optional unscheduled visit up to D15.

In details, the study will include an Inclusion visit (Day -7/Day 1), a Follow-up visit (Day 2, phone visit), a Final visit (Day 8± 3 days) and an Optional/Unscheduled visit (up to Day 15). In case of premature discontinuation, as far as possible, an early termination visit (ETV), involving the same procedures/activities of the final visit, will be performed.

- **Visit 1: Inclusion Visit (Day-7[1]to Day 1)**

The procedures will be conducted by the blinded investigator, except for product preparation and administration which will be performed by another appointed member of staff in open conditions.

- Patient and patient's parents/legal representative(s) information about the aims, procedures and possible risks of the study and signature of the informed consent form/assent form (when applicable) before any study related procedures

  Patient assent and written informed consent by his/her parents/legal representative(s) (mother and father, or tutor(s)) can be signed within 7 days before inclusion visit as per local practice. All other procedures must be done at D1.
- Recording of demography data
- Ocular and systemic medical and surgical histories
- Previous and concomitant ocular and non-ocular treatments
- Vital signs (blood pressure and heart rate) at screening
- Pregnancy test for post-menarchal girls only
- Slit lamp examination/Binocular indirect ophthalmoscopy before instillation (pre-dose; 0 min) – both eyes
- Verification of the study inclusion/exclusion criteria
- Patient's allocation to one treatment group (chloroprocaine 3% gel (Test) or oxybuprocaine chlorhydrate 0.4% solution (Reference)
- Assigned product administration by instillation (2 drops in each eye) – both eyes
- Slit lamp examination/Binocular indirect ophthalmoscopy after instillation (60 min post-dose) – both eyes

[1] Informed consent form and assent form can be signed, as applicable, within 7 days before inclusion visit. All other procedures must be done at D1

- Efficacy assessment - conjunctival anesthesia assessment with an eye spear sponge (just before the scheduled diagnostic examination) – both eyes
- Vital signs (blood pressure and heart rate) post-dose
- AEs occurrence
- Product global tolerance – post-dose – both eyes

The instillation of the product will be done by appointed unblinded staff member(s) in order to maintain the blind.

- **Visit 2: Follow-up phone visit (Day 2)**

The phone call will be done by a blinded investigator.

- Patient's or parents/legal representative(s) questioning about concomitant ocular and non-ocular treatments
- AEs occurrence

- **Visit 3: Final Visit (Day 8 ± 3 days)**

The procedures will be carried out by a blinded investigator.

- Patient's or parents/legal representative(s) questioning about concomitant ocular and non-ocular treatments
- Slit lamp examination/Binocular indirect ophthalmoscopy – both eyes
- AEs occurrence

- **Optional visit/Unscheduled visit - phone call or on-site visit - (Visit 4, up to Day 15 as per Investigator's judgement)**

In case of on-site visit, the following procedures will be carried out by a blinded investigator:

- Patient's or parents/legal representative(s) questioning about concomitant ocular and non-ocular treatments
- Slit lamp examination/Binocular indirect ophthalmoscopy – both eyes
- AEs occurrence

In case of phone call, a blinded investigator will question the patient/legal representative about:

- Patient's or parents/legal representative(s) questioning about concomitant ocular and non-ocular treatments
- AEs occurrence

6 STUDY/INVESTIGATION SUBJECT IDENTIFICATION METHOD AND TREATMENT ASSIGNMENT METHOD

6.1 Unique subject identifier

All the study subjects who sign the informed assent form and/or with the informed consent form signed by parents/legal representative(s)for the present study will be coded with "unique subject identifiers" when data are extracted from the study database into the domains of the CDISC SDTM model.
The unique subject identifier consists of the Sponsor study code (i.e., CHL.3-01-2021-M), the 2-digit site number (i.e., 01), the 6-digit screening number (e.g., 01-001, 01-002…., etc.) and, if applicable, the 3-digit subject randomization number (e.g., 101, 102, etc.). Study code, site number, screening number and subject randomization number are separated by slashes ("/").

6.2 Subject identifier for the study/investigation

The last 10 digits of the unique subject identifier (randomized subjects), corresponding to the subject screening and subject randomization numbers separated by a slash, or the last 6 digits of the unique subject identifier (not randomized subjects), corresponding to the subject screening number, will appear as subject identifier in the individual listings and figures of the clinical study report (CSR).

6.3 Randomization

Both the kit list and the randomization list will be computer-generated by the Biometry Unit of the CRO, using the PLAN procedure of SAS® version 9.3 (TS1M1) or higher.
The kit list will be supplied to the Supplier before subject's kit preparation.
The randomization list will be attached to the final CSR.

The randomization number will include a unique progressive 3-digit number (i.e., 101, 102, 103 …, 201. 202, 203, …, etc.), in which the first digit of the number is the clinical site identifier (i.e.: 1 for site 1, 2 for site 2 and so on) and the other two digits is the randomization number within the site. The kit number will be a unique progressive 5-digit code (i.e., K0401, K0402, K0403 …).

6.4 Treatment allocation

The subjects will be assigned to Test (chloroprocaine) arm or Reference (oxybuprocaine) arm in a 1:1 ratio according to the randomization list. The randomization numbers will be assigned to the subjects using IWRS in a progressive order. The IWRS system will assign the kit numbers to the subjects on the basis of their treatment arm (derived from the assigned randomization number) starting from the smallest available number (based on the unique progressive 4-digit kit number).

6.5 Blinding

This is an observer-blind study.

- An independent blinded investigator will evaluate successful conjunctival and corneal anesthesia (with the patient, if applicable) and safety parameters for each patient.
- The patient will be blinded.

The observer-blind design of the trial will be maintained for the entire duration of the study for the blinded investigator until database lock. However, blinded investigator and participants may be unblinded during the trial for the occurrence of a medical emergency.

Each IMP kit will be numbered according to a randomized kits list created by the appointed CRO blinded team and provided to the supplier before the start of the study. The tracking, delivery and allocation of IMP kit numbers will be handled through the IWRS system.

7 STUDY EVALUATION PARAMETERS

7.1 Study endpoints

7.1.1 Primary endpoints

The primary endpoint is the proportion of patients in each treatment group with a successful conjunctival anesthesia in the right eye (study eye), 5 minutes after IMP administration, i.e., right before ocular examination, assessed by eye spear sponge. Conjunctival anaesthesia will also be assessed in the left eye (non-study eye).

For patients aged equal to and more than 3 years old until 18 years old not completed, a successful conjunctiva anesthesia is defined as ocular discomfort equal to 0 (=no hurt) on the Wong-Baker faces pain rating scale (WBFPS), shown in Figure 1 below.

Figure 1 - Wong-Baker faces pain rating scale (WBFPS)

For patients less than 3 years old, a successful conjunctiva anesthesia is defined as ocular discomfort equal to an overall score of 0 (= relaxed and comfortable) on the FLACC scale (see tables below).

Table 1 - Faces, Legs, Activity, Cry, Consolability (FLACC) scale

Face		
0 - No particular expression or smile	1 - Occasional grimace or frown, withdrawn, disinterested	2 - Frequent to constant frown, clenched jaw, quivering chin
Legs		
0 - Normal position or relaxed	1 - Uneasy, restless, tense	2 - Kicking or legs drawn up
Activity		
0 - Lying quietly, normal position, moves easily	1 - Squirming, shifting back/forth, tense	2 - Arched, rigid, or jerking
Cry		
0 - No cry, awake or asleep	1 - Moans or whimpers, occasional complaint	2 - Crying steadily, screams or sobs, frequent complaints
Consolability		
0 - Content, relaxed	1 - Reassured by occasional touching, hugging, or "talking to," distractible	2 - Difficult to console or comfort

The scores are interpreted as follows:

Table 2 - FLACC scale overall scores

0 =	Relaxed and comfortable
1–3 =	Mild discomfort
4–6 =	Moderate pain
7–10 =	Severe pain or discomfort or both

7.1.2 Secondary endpoints

Ocular and systemic safety

- Objective ocular signs (Slit Lamp Examination [SLE]/Binocular Indirect Ophthalmoscopy [BIO]): palpebral edema, chemosis, conjunctival hyperemia, conjunctival discharge, follico-papillary conjunctivitis, corneal staining punctuations, anterior chamber cells and flare, and other objective ocular signs, assessed using the following scale:

  (0) = None
  (1) = Mild
  (2) = Moderate
  (3) = Severe

- Adverse events occurrence throughout the study
- Product global tolerance will be graded by the Investigator by answering the following question "How do you consider the study product global tolerance" using the following scale:

  (0) = Very unsatisfactory
  (1) = Unsatisfactory
  (2) = Satisfactory
  (3) = Very satisfactory

8 STATISTICAL METHODS

The data documented in this trial and the measured clinical parameters will be presented using classic descriptive statistics (i.e., total number of subjects treated [N], number of observations [n], mean standard deviation [SD], minimum [Min], median, maximum [Max]) for quantitative variables and frequencies (i.e., count and percentages) for qualitative variables if not stated otherwise. The statistical analysis of demographic, safety and efficacy data will be performed at the Biometry Unit of the CRO.

Not available data will be evaluated as detailed in § 8.5. The statistical analysis of demographic, safety and efficacy data will be performed using SAS® version 9.3 (TS1M1) (7) or higher (the actual versions will be stated in the CSR).

8.1 Tables, listings and figures layout

Tables, listings and figures will be provided according to the following settings:

- Background: White
- Foreground: Black
- Font face: Times
- Font style: Roman
- Font size: 10 pt
- Font weight: Medium (data, footers and notes), Bold (titles and headers)
- Font width: Normal
- Layout: Landscape
- Top Margin: 2.5 cm
- Bottom Margin: 2.5 cm
- Left Margin: 0.8 cm
- Right Margin: 0.8 cm
- Test label: Chloroprocaine 3% ophthalmic gel (T)
- Reference label: Oxybuprocaine chlorhydrate 0.4% eye drops (R)
- Date format: ddMMMyyyy
- Means, standard deviations, percent coefficient of variations, medians, lower confidence limits and upper confidence limits will be rounded to one digit more than the original data
- Minima and maxima will keep the same number of decimal digits as the source values
- p-values will be rounded to the fourth decimal digit and will be flagged by an asterisk (*) in case of statistical significance (i.e. p-value < 0.05 or, in case of centre by treatment interaction, p-value < 0.10)
- p-values lower than 0.0001 will be reported as "<.0001 *".

The data and results of the Test product will be presented before the data and results of the Reference product in all listings and tables.

8.2 Analysis sets

The following analysis sets will be considered:

Safety set: All patients who received at least a fraction of the dose of the investigational product.

Intention-to-treat (ITT): all randomized patients.

Per Protocol Set (PPS): all randomized patients who received the treatment without any major deviation from the protocol.

In accordance with the ITT principle, all randomized patients should be included in the efficacy analysis to preserve the benefits of randomization. However, as recognized in ICH E9 guidelines (4), limited exceptions are acceptable, particularly in cases where no post-randomization data are available, and the patient did not receive any treatment.

In case:

- The patient did not receive any dose of study treatment
- No efficacy data were collected after randomization
- No safety or exposure data are available post-randomization.

A patient can be excluded from the ITT population, as its inclusion would not contribute any meaningful information to the efficacy analysis and could compromise the statistical integrity of the analysed dataset.

The exclusion of patients from the analysis sets is discussed during a blind review meeting that is held before database lock and complete unblinding.

Subjects will be evaluated according to the treatment they were assigned to for the primary efficacy analysis (ITT, PPS) and according to the treatment they actually receive for the Safety set.

Data analysis for primary efficacy outcomes will be performed using the ITT set. A sensitivity analysis using the PP Set will also be performed for the primary endpoint. Safety parameters will be analyzed on the Safety set.

8.3 Sample size and power considerations

Considering the non-inferiority nature of the study, the hypotheses testing to be assessed is:
H0: $p2-p1 \leq 0 - m$
H1: $p2-p1 > 0 - m$
where m is the non-inferiority margin.

The test treatment will be considered not to be inferior to the reference treatment if the two treatments do not differ by more than a margin m.

Given the following parameters:
• Ratio is the ratio between the number of subjects in the test treatment arm and that in the reference treatment arm;
• α is Type I error rate;
• Power is the statistical power of the test (1 - type II error rate);
• p1 is the expected success rate in the reference treatment;
• p2 is the expected success rate in the test treatment;
• m is the non-inferiority margin,
and assuming an expected success rate of 0.85 in both the test (p2) and reference treatment (p1) arms, a non-inferiority margin of m = 0.25 and a ratio=1, a sample size of 33 subjects in

each treatment arm is estimated to be sufficient at a one-sided 2.5% significance level and a power of 80% to reject the null hypothesis of inferiority.

The total number of subjects to be enrolled is therefore 66.

Furthermore, assuming a drop-out rate of 10%, 74 subjects would be needed to have 66 completers.

8.4 Intercurrent events

According to the EMA addendum to ICH E9(R1) about estimands and sensitivity analysis (4), the primary efficacy analysis will be conducted under a "treatment policy strategy".

Under the treatment policy strategy, if an intercurrent event has occurred or not is irrelevant, the data will be collected and analysed regardless. For example, if a patient took rescue medication, or discontinued from the trial, the data post the event would be included in the analyses. This policy reflects the intention-to-treat (ITT) principle. Indeed, in this trial, in the case of unsuccessful anesthesia requiring the use of rescue anesthesia to proceed with the diagnostic procedure, the patients will be regarded as failure due to a score greater than 0.

If the primary efficacy parameter cannot be collected due to complications preventing to assess anesthesia success, a "composite strategy" for the handling of missing data will be used and the patient will be regarded as failure.

8.5 Handling of missing data

8.5.1 Methods for replacing missing data

- Primary efficacy parameter: patients with missing data for the primary efficacy parameter will be imputed as failure.
- Safety parameters: no imputation will be done for the safety parameters.

8.5.2 Replacement rules for each analysis set

In general, missing data will be replaced according to methods specified in § 8.5.1 In particular:

- Intention-to-Treat (ITT): all missing values of the primary endpoint will be treated as a failure of the anesthesia
- Per Protocol Set (PP): no replacement of missing data is required for the primary endpoint.
- Safety Set: no replacement of missing data is required for the safety endpoints.

8.6 Demographic, baseline and background characteristics

Demographic, baseline and background characteristics will be reported for all the randomised subjects and analyses will be performed according to the treatment they were assigned to (Intention-to-Treat Set, Per Protocol Set) or according to the treatment they received (Safety Set).

8.6.1 Subjects' disposition

The disposition of all subjects screened in the study will be listed by treatment group (Listing 16.2.4.1) and summarised (Table 14.1.1.1). The number of subjects screened, the number and proportion of screen failures, randomised, treated and completing the study, the number and proportion of withdrawals and the reasons for withdrawal will be presented.

8.6.2 Analysis sets

All subjects excluded from each analysis sets will be listed by treatment group (Listing 16.2.3.1) and the reasons for exclusion will be reported.
The randomised subjects included in each analysis sets will be summarised by treatment group and overall (Table 14.1.1.2).

8.6.3 Discontinued subjects

All randomised subjects who discontinued the clinical trial (if any) will be listed by treatment group (Listing 16.2.1.1). Gender, age, last visit performed before discontinuation, time elapsed from last IMP administration (days), date of premature discontinuation and primary reason for subject premature discontinuation will be reported.

8.6.4 Protocol deviations

All the protocol deviations reported during the clinical trial will be listed by treatment group (Listing 16.2.2.1) and summarised by analysis set, treatment group and overall (Table 14.1.1.7, Table 14.1.1.8, Table 14.1.1.9). For each deviation category, the number and proportion of subjects with at least one major or minor protocol deviation will be reported. Deviations' tables will be generated for all analysis set.

8.6.5 Treatment mismatch

All subjects with actual treatment different from the assigned one will be listed (Listing 16.2.2.2).

8.6.6 Demography

Demographic data (ethnicity, birth year, age) will be listed by treatment group (Listing 16.2.4.2) and summarised by analysis set and by treatment group and overall (Table 14.1.1.3, Table 14.1.1.4, Table 14.1.1.5). The number and proportion of subjects in each category for categorical variables (e.g. ethnicity, sex) and descriptive statistics (mean, SD, CV%, minimum, median and maximum) for continuous variables (e.g. age) will be presented. Demographic tables will be generated for all analysis set.

8.6.7 Inclusion/exclusion criteria not met

All enrolled subjects with unmet inclusion/exclusion criteria will be listed (Listing 16.2.4.3) and summarised by treatment group and overall (Table 14.1.1.6).

8.6.8 Ocular medical and surgical history

All the ocular diseases of medical history and the ocular surgeries of all subjects enrolled in the study will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) and listed (Listing 16.2.10.1) and summarised by treatment group and overall (Table 14.1.1.10) for subjects included in the Intention-to-Treat set. The number and proportion of subjects with any findings will be presented by PT and SOC by treatment group and overall. The actual version of Dictionary will be stated in the Clinical Study Report (CSR).

8.6.9 Systemic medical and surgical history

All the systemic diseases of medical history and the systemic surgeries of all subjects enrolled in the study will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) and listed (Listing 16.2.10.2) and summarised by treatment group and overall (Table

14.1.1.11) for subjects included in the Intention-to-Treat set. The number and proportion of subjects with any findings will be presented by PT and SOC by treatment group and overall. The actual version of Dictionary will be stated in the Clinical Study Report (CSR).

8.6.10 Prior and concomitant medication

All prior and concomitant medications will be coded using the World Health Organization Drug Dictionary Enhanced (WHODDE) and listed by treatment group (Listing 16.2.10.3). The actual version will be stated in the CSR.

Prior medications will be summarized by treatment group and overall (Table 14.1.1.12) for subjects included in the Intention-to-Treat set. The number and proportion of subjects with any concomitant medication will be presented by ATC 4th level (or the higher available ATC level if 4th level is missing) and standardised drug name.

Concomitant medications will be summarized by treatment group and overall (Table 14.3.5.4) for subjects included in the safety set. The number and proportion of subjects with any concomitant medication will be presented by ATC 4th level (or the higher available ATC level if 4th level is missing) and standardised drug name.

8.6.11 Pregnancy test

For female subjects, pregnancy test results for post-menarchal girls only will be listed by treatment group (Listing 16.2.8.1).

8.6.12 Subjects' study visits

The dates of all subjects' study visits will be listed by treatment group (Listing 16.2.10.4).

8.7 IMP administration

The date and time of all IMP administrations will be listed by treatment group (Listing 16.2.5.1).

8.8 Analysis of efficacy parameters

The efficacy analysis will be performed on the patients included in the Intention-to-Treat Set and the Per Protocol Set. Subjects will be analysed according to the treatment group they were assigned to.

Patient's discomfort assessment for the right eye (study eye) and for the left eye (non-study eye) will be listed by treatment group (Listing 16.2.6.1) and summarised by frequency by age group, treatment group and overall (Table 14.2.1.1, Table 14.2.1.2).
Patient's discomfort scores will also be summarised by descriptive statistics by age group and by treatment group and overall (Table 14.2.1.3, Table 14.2.1.4).
Scores will be dichotomized as success (score = 0) / no success (score > 0) on either scale (WBFPS or FLACC). Subjects who achieve clinical success will be listed by treatment group (Listing 16.2.6.2) and the proportion of patients summarised by treatment group and overall (Table 14.2.1.5, Table 14.2.1.6).

8.8.1 Primary analysis

A non-inferiority test will be used to compare the proportion of success in each treatment group. The difference in proportions and its one-sided 95% confidence interval will be derived from the SAS FREQ procedure using RISKDIFF option and specifying the NONINFERIORITY (or NONINF) to request the Farrington-Manning score test for noninferiority. The significance of the test and therefore the non-inferiority of the Test treatment versus the Reference treatment will be confirmed if the lower limit of the 95% confidence interval is greater than the noninferiority margin (-0.25). (Table 14.2.1.7, Table 14.2.1.8).

8.9 Safety and tolerability evaluation

The safety analysis will be performed on the subjects included in the Safety Set.

Subjects will be analysed according to the treatment they actually received.

8.9.1 Adverse events

Adverse events (AEs) will be coded by System Organ Class (SOC) and Preferred Term (PT), using the Medical Dictionary for Regulatory Activities (MedDRA). The actual version will be stated in the CSR. AEs will be classified as pre-treatment AEs (PTAEs) and TEAEs, according to the period of occurrence, as follows:

- PTAEs: all AEs occurring before the first dose of IMP
- TEAEs: all AEs occurring or worsening after the first dose of IMP

Individual PTAEs and TEAEs will be listed in subject data listings by treatment group (Listing 16.2.7.2, Listing 16.2.7.1).

No summary table will be provided for PTAEs.

TEAEs will be summarized by treatment group and overall.

The number and percentage of subjects with any TEAE and the number of TEAEs will be presented overall. (Table 14.3.1.1).
The number and percentage of subjects with any TEAE and the number of TEAEs will be presented by SOC and PT (Table 14.3.1.2).
The number and percentage of subjects with any TEAE by intensity and the number of TEAEs by intensity will be presented by SOC and PT (Table 14.3.1.3).
The number and percentage of subjects with any TEAE related to the IMP and the number of TEAEs related to the IMP will be presented by SOC and PT (Table 14.3.1.4).

If applicable, serious TEAE will be summarized by SOC and PT (Table 14.3.1.5) and by relationship to IMP (Table 14.3.1.6).

All TEAEs leading to death, Serious TEAEs and all TEAEs leading to discontinuation will be listed (Table 14.3.2.1).

8.9.2 Slit lamp examination/Binocular Indirect Ophthalmoscopy

Scores or values for Slit lamp examination/Binocular Indirect Ophthalmoscopy parameters will be listed by treatment group (Listing 16.2.9.2). Scores and their change from baseline will be summarised for each eye by treatment group and overall (Table 14.3.5.1).

8.9.3 Vital signs

Vital signs values will be listed by treatment group (Listing 16.2.9.1) and summarized by treatment group and overall (Table 14.3.5.2).

8.9.4 Product global tolerability

Scores of the product overall tolerance assessment will be listed by treatment group (Listing 16.2.9.3) and summarized for each eye by treatment group and overall (Table 14.3.5.3).

8.9.5 Slit lamp examination/Binocular Indirect Ophthalmoscopy – additional assessments

If applicable, scores or values for the additional assessments at the Slit lamp or performed by Binocular indirect ophthalmoscopy will be listed by treatment group (Listing 16.2.9.4).

8.10 Analysis datasets

Analysis datasets will be created according to the version 2.1 of the ADaM model of CDISC (8).

9 REFERENCES

1 ICH Topic E6 (R2): Good clinical practice.

2 ICH Topic E9. Statistical Principles for Clinical Trials. CPMP/ICH/363/96. September 1998

3 Study Protocol CRO-23-153. "A prospective, observer-blind, randomized clinical trial to investigate and compare the clinical efficacy of Chloroprocaine 3% gel and Oxybuprocaine 0.4% eye drops anesthesia for clinical practice in pediatric population". Final version 5.0, 10NOV2024

4 ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials. CHMP/ICH/436221/2017. 17 February 2020

5 Guideline on the choice of the non-inferiority margin. CPMP/EWP/2158/99. 27 July 2005

6 Points to consider on switching between superiority and non-inferiority guideline. CPMP/EWP/482/99. 27 July 2000

7 SAS/STAT® User's Guide

8 CDISC Analysis Data Model Version 2.1

10 APPENDICES

1. Section 14 - Tables Shells
2. Section 16.2 - Individual Subject Data Listings Shells

Section 14 - Tables Shells

Table 14.1.1.1 - Subjects' disposition

	Overall n (%)
Screened	nn (xx.x)
Not randomised [1]	nn (xx.x)
Screen failure [1]	nn (xx.x)
Randomised [1]	nn (xx.x)
Discontinued before treatment [2]	nn (xx.x)
Treated [2]	nn (xx.x)
Completed [3]	nn (xx.x)
Discontinued [3]	nn (xx.x)
Adverse event [3]	nn (xx.x)

Note: The number and the proportion of subjects of each disposition event are reported
Note 1: The denominator for calculating the proportions is the number of screened subjects
Note 2: The denominator for calculating the proportions is the number of randomised subjects
Note 3: The denominator for calculating the proportions is the number of randomised and treated subjects
Source: Listing 16.2.4.1 - Subjects' disposition
Program: Tables\c153-ds-tbl.sas

Table 14.1.1.2 - Analysis sets - Intention-to-treat set

	Chloroprocaine 3% ophthalmic gel (T) N=XX n (%)	**Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX n (%)**	**Overall N=XX n (%)**
PPS Set	nn (xx.x)	nn (xx.x)	nn (xx.x)
Safety Set	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: The number and the proportion of subjects included in each analysis set are reported
The denominator for calculating the proportions is the number of subjects in the intention-to-treat set
Source: Listing 16.2.3.1 - Subjects excluded from the analysis set
Program: Tables\c153-ds-tbl.sas

Table 14.1.1.3 - Demography - Intention-to-treat set

		Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ethnicity	Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Reported	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Unknown	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age (years)		N	nn	nn	nn
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x
		Min	xx	xx	xx
		Median	xx.x	xx.x	xx.x
		Max	xx	xx	xx

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of subjects of each sex and ethnicity are reported
The denominator for calculating the proportions is the number of subjects in the intention-to-treat set of each treatment group and overall
Source: Listing 16.2.4.2 - Demography
Program: Tables\c153-dm-tbl.sas

Table 14.1.1.4 - Demography - Per Protocol set

		Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ethnicity	Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Reported	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Unknown	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age (years)		N	nn	nn	nn
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x
		Min	xx	xx	xx
		Median	xx.x	xx.x	xx.x
		Max	xx	xx	xx

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of subjects of each sex and ethnicity are reported
The denominator for calculating the proportions is the number of subjects in the per protocol set of each treatment group and overall
Source: Listing 16.2.4.2 - Demography
Program: Tables\c153-dm-tbl.sas

Table 14.1.1.5 - Demography - Safety set

		Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ethnicity	Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Hispanic or Latino	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Not Reported	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Unknown	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age (years)		N	nn	nn	nn
		Mean	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x
		Min	xx	xx	xx
		Median	xx.x	xx.x	xx.x
		Max	xx	xx	xx

Note: Subjects are summarised according to the product they were actually receive
The number and the proportion of subjects of each sex and ethnicity are reported
The denominator for calculating the proportions is the number of subjects in the per safety set of each treatment group and overall
Source: Listing 16.2.4.2 - Demography
Program: Tables\c153-dm-tbl.sas

Table 14.1.1.6 - Inclusion/exclusion criteria not met - Intention-to-treat set

	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Number of subjects with any inclusion/exclusion criteria not met	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 1	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 2	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 1	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 2	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of subjects for any criterion not met are reported
The denominator for calculating the proportions is the number of subjects in the intention-to-treat set of each treatment group and overall
Source: Listing 16.2.4.3 - Inclusion/Exclusion criteria not met
Program: Tables\c153-ie-tbl.sas

Table 14.1.1.7 - Protocol deviations - Intention-to-treat set

	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treatment deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Medication not admitted	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled sampling time	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of subjects for any protocol violation are reported
The denominator for calculating the proportions is the number of subjects in the intention-to-treat set of each treatment group and overall
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\c153-dv-tbl.sas

Table 14.1.1.8 - Protocol deviations - Per Protocol set

	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treatment deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Medication not admitted	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled sampling time	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of subjects for any protocol violation are reported
The denominator for calculating the proportions is the number of subjects in the per protocol set of each treatment group and overall
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\c153-dv-tbl.sas

Table 14.1.1.9 - Protocol deviations - Safety set

	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treatment deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criteria violation	nn (xx.x)	nn (xx.x)	nn (xx.x)
Medication not admitted	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation from scheduled sampling time	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...

Note: Subjects are summarised according to the product they actually receive
The number and the proportion of subjects for any protocol violation are reported
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\c153-dv-tbl.sas

Table 14.1.1.10 - Ocular medical and surgical history - Intention-to-treat set

System Organ Class [1] Preferred Term [1]	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Number of subjects with any ocular disease or surgery	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ocular surgical and medical procedures	nn (xx.x)	nn (xx.x)	nn (xx.x)
LASIK eye surgery	nn (xx.x)	nn (xx.x)	nn (xx.x)
Glaucoma surgery	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Eye disorders	nn (xx.x)	nn (xx.x)	nn (xx.x)
Myopia	nn (xx.x)	nn (xx.x)	nn (xx.x)
Ophhtmalmic migraine	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of subjects with any ocular disease/surgery for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the intention-to-treat set of each treatment group and overall
Note 1: MedDRA version xx.x
Source: Source: Listing 16.2.10.1 - Ocular medical and surgical history
Program: Tables\c153-mh-tbl.sas

Table 14.1.1.11 - Systemic medical and surgical history - Intention-to-treat set

System Organ Class [1] Preferred Term [1]	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Number of subjects with any systemic disease or surgery	nn (xx.x)	nn (xx.x)	nn (xx.x)
Surgical and medical procedures	nn (xx.x)	nn (xx.x)	nn (xx.x)
Appendicectomy	nn (xx.x)	nn (xx.x)	nn (xx.x)
Tonsillectomy	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)
Immune system disorders	nn (xx.x)	nn (xx.x)	nn (xx.x)
Seasonal allergy	nn (xx.x)	nn (xx.x)	nn (xx.x)
Food allergy	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of subjects with any systemic disease/surgery for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the intention-to-treat set of each treatment group and overall
Note 1: MedDRA version xx.x
Source: Source: Listing 16.2.10.2 - Systemic medical and surgical history
Program: Tables\c153-mh-tbl.sas

Table 14.1.1.12 - Prior medication - Intention-to-treat set

Medication Class [1,2] **Standardised Medication Name [1]**	**Chloroprocaine 3% ophthalmic gel (T)** **N=XX**	**Oxybuprocaine chlorhydrate 0.4% eye drops (R)** **N=XX**	**Overall** **N=XX**
Number of subjects with any prior medication	nn (xx.x)	nn (xx.x)	nn (xx.x)
Proton pump inhibitors	nn (xx.x)	nn (xx.x)	nn (xx.x)
Pantozol	nn (xx.x)	nn (xx.x)	nn (xx.x)
Pantoprazol	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...
Vitamin D and analogues	nn (xx.x)	nn (xx.x)	nn (xx.x)
Vitamin d3	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of subjects with any prior medication for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the intention-to-treat set of each treatment group and overall
Note 1: WHO Drug Dictionary xx, xxxx
Note 2: Anatomical Therapeutic Chemical classification, 4th level term, 3rd level term or 2nd level term as applicable
Source: Source: Listing 16.2.10.3 - Prior and concomitant medications
Program: Tables\c153-cm-tbl.sas

Table 14.2.1.1 - Patient's discomfort assessment - Intention-to-treat set

Age group: 0-3 years

Scale [1]	Category	Eye	Score	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
FLACC	Faces	Right	0 - No particular expression or smile	nn (xx.x)	nn (xx.x)	nn (xx.x)
			1 - Occasional grimace or frown, withdrawn, disinterested	nn (xx.x)	nn (xx.x)	nn (xx.x)
			2 - Frequent to constant frown, clenched jaw, quivering chi	nn (xx.x)	nn (xx.x)	nn (xx.x)
FLACC	Faces	Left	0 - No particular expression or smile	nn (xx.x)	nn (xx.x)	nn (xx.x)
			1 - Occasional grimace or frown, withdrawn, disinterested	nn (xx.x)	nn (xx.x)	nn (xx.x)
			2 - Frequent to constant frown, clenched jaw, quivering chi	nn (xx.x)	nn (xx.x)	nn (xx.x)
FLACC	...	Right	...	...	...	...
FLACC	...	Left	...	...	...	...
FLACC	Overall	Right	0 Relaxed and comfortable	nn (xx.x)	nn (xx.x)	nn (xx.x)
			1-3 Mild discomfort	nn (xx.x)	nn (xx.x)	nn (xx.x)
			4-6 Moderate pain	nn (xx.x)	nn (xx.x)	nn (xx.x)
			7-10 Severe pain or discomfort or both	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of assessment for each score are reported
The denominator for calculating the proportions is the number of subjects included in the intention-to-treat set of each treatment group and overall
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.1 - Patient's discomfort assessment - Intention-to-treat set

Age group: 0-3 years

Scale [1]	Category	Eye	Score	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
FLACC	Overall	Left	0 Relaxed and comfortable	nn (xx.x)	nn (xx.x)	nn (xx.x)
			1-3 Mild discomfort	nn (xx.x)	nn (xx.x)	nn (xx.x)
			4-6 Moderate pain	nn (xx.x)	nn (xx.x)	nn (xx.x)
			7-10 Severe pain or discomfort or both	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of assessment for each score are reported
The denominator for calculating the proportions is the number of subjects included in the intention-to-treat set of each treatment group and overall
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.1 - Patient's discomfort assessment - Intention-to-treat set

Age group: 3-17 years

Scale [1]	Category	Eye	Score	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
WBFPS		Right	0 - No hurt	nn (xx.x)	nn (xx.x)	nn (xx.x)
			2 - Hurts little bit	nn (xx.x)	nn (xx.x)	nn (xx.x)
			4 - Hurts little more	nn (xx.x)	nn (xx.x)	nn (xx.x)
			6 - Hurts even more	nn (xx.x)	nn (xx.x)	nn (xx.x)
			8 - Hurts whole lot	nn (xx.x)	nn (xx.x)	nn (xx.x)
WBFPS		Left	0 - No hurt	nn (xx.x)	nn (xx.x)	nn (xx.x)
			2 - Hurts little bit	nn (xx.x)	nn (xx.x)	nn (xx.x)
			4 - Hurts little more	nn (xx.x)	nn (xx.x)	nn (xx.x)
			6 - Hurts even more	nn (xx.x)	nn (xx.x)	nn (xx.x)
			8 - Hurts whole lot	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of assessment for each score are reported
The denominator for calculating the proportions is the number of subjects included in the intention-to-treat set of each treatment group and overall
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.2 - Patient's discomfort assessment - Per Protocol set

Age group: 0-3 years

Scale [1]	Category	Eye	Score	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
FLACC	Faces	Right	0 - No particular expression or smile	nn (xx.x)	nn (xx.x)	nn (xx.x)
			1 - Occasional grimace or frown, withdrawn, disinterested	nn (xx.x)	nn (xx.x)	nn (xx.x)
			2 - Frequent to constant frown, clenched jaw, quivering chi	nn (xx.x)	nn (xx.x)	nn (xx.x)
FLACC	Faces	Left	0 - No particular expression or smile	nn (xx.x)	nn (xx.x)	nn (xx.x)
			1 - Occasional grimace or frown, withdrawn, disinterested	nn (xx.x)	nn (xx.x)	nn (xx.x)
			2 - Frequent to constant frown, clenched jaw, quivering chi	nn (xx.x)	nn (xx.x)	nn (xx.x)
FLACC	...	Right	...	...	...	...
FLACC	...	Left	...	...	...	...
FLACC	Overall	Right	0 Relaxed and comfortable	nn (xx.x)	nn (xx.x)	nn (xx.x)
			1-3 Mild discomfort	nn (xx.x)	nn (xx.x)	nn (xx.x)
			4-6 Moderate pain	nn (xx.x)	nn (xx.x)	nn (xx.x)
			7-10 Severe pain or discomfort or both	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of assessment for each score are reported
The denominator for calculating the proportions is the number of subjects included in the per protocol set of each treatment group and overall
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.2 - Patient's discomfort assessment - Per Protocol set

Age group: 0-3 years

Scale [1]	Category	Eye	Score	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
FLACC	Overall	Left	0 Relaxed and comfortable	nn (xx.x)	nn (xx.x)	nn (xx.x)
			1-3 Mild discomfort	nn (xx.x)	nn (xx.x)	nn (xx.x)
			4-6 Moderate pain	nn (xx.x)	nn (xx.x)	nn (xx.x)
			7-10 Severe pain or discomfort or both	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of assessment for each score are reported
The denominator for calculating the proportions is the number of subjects included in the per protocol set of each treatment group and overall
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.2 - Patient's discomfort assessment - Per Protocol set

Age group: 3-17 years

Scale [1]	Category	Eye	Score	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
WBFPS		Right	0 - No hurt	nn (xx.x)	nn (xx.x)	nn (xx.x)
			2 - Hurts little bit	nn (xx.x)	nn (xx.x)	nn (xx.x)
			4 - Hurts little more	nn (xx.x)	nn (xx.x)	nn (xx.x)
			6 - Hurts even more	nn (xx.x)	nn (xx.x)	nn (xx.x)
			8 - Hurts whole lot	nn (xx.x)	nn (xx.x)	nn (xx.x)
WBFPS		Left	0 - No hurt	nn (xx.x)	nn (xx.x)	nn (xx.x)
			2 - Hurts little bit	nn (xx.x)	nn (xx.x)	nn (xx.x)
			4 - Hurts little more	nn (xx.x)	nn (xx.x)	nn (xx.x)
			6 - Hurts even more	nn (xx.x)	nn (xx.x)	nn (xx.x)
			8 - Hurts whole lot	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The number and the proportion of assessment for each score are reported
The denominator for calculating the proportions is the number of subjects included in the per protocol set of each treatment group and overall
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.3 - Patient's discomfort score - Intention-to-treat set

Age group: 0-3 years

Scale [1]	Category	Eye	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
FLACC	Faces	Right	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
FLACC	Faces	Left	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
FLACC	...	...	.	..	..	..

Note: Subjects are summarised according to the product they were assigned to
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.3 - Patient's discomfort score - Intention-to-treat set

Age group: 0-3 years

Scale [1]	Category	Eye	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
FLACC	Overall	Right	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
FLACC	Overall	Left	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx

Note: Subjects are summarised according to the product they were assigned to
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.3 - Patient's discomfort score - Intention-to-treat set

Age group: 3-17 years

Scale [1]	Category	Eye	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
WBFPS		Right	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
WBFPS		Left	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx

Note: Subjects are summarised according to the product they were assigned to
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.3 - Patient's discomfort score - Intention-to-treat set

Age group: Overall

Scale [1]	Category	Eye	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
WBFPS\FLACC		Right	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
WBFPS\FLACC		Left	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx

Note: Subjects are summarised according to the product they were assigned to
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.4 - Patient's discomfort score - Per Protocol set

Age group: 0-3 years

Scale [1]	Category	Eye	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
FLACC	Faces	Right	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
FLACC	Faces	Left	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
FLACC	...	...	.	..	..	..

Note: Subjects are summarised according to the product they were assigned to
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.4 - Patient's discomfort score - Per Protocol set

Age group: 0-3 years

Scale [1]	Category	Eye	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
FLACC	Overall	Right	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
FLACC	Overall	Left	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx

Note: Subjects are summarised according to the product they were assigned to
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.4 - Patient's discomfort score - Per Protocol set

Age group: 3-17 years

Scale [1]	Category	Eye	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
WBFPS		Right	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
WBFPS		Left	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx

Note: Subjects are summarised according to the product they were assigned to
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.4 - Patient's discomfort score - Per Protocol set

Age group: Overall

Scale [1]	Category	Eye	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
WBFPS\FLACC		Right	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
WBFPS\FLACC		Left	N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx

Note: Subjects are summarised according to the product they were assigned to
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Source: Listing 16.2.6.1 - Patient's discomfort assessment
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.5 - Proportion of subjects with successful anesthesia - Intention-to-treat set

Analysis Criterion		Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Subjects with a successful conjunctival anesthesia	Yes (Score = 0)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	No (Score > 0)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The denominator for calculating the proportions is the number of subjects included in the intention-to-treat set of each treatment group and overall
Success was evaluted with WBFPS for patients = 3 years or FLACC scale for patients <3 years
All missing values of the primary endpoint have been treated as a failure of the anesthesia
Source: Listing 16.2.6.2 - Conjunctival anaesthesia success
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.6 - Proportion of subjects with successful anesthesia - Per Protocol set

Analysis Criterion		Chloroprocaine 3% ophthalmic gel (T) N=XX	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Overall N=XX
Subjects with a successful conjunctival anesthesia	Yes (Score = 0)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	No (Score > 0)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they were assigned to
The denominator for calculating the proportions is the number of subjects included in the per protocol set of each treatment group and overall
Success was evaluted with WBFPS for patients = 3 years or FLACC scale for patients <3 years
All missing values have not been replaced
Source: Listing 16.2.6.2 - Conjunctival anaesthesia success
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.7 - Analysis of proportions on successful anesthesia - Intention-to-treat set

	Comparison [1]	Proportion Difference	95% One-sided Confidence Interval Low Limit	p-value [2]
Proportion of patients with a successful conjunctival anesthesia	T vs R	x.xxxx	-x.xxxx	x.xxxx

Note: Subjects are summarised according to the product they were assigned to
Non-inferiority margin: -0.25
Note 1: T= Chloroprocaine 3% ophthalmic gel, R= Oxybuprocaine chlorhydrate 0.4% eye drops
Note 2: Farrington-Manning score test for non-inferiority
Source: Listing 16.2.6.2 - Conjunctival anaesthesia success
Program: Tables\c153-fa-01-tbl.sas

Table 14.2.1.8 - Analysis of proportions on successful anesthesia - Per Protocol set

	Comparison [1]	Proportion Difference	95% One-sided Confidence Interval Low Limit	p-value [2]
Proportion of patients with a successful conjunctival anesthesia	T vs R	x.xxxx	-x.xxxx	x.xxxx

Note: Subjects are summarised according to the product they were assigned to
Non-inferiority margin: -0.25
Note 1: T= Chloroprocaine 3% ophthalmic gel, R= Oxybuprocaine chlorhydrate 0.4% eye drops
Note 2: Farrington-Manning score test for non-inferiority
Source: Listing 16.2.6.2 - Conjunctival anaesthesia success
Program: Tables\c153-fa-01-tbl.sas

Table 14.3.1.1 - Global incidence of subjects with treatment-emergent adverse events - Safety set

	Safety Set		
	Chloroprocaine 3% ophthalmic gel (T) N=XX n (%) [n AE]	**Oxybuprocaine chlorhydrate 0.4% eye drops (R)** N=XX n (%) [n AE]	**Overall** N=XX n (%) [n AE]
Treatment-emergent Adverse Events	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Related	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]

Note: Subjects are summarised according to the product they actually received
The same adverse event occurring with different intensities has been counted as one adverse event with the worst reported intensity
Subjects are summarised according to the each level of relationship and severity reported in each treatment group and overall
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c153-ae-01-tbl.sas

Table 14.3.1.1 - Global incidence of subjects with treatment-emergent adverse events - Safety set

	Safety Set		
	Chloroprocaine 3% ophthalmic gel (T) N=XX n (%) [n AE]	**Oxybuprocaine chlorhydrate 0.4% eye drops (R)** N=XX n (%) [n AE]	**Overall** N=XX n (%) [n AE]
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Relationship	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Related	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Not related	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Severity	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Mild	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Moderate	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Severe	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Leading to discontinuation	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]

Note: Subjects are summarised according to the product they actually received
The same adverse event occurring with different intensities has been counted as one adverse event with the worst reported intensity
Subjects are summarised according to the each level of relationship and severity reported in each treatment group and overall
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c153-ae-01-tbl.sas

Table 14.3.1.2 - Subjects with treatment-emergent adverse events by system organ class and preferred term - Safety set

System Organ Class [1] Preferred Term [1]	Safety Set Chloroprocaine 3% ophthalmic gel (T) N=XX n (%) [n AE]	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX n (%) [n AE]	Overall N=XX n (%) [n AE]
Treatment-emergent Adverse Events	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	...	...	...
Gastrointestinal disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	...	...	...

Note: Subjects are summarised according to the product they actually received
The same adverse event occurring with different severities has been counted as one adverse event with the worst reported severity
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
Note 1: MedDRA version xx.x
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c153-ae-02-tbl.sas

Table 14.3.1.3 - Subjects with treatment-emergent adverse events by severity, system organ class and preferred term - Safety set

	Safety Set								
	Chloroprocaine 3% ophthalmic gel (T) N=XX			Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX			Overall N=XX		
System Organ Class [1] Preferred Term [1]	Mild n (%) [n AE]	Moderate n (%) [n AE]	Severe n (%) [n AE]	Mild n (%) [n AE]	Moderate n (%) [n AE]	Severe n (%) [n AE]	Mild n (%) [n AE]	Moderate n (%) [n AE]	Severe n (%) [n AE]
Treatment-emergent Adverse Events	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Nervous system disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Headache	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...	...	...	...	...	...	...
Gastrointestinal disorders	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
Abdominal pain upper	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]	nn (x.x) [kk]
...	...	...	...	...	...	...	...	...	...

Note: Subjects are summarised according to the treatment they actually received
The same adverse event occurring with different severities has been counted as one adverse event with the worst reported severity
The number and the proportion of subjects with any adverse event and the number of adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
Note 1: MedDRA version xx.x
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c153-ae-02-tbl.sas

Table 14.3.1.4 - Subjects with treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

System Organ Class [1] Preferred Term [1]	Safety Set Chloroprocaine 3% ophthalmic gel (T) N=XX n (%) [n AE]	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX n (%) [n AE]	Overall N=XX n (%) [n AE]
Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	...	...	...
Gastrointestinal disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	...	...	...

Note: Subjects are summarised according to the product they actually received
The same adverse event occurring with different severities has been counted as one adverse event with the worst reported severity
The number and the proportion of subjects with any related adverse event and the number of related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
Note 1: MedDRA version xx.x
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c153-ae-02-tbl.sas

Table 14.3.1.5 - Subjects with serious treatment-emergent adverse events by system organ class and preferred term - Safety set

System Organ Class [1] Preferred Term [1]	Safety Set Chloroprocaine 3% ophthalmic gel (T) N=XX n (%) [n AE]	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX n (%) [n AE]	Overall N=XX n (%) [n AE]
Serious Treatment-emergent Adverse Events	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	...	...	...
Gastrointestinal disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	...	...	...

Note: Subjects are summarised according to the product they actually received
The same adverse event occurring with different severities has been counted as one adverse event with the worst reported severity
The number and the proportion of subjects with any serious adverse event and the number of serious adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
Note 1: MedDRA version xx.x
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c153-ae-02-tbl.sas

Table 14.3.1.6 - Subjects with serious treatment-emergent adverse events related to the IMP by system organ class and preferred term - Safety set

System Organ Class [1] Preferred Term [1]	Safety Set Chloroprocaine 3% ophthalmic gel (T) N=XX n (%) [n AE]	Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX n (%) [n AE]	Overall N=XX n (%) [n AE]
Serious Treatment-emergent Adverse Events related to the IMP	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Nervous system disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Headache	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	...	...	...
Gastrointestinal disorders	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Abdominal pain upper	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
Diarrhoea	nn (xx.x) [kk]	nn (xx.x) [kk]	nn (xx.x) [kk]
...	...	...	...

Note: Subjects are summarised according to the product they actually received
The same adverse event occurring with different severities has been counted as one adverse event with the worst reported severity
The number and the proportion of subjects with any serious related adverse event and the number of serious related adverse events for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
Note 1: MedDRA version xx.x
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c153-ae-02-tbl.sas

Table 14.3.2.1 - Treatment emergent adverse events leading to death, serious adverse events or treatment emergent adverse events leading to discontinuation - Safety set

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Adverse Event ID	Follow Up ID		
01-020/001	1		Description:	Drowsiness
			Body area affected	Nervous system
			Preferred Term [1]:	Somnolence
			System Organ Class [1]:	Nervous system disorders
			Acknowledgment Date:	ddMMMyyyy
			Acknowledgment Time:	hh:mm
			Start - End Date (Day):	ddMMMyyyy (k) - ddMMMyyyy hh:mm (j)
			AE Duration:	xx days
			Has the Adverse Event Started After IMP Administration?:	Yes
			Last Study Product Administration Date&Time:	ddMMMyyyy hh:mm
			Time Elapsed form Last Study Drug intake before AE:	hh:mm
			Reasonable Possibility of a Causal Relationship with the Study Product:	No
			Other Casual Relationship:	NA
			Severity:	Mild
			Pattern:	Single Event
			Serious Adverse Event?	Y
			Reason for seriousness:	Requires Inpatient Hospitalisation
			Action Taken with Study Drug:	Not Applicable
			Other Action Taken:	---
			Any Concomitant Therapy?	No
			Caused Study Discontinuation?	No
			Outcome:	Recovered/Resolved
...	...	...	...	...

Note: Subjects are listed according to the product they actually received
Note 1: MedDRA version xx.x
Sources: Listing 16.2.7.1 - Treatment-emergent adverse events, Listing 16.2.7.2 - Pre-treatment adverse events
Program: Tables\c153-ae-03-tbl.sas

Table 14.3.2.1 - Treatment emergent adverse events leading to death, serious adverse events or treatment emergent adverse events leading to discontinuation - Safety set

Investigational Medicinal Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Adverse Event ID	Follow Up ID		
01-020/001	2		Description:	Drowsiness
			Body area affected	Nervous system
			Preferred Term [1]:	Somnolence
			System Organ Class [1]:	Nervous system disorders
			Acknowledgment Date:	ddMMMyyyy
			Acknowledgment Time:	hh:mm
			Start - End Date (Day):	ddMMMyyyy (k) - ddMMMyyyy hh:mm (j)
			AE Duration:	xx days
			Has the Adverse Event Started After IMP Administration?:	Yes
			Last Study Product Administration Date&Time:	ddMMMyyyy hh:mm
			Time Elapsed form Last Study Drug intake before AE:	hh:mm
			Reasonable Possibility of a Causal Relationship with the Study Product:	No
			Other Casual Relationship:	NA
			Severity:	Mild
			Pattern:	Single Event
			Serious Adverse Event?	Y
			Reason for seriousness:	Requires Inpatient Hospitalisation
			Action Taken with Study Drug:	Not Applicable
			Other Action Taken:	---
			Any Concomitant Therapy?	No
			Caused Study Discontinuation?	No
			Outcome:	Recovered/Resolved
...	...	...	...	...

Note: Subjects are listed according to the product they actually received
Note 1: MedDRA version xx.x
Sources: Listing 16.2.7.1 - Treatment-emergent adverse events, Listing 16.2.7.2 - Pre-treatment adverse events
Program: Tables\c153-ae-03-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Palpebral edema	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--
Chemosis	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

			Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
Conjunctival hyperemia	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--
Conjunctival discharge	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

			Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
Folliculo-papillary conjunctivitis	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--
Corneal staining punctuations	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

			Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
Anterior chamber cells	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--
Flare	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Palpebral edema	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Chemosis	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Conjunctival hyperemia	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Conjunctival discharge	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Folliculo-papillary conjunctivitis	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Corneal staining punctuations	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Anterior chamber cells	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Flare	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Palpebral edema	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Chemosis	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Conjunctival hyperemia	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Conjunctival discharge	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Folliculo-papillary conjunctivitis	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Corneal staining punctuations	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Anterior chamber cells	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Flare	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Palpebral edema	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Chemosis	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Conjunctival hyperemia	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Conjunctival discharge	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Folliculo-papillary conjunctivitis	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Corneal staining punctuations	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Right

			Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
Anterior chamber cells	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Flare	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Palpebral edema	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--
Chemosis	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Conjunctival hyperemia	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--
Conjunctival discharge	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

			Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
Folliculo-papillary conjunctivitis	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--
Corneal staining punctuations	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

			Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
Anterior chamber cells	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--
Flare	Day 1 - Pre-dose	N	nn	--	nn	--	nn	--
		Mean	xx.x	--	xx.x	--	xx.x	--
		SD	xx.x	--	xx.x	--	xx.x	--
		CV%	xx.x	--	xx.x	--	xx.x	--
		Min	xx	--	xx	--	xx	--
		Median	xx.x	--	xx.x	--	xx.x	--
		Max	xx	--	xx	--	xx	--

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Palpebral edema	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Chemosis	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Conjunctival hyperemia	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Conjunctival discharge	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Folliculo-papillary conjunctivitis	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Corneal staining punctuations	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

			Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
Anterior chamber cells	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Flare	Day 1 - Post-dose	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Palpebral edema	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Chemosis	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Conjunctival hyperemia	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Conjunctival discharge	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

			Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
Folliculo-papillary conjunctivitis	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Corneal staining punctuations	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Anterior chamber cells	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Flare	Day 8	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Palpebral edema	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Chemosis	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Conjunctival hyperemia	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Conjunctival discharge	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

			Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
Parameter	**Time Point**	**Statistics**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**	**Value**	**Change from Baseline**
Folliculo-papillary conjunctivitis	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Corneal staining punctuations	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.1 - Descriptive statistics of objective ocular signs - Safety set

Eye: Left

Parameter	Time Point	Statistics	Chloroprocaine 3% ophthalmic gel (T) N=XX		Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX		Overall N=XX	
			Value	Change from Baseline	Value	Change from Baseline	Value	Change from Baseline
Anterior chamber cells	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx
Flare	Day 15	N	nn	nn	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx	xx	xx

Note: Subjects are summarised according to the product they actually received _
Baseline: Day 1 - Pre-dose
Source: Listing 16.2.9.2 - Objective ocular signs
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

			Safety Set		
Parameter	**Time Point**	**Statistics**	**Chloroprocaine 3% ophthalmic gel (T) N=XX**	**Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX**	**Overall N=XX**
Systolic Blood Pressure [mmHg]	Visit 1 - D1 - Pre-Dose	N	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx
Systolic Blood Pressure [mmHg]	Visit 1 - D1 - Post-Dose	N	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx
Diastolic Blood Pressure [mmHg]	Visit 1 - D1 - Pre-Dose	N	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx

Note: Subjects are summarised according to the product they actually received
Source: Listing 16.2.9.1 - Vital signs
Program: Tables\c153-vs-tbl.sas

Table 14.3.5.2 - Descriptive statistics of vital signs - Safety set

			Safety Set		
Parameter	**Time Point**	**Statistics**	**Chloroprocaine 3% ophthalmic gel (T) N=XX**	**Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX**	**Overall N=XX**
Diastolic Blood Pressure [mmHg]	Visit 1 - D1 - Post-Dose	N	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx
Heart Rate [beats/min]	Visit 1 - D1 - Pre-Dose	N	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx
Heart Rate [beats/min]	Visit 1 - D1 - Post-Dose	N	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx

Note: Subjects are summarised according to the product they actually received
Source: Listing 16.2.9.1 - Vital signs
Program: Tables\c153-vs-tbl.sas

Table 14.3.5.3 - Product global tolerability assessment - Safety set

Parameter	Eye		Statistics	Safety Set Chloroprocaine 3% ophthalmic gel (T) N=XX	Safety Set Oxybuprocaine chlorhydrate 0.4% eye drops (R) N=XX	Safety Set Overall N=XX
Product global tolerance	Right		N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
Product global tolerance	Right	3 - Very satisfactory	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		2 - Satisfactory	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		1 - Unsatisfactory	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		0 - Very unsatisfactory	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Product global tolerance	Left		N	nn	nn	nn
			Mean	xxx.x	xxx.x	xxx.x
			SD	xxx.x	xxx.x	xxx.x
			CV%	xxx.x	xxx.x	xxx.x
			Min	xxx	xxx	xxx
			Median	xxx.x	xxx.x	xxx.x
			Max	xxx	xxx	xxx
Product global tolerance	Left	3 - Very satisfactory	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		2 - Satisfactory	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		1 - Unsatisfactory	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		0 - Very unsatisfactory	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the product they actually received
Source: Listing 16.2.9.4 - Product global tolerability assessment
Program: Tables\c153-fa-02-tbl.sas

Table 14.3.5.4 - Concomitant medications - Safety set

Medication Class [1,2] **Standardised Medication Name [1]**	**Chloroprocaine 3% ophthalmic gel (T)** **N=XX**	**Oxybuprocaine chlorhydrate 0.4% eye drops (R)** **N=XX**	**Safety set** **N=XX** **n (%)**
Number of subjects with any medication	nn (xx.x)	nn (xx.x)	nn (xx.x)
Proton pump inhibitors	nn (xx.x)	nn (xx.x)	nn (xx.x)
Pantozol	nn (xx.x)	nn (xx.x)	nn (xx.x)
Pantoprazol	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...
Vitamin D and analogues	nn (xx.x)	nn (xx.x)	nn (xx.x)
Vitamin d3	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...

Note: Subjects are summarised according to the product they actually receive
The number and the proportion of subjects with any concomitant medication for each classification level are reported
The denominator for calculating the proportions is the number of subjects in the safety set of each treatment group and overall
Note 1: WHO Drug Dictionary xx, xxxx
Note 2: Anatomical Therapeutic Chemical classification, 4th level term, 3rd level term or 2nd level term as applicable
Source: Source: Listing 16.2.10.3 - Prior and concomitant medications
Program: Tables\c153-cm-tbl.sas

Section 16.2 - Individual Subject Data Listings Shells

Listing 16.2.1.1 - Discontinued subjects - Intention-to-treat set

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Sex	Age (years)	Last visit	Time elapsed from last drug administration (days)	Date of premature discontinuation	Primary reason for subject premature study termination
01-020/101	Female	14	Visit 1 - D1	0	ddMMMyyyy	Adverse event
...	...		...	...	...	...

Note: Subjects are listed according to the last product they were assigned to before discontinuation
Program: Listings\c153-ds-lst.sas

Listing 16.2.1.1 - Discontinued subjects - Intention-to-treat set

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Sex	Age (years)	Last visit	Time elapsed from last drug administration (days)	Date of premature discontinuation	Primary reason for subject premature study termination
01-015/107	Male	5	Visit 2 - D2	1	ddMMMyyyy	Withdrawal by subject
...	...		...	...	...	...

Note: Subjects are listed according to the last product they were assigned to before discontinuation
Program: Listings\c153-ds-lst.sas

Listing 16.2.2.1 - Protocol deviations

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Deviation Number	Deviation Category	Deviation Coded Term	Deviation Description
01-014/105	1	Major	Exclusion criteria violation	Exclusion criteria nr. 6 violation
...		...	...	...

Note: Subjects are listed according to the product they were assigned to
Program: Listings\c153-dv-lst.sas

Listing 16.2.2.1 - Protocol deviations

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Deviation Number	Deviation Category	Deviation Coded Term	Deviation Description
01-003/102	1	Major	Exclusion criteria violation	Exclusion criteria nr. 4 violation
...		...	...	...

Note: Subjects are listed according to the product they were assigned to
Program: Listings\c153-dv-lst.sas

Listing 16.2.2.2 - Assigned and actual treatment mismatches

Subject ID	Assigned Treatment	Actual Treatment
01-008/107	T	R
...	...	...

Note: T: Chloroprocaine 3% ophthalmic gel
R: Oxybuprocaine chlorhydrate 0.4% eye drops
Program: Listings\c153-ds-lst.sas

Listing 16.2.3.1 - Subjects excluded from the analysis sets

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Age (years)	ITT Set	PP Set	Safety Set	Reason for the exclusion
01-016/108	7	Y	N	N	Lack of IMP administration
...		...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Program: Listings\c153-ds-lst.sas

Listing 16.2.3.1 - Subjects excluded from the analysis sets

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Age (years)	ITT Set	PP Set	Safety Set	Reason for the exclusion
01-021/113	3	Y	N	Y	Major protocol deviations
...		...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Program: Listings\c153-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Date of Informed Consent	Date of Screening	Date of Randomisation	Date of IMP Administration	End of Study Status	Date of End of Study	Date of Study Completion or Discontinuation [1]
01-015	ddMMMyyyy	ddMMMyyyy	-	-	Screen failure	ddMMMyyyy	-
01-020/101	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Completed	ddMMMyyyy	ddMMMyyyy
...	...	...	...	...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1 : Only for enrolled subjects
Listings\c153-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Date of Informed Consent	Date of Screening	Date of Randomisation	Date of IMP Administration	End of Study Status	Date of End of Study	Date of Study Completion or Discontinuation [1]
01-007/111111	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Discontinued	ddMMMyyyy	ddMMMyyyy
01-020/105	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Completed	ddMMMyyyy	ddMMMyyyy
...	...	...	...	...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1 : Only for enrolled subjects
Listings\c153-ds-lst.sas

Listing 16.2.4.2 - Demography

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Ethnicity	Sex	Birth Year	Age	Age unit of measure
01-002/101	Not Hispanic or Latino	Female	2015	9	Years
...	...	...	...		...

Note: Subjects are listed according to the product they were assigned to
Program:Listings\c153-dm-lst.sas

Listing 16.2.4.2 - Demography

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Ethnicity	Sex	Birth Year	Age	Age unit of measure
01-005/102	Unknown	Male	2024	12	Weeks
...	...	...	...		...

Note: Subjects are listed according to the product they were assigned to
Program:Listings\c153-dm-lst.sas

Listing 16.2.4.3 - Inclusion/Exclusion criteria not met

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Criterion	Verbatim
01-020/101	Exclusion criterion 3	History of herpetic keratitis
...	...	...

Note: Subjects are listed according to the product they were assigned to
Program: Listings\c153-ie-lst.sas

Listing 16.2.4.3 - Inclusion/Exclusion criteria not met

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Criterion	Verbatim
01-12/104	Exclusion criterion 2	Eye movement disorder
...	...	...

Note: Subjects are listed according to the product they were assigned to
Program: Listings\c153-ie-lst.sas

Listing 16.2.5.1 - Investigational medicinal products administration

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Admin Visit	Eye	Administration Date	Administration tme First drop (hh:mm:ss)	Administration time Second drop (hh:mm:ss)
01-020/101	Visit 1 - D1	Left	ddMMMyyyy	hh:mm:ss	hh:mm:ss
01-020/101	Visit 1 - D1	Right	ddMMMyyyy	hh:mm:ss	hh:mm:ss
...	...	...	...	...	...

Note: Subjects are listed according to the product they actually received
Program: Listings\c153-ex-lst.sas

Listing 16.2.5.1 - Investigational medicinal products administration

Investigational Medicinal Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Admin Visit	Eye	Administration Date	Administration tme First drop (hh:mm:ss)	Administration time Second drop (hh:mm:ss)
01-018/102	Visit 1 - D1	Left	ddMMMyyyy	hh:mm:ss	hh:mm:ss
01-018/102	Visit 1 - D1	Right	ddMMMyyyy	hh:mm:ss	hh:mm:ss
...	...	...	...	...	...

Note: Subjects are listed according to the product they actually received
Program: Listings\c153-ex-lst.sas

Listing 16.2.6.1 - Patient's discomfort assessment

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Assessment Start Date/Time (hh:mm)	Age (years)	Eye	Discomfort Scale [1]	Category	Value
01-006/101	ddMMMyyyy hh:mm	8	Right	WBFPS		2 - Hurts little bit
01-006/101	ddMMMyyyy hh:mm	8	Left	WBFPS		0 - No hurt
01-009/102	ddMMMyyyy hh:mm	2	Right	FLACC	Face	0 - No particular expression or smile
01-009/102	ddMMMyyyy hh:mm	2	Right	FLACC	Legs	1 - Uneasy, restless, tense
01-009/102	ddMMMyyyy hh:mm	2	Right	FLACC	Activity	0 - Lying quietly, normal position, moves easily
01-009/102	ddMMMyyyy hh:mm	2	Right	FLACC	Cry	0 - No cry, awake or sleep
01-009/102	ddMMMyyyy hh:mm	2	Right	FLACC	Consolability	0 - Content, relaxed
01-009/102	ddMMMyyyy hh:mm	2	Left	FLACC	Face	1 - Occasional grimace or frown, withdrawn, disinterested
01-009/102	ddMMMyyyy hh:mm	2	Left	FLACC	Legs	1 - Uneasy, restless, tense
01-009/102	ddMMMyyyy hh:mm	2	Left	FLACC	Activity	0 - Lying quietly, normal position, moves easily
01-009/102	ddMMMyyyy hh:mm	2	Left	FLACC	Cry	1 - Moans or whimpers, occasional complaint
01-009/102	ddMMMyyyy hh:mm	2	Left	FLACC	Consolability	0 - Content, relaxed
...	...		...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Program: Listings\c153-fa-lst.sas

Listing 16.2.6.1 - Patient's discomfort assessment

Investigational Medicinal Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Assessment Start Date/Time (hh:mm)	Age (years)	Eye	Discomfort Scale [1]	Category	Value
01-008/103	ddMMMyyyy hh:mm	15	Right	WBFPS		2 - Hurts little bit
01-008/103	ddMMMyyyy hh:mm	15	Left	WBFPS		0 - No hurt
01-009/104	ddMMMyyyy hh:mm	1	Right	FLACC	Face	0 - No particular expression or smile
01-009/104	ddMMMyyyy hh:mm	1	Right	FLACC	Legs	1 - Uneasy, restless, tense
01-009/104	ddMMMyyyy hh:mm	1	Right	FLACC	Activity	0 - Lying quietly, normal position, moves easily
01-009/104	ddMMMyyyy hh:mm	1	Right	FLACC	Cry	0 - No cry, awake or sleep
01-009/104	ddMMMyyyy hh:mm	1	Right	FLACC	Consolability	0 - Content, relaxed
01-009/104	ddMMMyyyy hh:mm	1	Left	FLACC	Face	1 - Occasional grimace or frown, withdrawn, disinterested
01-009/104	ddMMMyyyy hh:mm	1	Left	FLACC	Legs	1 - Uneasy, restless, tense
01-009/104	ddMMMyyyy hh:mm	1	Left	FLACC	Activity	0 - Lying quietly, normal position, moves easily
01-009/104	ddMMMyyyy hh:mm	1	Left	FLACC	Cry	1 - Moans or whimpers, occasional complaint
01-009/104	ddMMMyyyy hh:mm	1	Left	FLACC	Consolability	0 - Content, relaxed
...	...		...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1: FLACC: Faces, Legs, Activity, Cry, Consolability scale; WBFPS=Wong-Baker faces pain rating scale
Program: Listings\c153-fa-lst.sas

Listing 16.2.6.2 - Conjunctival anaesthesia success

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Eye	Value	Conjunctival anaesthesia success [1]
01-006/101	Right	0 - No hurt	Yes
01-006/101	Left	2 - Hurts little bit	No
...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1: Success was evaluted with WBFPS for patients = 3 years or FLACC scale for patients <3 years
Program: Listings\c153-fa-lst.sas

Listing 16.2.6.2 - Conjunctival anaesthesia success

Investigational Medicinal Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Eye	Value	Conjunctival anaesthesia success [1]
01-008/102	Right	0 - Relaxed and comfortable	Yes
01-008/102	Left	0 - Relaxed and comfortable	Yes
...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1: Success was evaluted with WBFPS for patients = 3 years or FLACC scale for patients <3 years
Program: Listings\c153-fa-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Adverse Event ID	Follow Up ID		
01-020/101	1		Description:	Drowsiness
			Body area affected	Nervous system
			Preferred Term [1]:	Somnolence
			System Organ Class [1]:	Nervous system disorders
			Acknowledgment Date:	ddMMMyyyy
			Acknowledgment Time:	hh:mm
			Start - End Date (Day):	ddMMMyyyy (k) - ddMMMyyyy hh:mm (j)
			AE Duration:	xx days
			Has the Adverse Event Started After IMP Administration?:	Yes
			Last Study Product Administration Date&Time:	ddMMMyyyy hh:mm
			Time Elapsed form Last Study Drug intake before AE:	hh:mm
			Reasonable Possibility of a Causal Relationship with the Study Product:	No
			Other Casual Relationship:	NA
			Severity:	Mild
			Pattern:	Single Event
			Serious Adverse Event?	N
			Reason for seriousness:	---
			Action Taken with Study Drug:	Not Applicable
			Other Action Taken:	---
			Any Concomitant Therapy?	No
			Caused Study Discontinuation?	No
			Outcome:	Recovered/Resolved
...	...	...	...	...

Note: Subjects are listed according to the product they actually received
Note 1: MedDRA version xx.x
Program: Listings\c153-ae-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Adverse Event ID	Follow Up ID		
01-020/101	2		Description:	Drowsiness
			Body area affected	Nervous system
			Preferred Term [1]:	Somnolence
			System Organ Class [1]:	Nervous system disorders
			Acknowledgment Date:	ddMMMyyyy
			Acknowledgment Time:	hh:mm
			Start - End Date (Day):	ddMMMyyyy (k) - ddMMMyyyy hh:mm (j)
			AE Duration:	xx days
			Has the Adverse Event Started After IMP Administration?:	Yes
			Last Study Product Administration Date&Time:	ddMMMyyyy hh:mm
			Time Elapsed form Last Study Drug intake before AE:	hh:mm
			Reasonable Possibility of a Causal Relationship with the Study Product:	No
			Other Casual Relationship:	NA
			Severity:	Mild
			Pattern:	Single Event
			Serious Adverse Event?	N
			Reason for seriousness:	---
			Action Taken with Study Drug:	Not Applicable
			Other Action Taken:	---
			Any Concomitant Therapy?	No
			Caused Study Discontinuation?	No
			Outcome:	Recovered/Resolved
...	...	...	...	...

Note: Subjects are listed according to the product they actually received
Note 1: MedDRA version xx.x
Program: Listings\c153-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Subject ID	Adverse Event ID	Follow Up ID		
01-020/101	1		Description:	Drowsiness
			Body area affected	Nervous system
			Preferred Term [1]:	Somnolence
			System Organ Class [1]:	Nervous system disorders
			Acknowledgment Date:	ddMMMyyyy
			Acknowledgment Time:	hh:mm
			Start - End Date (Day):	ddMMMyyyy (k) - ddMMMyyyy hh:mm (j)
			AE Duration:	xx days
			Has the Adverse Event Started After IMP Administration?:	No
			Last Study Product Administration Date&Time:	NA
			Time Elapsed form Last Study Drug intake before AE:	NA
			Reasonable Possibility of a Causal Relationship with the Study Product:	NA
			Other Casual Relationship:	NA
			Severity:	Mild
			Pattern:	Single Event
			Serious Adverse Event?	N
			Reason for seriousness:	---
			Action Taken with Study Drug:	Not Applicable
			Other Action Taken:	---
			Any Concomitant Therapy?	No
			Caused Study Discontinuation?	No
			Outcome:	Recovered/Resolved
...	...	...	...	...

Note 1: MedDRA version xx.x
Program: Listings\c153-ae-lst.sas

Listing 16.2.8.1 - Pregnancy test

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Urine Sampling Date/Time	Pregnancy Test Result
01-006/101	ddMMMyyyy hh:mm	Negative
...	...	...

Note: Postmenarchal girls only
Subjects are listed according to the product they were assigned to
Program: Listings\c153-lb-lst.sas

Listing 16.2.8.1 - Pregnancy test

Investigational Medicinal Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Urine Sampling Date/Time	Pregnancy Test Result
01-009/104	ddMMMyyyy hh:mm	Negative
...	...	...

Note: Postmenarchal girls only
Subjects are listed according to the product they were assigned to
Program: Listings\c153-lb-lst.sas

Listing 16.2.9.1 - Vital signs

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value	Clinically Significant?
01-004/101	Visit 1 - D1 - Pre-Dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	96	N
01-004/101	Visit 1 - D1 - Pre-Dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	58	N
01-004/101	Visit 1 - D1 - Pre-Dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	60	N
01-004/101	Visit 1 - D1 - Post-Dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	105	N
01-004/101	Visit 1 - D1 - Post-Dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	70	N
01-004/101	Visit 1 - D1 - Post-Dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	55	N
...	...	...	...	...	...

Note: Subjects are listed according to the product they actually received
Program: Listings\c153-vs-lst.sas

Listing 16.2.9.1 - Vital signs

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Time Point	Assessment Date/Time	Parameter	Value	Clinically Significant?
01-007/102	Visit 1 - D1 - Pre-Dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	110	N
01-007/102	Visit 1 - D1 - Pre-Dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	65	N
01-007/102	Visit 1 - D1 - Pre-Dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	60	N
01-007/102	Visit 1 - D1 - Post-Dose	ddMMMyyyy hh:mm	Systolic Blood Pressure [mmHg]	110	N
01-007/102	Visit 1 - D1 - Post-Dose	ddMMMyyyy hh:mm	Diastolic Blood Pressure [mmHg]	65	N
01-007/102	Visit 1 - D1 - Post-Dose	ddMMMyyyy hh:mm	Heart Rate [beats/min]	60	N
...	...	...	...	...	...

Note: Subjects are listed according to the product they actually received
Program: Listings\c153-vs-lst.sas

Listing 16.2.9.2 - Objective ocular signs

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Time Point	Assessment Start Date/Time (hh:mm)	Eye	Category	
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Palpebral edema	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Chemosis	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Conjunctival hyperemia	2 - Moderate
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Conjunctival discharge	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Corneal staining punctuations	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Anterior chamber cells	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Flare	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Palpebral edema	1 - Mild
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Chemosis	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Conjunctival hyperemia	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Conjunctival discharge	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Corneal staining punctuations	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Anterior chamber cells	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Flare	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Palpebral edema	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Chemosis	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Conjunctival hyperemia	2 - Moderate
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Conjunctival discharge	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Corneal staining punctuations	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Anterior chamber cells	0 - None

Note: Subjects are listed according to the product they actually receive
Program: Listings\c153-fa-lst.sas

Listing 16.2.9.2 - Objective ocular signs

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Time Point	Assessment Start Date/Time (hh:mm)	Eye	Category	
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Flare	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Palpebral edema	1 - Mild
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Chemosis	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Conjunctival hyperemia	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Conjunctival discharge	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Corneal staining punctuations	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Anterior chamber cells	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Flare	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Palpebral edema	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Chemosis	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Conjunctival hyperemia	2 - Moderate
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Conjunctival discharge	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Corneal staining punctuations	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Anterior chamber cells	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Flare	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Palpebral edema	1 - Mild
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Chemosis	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Conjunctival hyperemia	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Conjunctival discharge	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Corneal staining punctuations	0 - None

Note: Subjects are listed according to the product they actually receive
Program: Listings\c153-fa-lst.sas

Listing 16.2.9.2 - Objective ocular signs

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Time Point	Assessment Start Date/Time (hh:mm)	Eye	Category	
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Anterior chamber cells	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Flare	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Right	Palpebral edema	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Right	Chemosis	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Right	Conjunctival hyperemia	2 - Moderate
01-006/101	Day 15	ddMMMyyyy hh:mm	Right	Conjunctival discharge	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 15	ddMMMyyyy hh:mm	Right	Corneal staining punctuations	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Right	Anterior chamber cells	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Right	Flare	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Left	Palpebral edema	1 - Mild
01-006/101	Day 15	ddMMMyyyy hh:mm	Left	Chemosis	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Left	Conjunctival hyperemia	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Left	Conjunctival discharge	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 15	ddMMMyyyy hh:mm	Left	Corneal staining punctuations	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Left	Anterior chamber cells	0 - None
01-006/101	Day 15	ddMMMyyyy hh:mm	Left	Flare	0 - None

Note: Subjects are listed according to the product they actually receive
Program: Listings\c153-fa-lst.sas

Listing 16.2.9.2 - Objective ocular signs

Investigational Medicinal Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Time Point	Assessment Start Date/Time (hh:mm)	Eye	Category	
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Palpebral edema	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Chemosis	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Conjunctival hyperemia	2 - Moderate
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Conjunctival discharge	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Corneal staining punctuations	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Anterior chamber cells	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Flare	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Palpebral edema	1 - Mild
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Chemosis	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Conjunctival hyperemia	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Conjunctival discharge	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Corneal staining punctuations	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Anterior chamber cells	0 - None
01-008/102	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Flare	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Palpebral edema	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Chemosis	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Conjunctival hyperemia	2 - Moderate
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Conjunctival discharge	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Corneal staining punctuations	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Anterior chamber cells	0 - None

Note: Subjects are listed according to the product they actually receive
Program: Listings\c153-fa-lst.sas

Listing 16.2.9.2 - Objective ocular signs

Investigational Medicinal Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Time Point	Assessment Start Date/Time (hh:mm)	Eye	Category	
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Flare	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Palpebral edema	1 - Mild
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Chemosis	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Conjunctival hyperemia	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Conjunctival discharge	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Corneal staining punctuations	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Anterior chamber cells	0 - None
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Flare	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Right	Palpebral edema	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Right	Chemosis	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Right	Conjunctival hyperemia	2 - Moderate
01-008/102	Day 8	ddMMMyyyy hh:mm	Right	Conjunctival discharge	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-008/102	Day 8	ddMMMyyyy hh:mm	Right	Corneal staining punctuations	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Right	Anterior chamber cells	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Right	Flare	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Left	Palpebral edema	1 - Mild
01-008/102	Day 8	ddMMMyyyy hh:mm	Left	Chemosis	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Left	Conjunctival hyperemia	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Left	Conjunctival discharge	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild
01-008/102	Day 8	ddMMMyyyy hh:mm	Left	Corneal staining punctuations	0 - None

Note: Subjects are listed according to the product they actually receive
Program: Listings\c153-fa-lst.sas

Listing 16.2.9.2 - Objective ocular signs

Investigational Medicinal Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Time Point	Assessment Start Date/Time (hh:mm)	Eye	Category	
01-008/102	Day 8	ddMMMyyyy hh:mm	Left	Anterior chamber cells	0 - None
01-008/102	Day 8	ddMMMyyyy hh:mm	Left	Flare	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Right	Palpebral edema	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Right	Chemosis	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Right	Conjunctival hyperemia	2 - Moderate
01-008/102	Day 15	ddMMMyyyy hh:mm	Right	Conjunctival discharge	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-008/102	Day 15	ddMMMyyyy hh:mm	Right	Corneal staining punctuations	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Right	Anterior chamber cells	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Right	Flare	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Left	Palpebral edema	1 - Mild
01-008/102	Day 15	ddMMMyyyy hh:mm	Left	Chemosis	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Left	Conjunctival hyperemia	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Left	Conjunctival discharge	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild
01-008/102	Day 15	ddMMMyyyy hh:mm	Left	Corneal staining punctuations	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Left	Anterior chamber cells	0 - None
01-008/102	Day 15	ddMMMyyyy hh:mm	Left	Flare	0 - None

Note: Subjects are listed according to the product they actually receive
Program: Listings\c153-fa-lst.sas

Listing 16.2.9.3 - Additional Slit Lamp Examination/Binocular Indirect Ophthalmoscopy

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Time Point	Assessment Start Date/Time (hh:mm)	Eye	Category	Value
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Blepharitis	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Eyelid oedema	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Iris pigmentation modification	2 - Moderate
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Abnormal eyelashes aspect	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Blepharitis	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Eyelid oedema	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Iris pigmentation modification	2 - Moderate
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Abnormal eyelashes aspect	0 - None
01-006/101	Day 1 - Pre Dose	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Blepharitis	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Eyelid oedema	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Iris pigmentation modification	2 - Moderate
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Abnormal eyelashes aspect	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Blepharitis	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Eyelid oedema	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Iris pigmentation modification	2 - Moderate
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Abnormal eyelashes aspect	0 - None
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Blepharitis	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Eyelid oedema	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Iris pigmentation modification	2 - Moderate

Note: Subjects are listed according to the product they actually receive
Program: Listings\c153-fa-lst.sas

Listing 16.2.9.3 - Additional Slit Lamp Examination/Binocular Indirect Ophthalmoscopy

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Time Point	Assessment Start Date/Time (hh:mm)	Eye	Category	Value
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Abnormal eyelashes aspect	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Right	Folliculo-papillary conjunctivitis	1 - Mild
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Blepharitis	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Eyelid oedema	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Iris pigmentation modification	2 - Moderate
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Abnormal eyelashes aspect	0 - None
01-006/101	Day 8	ddMMMyyyy hh:mm	Left	Folliculo-papillary conjunctivitis	1 - Mild

Note: Subjects are listed according to the product they actually receive
Program: Listings\c153-fa-lst.sas

Listing 16.2.9.4 - Product global tolerability assessment

Investigational Medicinal Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Time Point	Assessment Start Date/Time (hh:mm)	Eye	Product global tolerance
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	3 - Very satisfactory
01-006/101	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	2 - Satisfactory
...	...	...	...	...

Note: Subjects are listed according to the product they actually receive
Program: Listings\c153-fa-lst.sas

Listing 16.2.9.4 - Product global tolerability assessment

Investigational Medicinal Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Time Point	Assessment Start Date/Time (hh:mm)	Eye	Product global tolerance
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Right	2 - Satisfactory
01-008/102	Day 1 - Post Dose	ddMMMyyyy hh:mm	Left	1 - Unsatisfactory
...	...	...	...	...

Note: Subjects are listed according to the product they actually receive
Program: Listings\c153-fa-lst.sas

Listing 16.2.10.1 - Ocular medical and surgical history

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Category	Disease/Surgery ID		
01-007/102	Ocular Medical History	M1	Verbatim:	Glaucoma
			Preferred Term [1]:	Ocular hypertension
			System Organ Class [1]:	Eye disorder
			Disease Start - End Date:	MAR2021
	Ocular Surgery	S1	Verbatim:	Trabeculectomy
			Preferred Term [1]:	Trabeculectomy
			System Organ Class [1]:	Surgical and medical procedures
			Surgery Date:	GEN2022
	...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1: MedDRA version xx.x
Program: Listings\c153-mh-lst.sas

Listing 16.2.10.1 - Ocular medical and surgical history

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Category	Disease/Surgery ID		
01-005/102	Ocular Medical History	M1	Verbatim:	Glaucoma
			Preferred Term [1]:	Ocular hypertension
			System Organ Class [1]:	Eye disorder
			Disease Start - End Date:	MAR2021
	Ocular Surgery	S1	Verbatim:	Trabeculectomy
			Preferred Term [1]:	Trabeculectomy
			System Organ Class [1]:	Surgical and medical procedures
			Surgery Date:	GEN2022
	...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1: MedDRA version xx.x
Program: Listings\c153-mh-lst.sas

Listing 16.2.10.2 - Systemic medical and surgical history

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Category	Disease/Surgery ID		
01-007/101	Medical History	M1	Verbatim:	Right clavicula fracture
			Preferred Term [1]:	Clavicle fracture
			System Organ Class [1]:	Injury, poisoning and procedural complications
			Disease Start - End Date:	FEB2023
	Surgery	S1	Verbatim:	Tonsillectomy
			Preferred Term [1]:	Tonsillectomy
			System Organ Class [1]:	Surgical and medical procedures
			Surgery Date:	2022
	...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1: MedDRA version xx.x
Program: Listings\c153-mh-lst.sas

Listing 16.2.10.2 - Systemic medical and surgical history

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Category	Disease/Surgery ID		
01-005/102	Medical History	M1	Verbatim:	Right clavicula fracture
			Preferred Term [1]:	Clavicle fracture
			System Organ Class [1]:	Injury, poisoning and procedural complications
			Disease Start - End Date:	FEB2023
	Surgery	S1	Verbatim:	Tonsillectomy
			Preferred Term [1]:	Tonsillectomy
			System Organ Class [1]:	Surgical and medical procedures
			Surgery Date:	2022
	...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1: MedDRA version xx.x
Program: Listings\c153-mh-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Category	Medication ID		
01-009/106	Prior	1	Verbatim:	Alerid
			Standardised Medication Name [1]:	Alerid
			Active Ingredients [1]:	Cetirizine hydrochloride
			Medication Class [1, 2]:	Piperazine derivatives (R06AE)
			Indication:	Pollinosis
			Dose:	10 mg
			Start - End Date/Time:	2023 - Ongoing
			Frequency - Dosage Form - Route:	1 time per day - Tablet - Oral
			Related to:	Disease M1
	Concomitant	2	Verbatim:	Tachipirina (paracetamolo 500 mg)
			Standardised Medication Name [1]:	Paracetamol
			Active Ingredients [1]:	Paracetamol
			Medication Class [1, 2]:	Anilides (N02BE)
			Indication:	Headache
			Dose:	500 mg
			Start - End Date/Time:	15JUN2024 19:08 - 15JUN2024 19:08
			Frequency - Dosage Form - Route:	Once - Tablet - Oral
			Related to:	Adverse Event 1
	...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1: WHO Drug Dictionary xx, xxxx
Note 2: Anatomical Therapeutic Chemical classification, 4th level term
Program: Listings\c153-cm-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Category	Medication ID		
01-012/109	Prior	1	Verbatim:	Alerid
			Standardised Medication Name [1]:	Alerid
			Active Ingredients [1]:	Cetirizine hydrochloride
			Medication Class [1, 2]:	Piperazine derivatives (R06AE)
			Indication:	Pollinosis
			Dose:	10 mg
			Start - End Date/Time:	2023 - Ongoing
			Frequency - Dosage Form - Route:	1 time per day - Tablet - Oral
			Related to:	Disease M1
	Concomitant	2	Verbatim:	Tachipirina (paracetamolo 500 mg)
			Standardised Medication Name [1]:	Paracetamol
			Active Ingredients [1]:	Paracetamol
			Medication Class [1, 2]:	Anilides (N02BE)
			Indication:	Headache
			Dose:	500 mg
			Start - End Date/Time:	15JUN2024 19:08 - 15JUN2024 19:08
			Frequency - Dosage Form - Route:	Once - Tablet - Oral
			Related to:	Adverse Event 1
	...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Note 1: WHO Drug Dictionary xx, xxxx
Note 2: Anatomical Therapeutic Chemical classification, 4th level term
Program: Listings\c153-cm-lst.sas

Listing 16.2.10.4 - Subjects study visits

Investigational Medical Product: Chloroprocaine 3% ophthalmic gel (T)

Subject ID	Visit	Visit Start Date (Day)	Visit End Date (Day)
01-020/101	Visit 1 - Inclusion Visit - Day -7/1	ddMMMyyyy (-j)	-ddMMMyyyy (x)
01-020/101	Visit 2 - Follow-up phone visit - Day 2	ddMMMyyyy (y)	---
01-020/101	Visit 3 - Final Visit - Day 8 ± 3	ddMMMyyyy (z)	---
01-020/101	Visit 4 - Optional Visit - Day 15	ddMMMyyyy (k)	---
...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Program: Listings\c153-sv-lst.sas

Listing 16.2.10.4 - Subjects study visits

Investigational Medical Product: Oxybuprocaine chlorhydrate 0.4% eye drops (R)

Subject ID	Visit	Visit Start Date (Day)	Visit End Date (Day)
01-007/102	Visit 1 - Inclusion Visit - Day -7/1	ddMMMyyyy (-j)	-ddMMMyyyy (x)
01-007/102	Visit 2 - Follow-up phone visit - Day 2	ddMMMyyyy (y)	---
01-007/102	Visit 3 - Final Visit - Day 8 ± 3	ddMMMyyyy (z)	---
01-007/102	Visit 4 - Optional Visit - Day 15	ddMMMyyyy (k)	---
...	...	...	...

Note: Subjects are listed according to the product they were assigned to
Program: Listings\c153-sv-lst.sas