STATISTICAL ANALYSIS PLAN

Study CRO-14-122 - Sponsor code CHL.1/02-2014

Spinal anaesthesia with Chloroprocaine HCl 1% for elective lower limb procedures of short duration: a prospective, randomised, observer-blind study in adult patients

Prospective, single centre, randomised, parallel-group, observer-blind, three doses, efficacy and pharmacokinetic study

EudraCT Number: 2014-003778-17

Investigational medicinal product:	Chloroprocaine HCl 1% solution for injection (10 mg/mL), Sintetica S.A., Switzerland
Indication:	Spinal anaesthesia
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Development phase:	Phase II
Version and date:	Final version 1.0, 02FEB2016

This study was conducted in accordance with Good Clinical Practice (GCP), ICH topic E6

This document comprises 32 pages plus appendices

1 STATISTICAL ANALYSIS PLAN VERSIONS' HISTORY

Version	Date of Issue	Reason for change
Draft version 0.1	30DEC2015	Issue of the first draft
Draft version 0.2	02FEB2016	Updated by Matteo Rossini in order to implement the changes required by Chiara Leuratti
Final version 1.0	02FEB2016	Final version issued by Matteo Rossini

2 STATISTICAL ANALYSIS PLAN APPROVAL AND ACKNOWLEDGEMENT

2.1 SPONSOR APPROVAL AND ACKNOWLEDGEMENT

Sintetica S.A., Switzerland

Sponsor Representative (for approval)
Elisabetta Donati, Corporate Director Scientific Affairs

03 FEB 2016 _____
Date Signature

2.2 CRO APPROVAL AND ACKNOWLEDGEMENT

CROSS Research S.A. and CROSS Metrics S.A., sister-owned companies

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02FEB 2016 _____ Emanuela Terragni
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5 LIST OF ABBREVIATIONS

ADR	Adverse Drug Reaction
AE	Adverse Event
ALCOA	Attributable-Legible-Contemporaneous-Original-Accurate
ANOVA	Analysis of Variance
ASA	American Society of Anesthesiologists
BMI	Body Mass Index
BP	Blood Pressure
BW	Body Weight
CA	Competent Authority
CABA	2-chloro-4-aminobenzoic acid
CDISC	Clinical Data Interchange Standards Consortium
CSF	Cerebrospinal fluid
CI	Confidence Interval
CNS	Central Nervous System
CRF	Case Report Form
CRO	Contract Research Organisation
CSP	Clinical Study Protocol
CRS	Clinical Study Report
CV	Coefficient of Variation
DBP	Diastolic Blood Pressure
EC	Ethics Committee
ECG	Electrocardiogram
ETV	Early Termination Visit
FAS	Full Analysis Set
FSFV	First Subject First Visit
GCP	Good Clinical Practice
GLP	Good Laboratory Practice
HR	Heart Rate
IB	Investigator's Brochure
ICH	International Conference on Harmonisation
IRB/IEC	Institutional Review Board/Independent Ethics Committee
IMP	Investigational Medicinal Product
IUD	Intra-Uterine Device
IV	Intravenous
IVRA	Intravenous Regional Anaesthesia
LSLV	Last Subject Last Visit
MedDRA	Medical Dictionary for Regulatory Activities
NA	Not Applicable
NRS	Numerical rating scale
NSAIDs	Non-Steroidal Anti-Inflammatory Drugs
OTC	Over The Counter
PK	Pharmacokinetic
PP	Per Protocol
PT	Preferred Term
PTAE	Pre-Treatment Adverse Event
SAE	Serious Adverse Event
SBP	Systolic Blood Pressure
SB_{max}	Maximum level of sensory block
SBML	Sensory block metameric level
SD	Standard Deviation
SmPC	Summary of Product Characteristics
SOC	System Organ Class
SOP	Standard Operating Procedure
SpO_2	Peripheral oxygen saturation
SDTM	Study Data Tabulation Model
TEAE	Treatment-Emergent Adverse Event

T_{ea}	Time to regression of spinal block (i.e. end of anaesthesia)
T_{hd}	Time to eligibility for home discharge
T_{mb}	Time to onset of motor block
T_{SBmax}	Time to maximum level of sensory block
T_{pa}	Time to first post-operative analgesia
T_{ra}	Time to administration of rescue anaesthesia or rescue analgesia
T_{rd}	Time to regression of two dermatomers with respect to the maximum level of sensory block
T_{rmb}	Time to regression of motor block
T_{rs}	Time to readiness for surgery
T_{S1}	Time to regression of sensory block to S1
T_{sb}	Time to onset of sensory block
T_{sp}	Time of spinal injection
T_{ua}	Time to unassisted ambulation
T_{uv}	Time to first spontaneous urine voiding
TNS	Transient Neurological Symptoms
WHODDE	World Health Organisation Drug Dictionary Enhanced

6 INTRODUCTION

The statistical analysis of demographic, efficacy and safety data and the PK analysis will be performed by the Contract Research Organisation (CRO) Biometry Unit. The present Statistical Analysis Plan (SAP) was compiled by the CRO Biometry Unit, reviewed by the Sponsor and finalized before database lock.

6.1 Changes with respect to the study protocol

No changes with respect to the the final version 2.0 of the study protocol (1) and the final version 1.0 of the amendment number 3 (2) are present in the SAP.

7 STUDY DESCRIPTION

7.1 Study Objective

The objective of this study is to evaluate the effect of the three doses of Chloroprocaine HCl 1% (30, 40 and 50 mg) for spinal anaesthesia in adult patients undergoing short duration elective surgery of the lower limb.

7.1.1 Primary end-point

- The primary end-point of the study is to evaluate the efficacy of the three Chloroprocaine HCl 1% doses (30 mg [D1], 40 mg [D2] and 50 mg [D3]) in terms of time to complete regression of spinal block (T_{ea}).

7.1.2 Secondary end-points

- To evaluate the efficacy of three Chloroprocaine HCl 1% doses (D1, D2 and D3) in terms of time to onset of sensory block (T_{sb}), time to onset of motor block (T_{mb}), time to readiness for surgery (T_{rs}), time to regression of motor block, time to unassisted ambulation (T_{ua}), time to regression of sensory block to S1 (T_{S1}), Sensory block metameric levels during the block, Maximum level of sensory block (SB_{max}), time to maximum level of sensory block (T_{SBmax}), time to regression of two dermatomers with respect to the maximum level of sensory block (T_{rd}), time to first spontaneous urine voiding (T_{uv}), time to administration of rescue anaesthesia or rescue analgesia (T_{ra}), time to first post-operative analgesia (T_{pa}), time to eligibility for home discharge (T_{hd}), proportion of patients achieving effective anaesthesia, quality of spinal block;
- To assess the concentration of chloroprocaine and its metabolite 2-chloro-4-aminobenzoic acid (CABA) in plasma after administration of D1, D2 and D3;
- To assess the excretion of CABA in urine (as % of the administered dose);
- To investigate the safety and tolerability of the administered Chloroprocaine HCl 1% doses on the basis of treatment emergent adverse events, transient neurological symptoms (TNS), vital signs (blood pressure, heart rate and peripheral oxygen saturation [SpO_2]) check and ECG recording.

7.2 Study Design

Prospective, single centre, randomised, parallel-group, observer-blind, three doses, efficacy and pharmacokinetic study.

For details on the study schedule see below (Table 7.2.1).

Table 7.2.1 Study schedule

ACTIVITIES	Screening Phase	Treatment Phase		Follow-up Phase	
Visit	**Visit 1 Days -14/1**	**Visit 2 Day 1**	**Final Visit or ETV Day1/2**	**Day 2 24 h post-surgery**	**Day 7±1**
Informed consent	x				
Demography and lifestyle	x				
Medical/surgical history	x				
Physical examination	x				
Previous and concomitant medication	x	x	x	x	x
Height	x				
Body weight	x				
Vital signs (blood pressure, heart rate)[1]	x	x	x		
SpO_2[1]	x	x	x		
ECG[1]		x	x		
Pregnancy test (urine)	x				
Inclusion/exclusion criteria	x	x			
Enrolment and Randomisation		x			
I.v. Midazolam premedication		x			
Ringer's solution infusion		x[2]			
Spinal injection		x			
Surgery (< 40 min)		x			
Sensory block assessment		x[5]			
Motor block assessment		x[5]			
Blood sampling[3]		x			
Urine collection[4]		x			
Pain assessment		x[7]	x[7]	x[7]	x[7]
TNS questionnaire				x	x
Home discharge[6]			x	x	
Adverse events monitoring	x	x	x	x	x

1. *Vital signs and SpO_2 at screening, at baseline, during the block until the end of the anaesthesia and during post-operative recovery (final visit). ECG (if foreseen by the standard hospital procedures) at baseline, during the block until the end of the anaesthesia and during post-operative recovery (final visit)*
2. *If needed*
3. *Blood samples for PK analysis were collected at baseline and at 5, 10, 30 and 60 min after spinal puncture*
4. *Urine was collected for PK analysis at the time of first spontaneous voiding*
5. *The evolution of both sensory and motor blocks, including sensory block metameric level, were evaluated by a blinded observer every 2 min until readiness for surgery, every 5 min until the maximum level is reached (two consecutive observations with the same level of sensory block) and then every 5 min until regression of two dermatomers with respect to the maximum level of sensory block. After that, sensory and motor block assessments were repeated every 30 min until regression of motor block and complete regression of sensory block to S1 (if compatible with surgical procedure)*
6. *Patients were discharged on Day 1 or on a following day after the criteria for discharge, including Aldrete's scoring scale criteria, are met and according to the hospital's standard procedures. In case of discontinuation, subjects underwent an early termination visit (ETV)*
7. *Pain at the site of injection and pain at the site of surgery was assessed using a 0-10 NRS, where 0 indicates "No pain" and 10 indicates "Worst imaginable pain". At 24 h (day 2) and 6±1 days (day 7±1) after spinal puncture, pain assessment was performed using the TNS questionnaire*

8 STUDY POPULATION

8.1 Target population

Forty-five (45) male/female patients, 15/dose group, aged 18-65 years, scheduled for lower limb surgery (< 40 min) under spinal block, i.e. requiring ≥ T12 metameric level of sensory block.

8.2 Inclusion criteria

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

1. *Sex, age and surgery*: male/female patients, 18-65 years old, scheduled for short duration (less than 40 min) lower limb surgery requiring ≥ T12 metameric level of sensory block
2. *Body Mass Index (BMI)*: 18 - 32 kg/m^2 inclusive
3. *ASA physical status*: I-II
4. *Informed consent*: signed written informed consent before inclusion in the study
5. *Full comprehension*: ability to comprehend the full nature and purpose of the study, including possible risks and side effects; ability to co-operate with the investigator and to comply with the requirements of the entire study

8.3 Exclusion criteria

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

1. *Physical findings*: clinically significant abnormal physical findings which could interfere with the objectives of the study. Contraindications to spinal anaesthesia. History of neuromuscular diseases to the lower extremities
2. *ASA physical status*: III-V
3. *Further anaesthesia*: patients expected to require further anaesthesia
4. *Allergy*: ascertained or presumptive hypersensitivity to the active principle and/or formulations ingredients; ascertained or presumptive hypersensitivity to the ester type and major anaesthetics
5. *Diseases*: significant history of renal, hepatic, gastrointestinal, cardiovascular, respiratory, skin, haematological, endocrine or neurological diseases that may interfere with the aim of the study; ascertained psychiatric and neurological diseases, sepsis, blood coagulation disorders, severe cardiopulmonary disease, thyroid disease, diabetes or other neuropathies
6. *Investigative drug studies*: participation in the evaluation of any investigational product for 3 months before this study, calculated from the first day of the month following the last visit of the previous study
7. *Drug, alcohol*: history of drug or alcohol abuse
8. *Blood donation*: blood donations in the 3 months before this study

9. *Pregnancy and lactation*: missing or positive pregnancy test at screening, pregnant or lactating women
10. *Chronic pain syndromes*: patients with chronic pain syndromes (taking opioids, antidepressants, anticonvulsant agents or chronic analgesic therapy)
11. *Medications*: medication known to interfere with the extent of spinal blocks for 2 weeks before the start of the study. Hormonal contraceptives for females are allowed.

8.3.1 Not allowed treatments and other treatments

No medication known to interfere with the extent of spinal block (see chloroprocaine SmPC), in particular no therapeutic use of opioids, was allowed for 2 weeks before the start of the study and during the whole study duration. Hormonal contraceptives for women are allowed.

The area to be operated was aseptically prepared with disinfectants, e.g. chlorhexidine, not containing iodine. Iodine-based disinfectants must not be used. The information on the iodine-free disinfectant used for each patient was reported in the individual CRFs.

After admission to the operating theatre and before the spinal puncture all patients were premedicated with i.v. midazolam (about 0.03 mg/kg). In addition, only if the investigator deems it necessary, patients were premedicated with 500 or 1000 mL of Ringer's solution administered by infusion.
Post-operative analgesia was given to all patients, if necessary, according to the hospital standard procedures.

9 STUDY SCHEDULE

The schedule of the study is summarised at page 12 (Table 7.2.1).

9.1 Study visits and procedures

The study protocol foresees a screening visit, one study treatment for each patient, followed by post-operative recovery, final visit and 2 follow-ups. Maximum study duration will be 22 days, screening visit and follow-up included. A written informed consent was obtained before any study assessment or procedure.

The first subject first visit (FSFV) is defined as the 1st visit performed at the clinical centre by the 1st screened subject. The last subject last visit (LSLV) is defined as the last telephonic follow-up performed by the last subject, i.e. the last visit foreseen by the study protocol, independently of the fact that the subject is a completer or a withdrawn subject.

The following phases, visits and procedures were performed:

- **Screening phase**
  - Screening - visit 1: between day -14 and day 1
- **Treatment phase**
  - Visit 2 - day 1: anaesthesia and surgery
- **Follow-up phase**
  - Post-operative recovery – day 1 (immediately after surgery)
  - Final visit/early termination visit (ETV). In case of early discontinuation, discontinued subjects underwent an early termination visit (ETV)
  - Day 2 (i.e. 24 h after surgery) - Telephonic follow-up, if the patient has left the hospital on day 1
  - Day 7±1 (6±1 days after surgery) - Telephonic follow-up

	Day	Procedures/Assessments	Notes
Screening - Visit 1	*From day -14 to day 1*	➢ Explanation to the subject of study aims, procedures and possible risks ➢ Informed consent signature ➢ Screening number (as S001, S002, etc.) ➢ Demographic data and life style recording ➢ Previous/concomitant medications ➢ Routine pre-surgery assessments according to the hospital standard procedures, including medical/surgical history, physical examination, height, weight, vital signs (blood pressure, heart rate), SpO_2 ➢ Urine pregnancy test for women ➢ Inclusion/exclusion criteria evaluation ➢ AE monitoring	
Treatment - Visit 2	*Day 1*	➢ Concomitant medications ➢ Adverse events (before, during and after block placement and surgery) ➢ Inclusion/exclusion criteria evaluation ➢ Subject randomisation ➢ Vital signs, SpO_2 and ECG (if foreseen by the standard hospital procedures) ➢ Premedication 1: i.v. midazolam – all patients ➢ Premedication 2: 500 or 1000 mL of Ringer's solution, if needed ➢ Anaesthesia administration (intrathecal injection) ➢ Pain assessment (0-10 NRS) ➢ Post-operative analgesia according to the hospital standard procedures ➢ Sensory and motor block assessments, including sensory block metameric level ➢ Quality of spinal block assessment ➢ Surgery (< 40 min) ➢ Blood sampling for PK analysis at pre-dose (0h) and at 5, 10, 30 and 60 min after spinal puncture ➢ Urine collection for PK analysis at the time of first urine voiding	
Final Visit/ETV	*Day 1/2 or upon discontinuation for ETV*	➢ Final assessments, including pain assessment (0-10 NRS), before discharge according to the hospital's standard procedures ➢ Aldrete's scoring scale ➢ Vital signs (BP, HR, SpO_2) and ECG (if foreseen by the standard hospital procedures) ➢ AE and concomitant medications ➢ Discharge (when criteria for discharge are met and according to the hospital's standard procedures) In case of clinically significant results at the final visit, the subjects will be followed-up by the investigator until the normalisation of the concerned clinical parameter(s)	Standardised meals will be served according to the hospital procedures. Patients will be discharged on Day 1 or on a following day after the criteria for discharge are met and according to the hospital's standard procedures.

	Day	Procedures/Assessments	Notes
Follow-up	*Day 2 (24 h after surgery)*	➢ AE, in particular TNS (questionnaire) ➢ Concomitant medications	
Follow-up	*Day 7±1 post-surgery*	➢ AE, in particular TNS (questionnaire) ➢ Concomitant medications	

9.2 Diet and lifestyle

Study participants underwent study procedures as outpatients or in-patients, according to the decision of the study investigator. Patients arrived at the clinical centre either in the morning of the scheduled surgery day or the previous evening, according to the hospital requirements, and were discharged on Day 1 or on a following day after meeting the criteria for discharge, according to the hospital procedures.

On day 1, patients were under fasting conditions before surgery. Clear fluids intake was allowed until 2 h before surgery. The patients remained under fasting conditions until surgery has been completed and according to the investigator's opinion. Meals were served according to the hospital's standard procedures.

10 SUBJECT IDENTIFICATION AND ASSIGNMENT OF STUDY TREATMENT

10.1 Unique subject identifier

All the subjects who sign the informed consent form 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.1/2-2014), the 3-digit centre number (i.e. 001), the 4-digit screening number (e.g. S001, S002, etc.) and, if applicable, the 3-digit subject randomisation number (i.e. 001, 002, …, 046). Study code, centre number, screening number and subject randomisation number are separated by slashes ("/"). The last 8 digits of the unique subject identifier (enrolled subjects), corresponding to the subject screening and subject randomisation numbers separated by a slash, will appear as subject identifier in the individual listings and figures of the clinical study report and will be used to identify the subjects in in-text tables or wording (if applicable).

10.2 Randomisation

The randomisation list was computer generated by the Biometry Unit of the Clinical Contract Research Organization (CRO), using the PLAN procedure of the SAS® system version 9.3 (TS1M1) (4) or higher for Windows (the version will be stated in the final clinical study report). The randomisation list will be attached to the final clinical study report.

10.3 Treatment allocation

Patients were allocated to D1, D2 or D3 dose group in a 1:1:1 ratio according to the study randomisation list.

Randomisation number was given to the patients on study Day 1 and was used to allocate each patient to a dose group, as detailed above.

The 5-mL ampoules with the investigational product were numbered. Each patient was allocated the product ampoule corresponding to his/her randomisation number.

10.4 Blinding

This is an observer-blind study. No masking procedure was applied.

The physician preparing and the physician administering the doses was not involved in data recording and evaluation. An independent blinded observer evaluated sensory and motor blocks for each patient.

Emergency envelopes containing individual randomisation codes were sent to the clinical centre. Breaking of an individual randomisation code during the study was allowed only when knowledge of the code was essential for the patient's health. In this case, only the envelope related to the concerned subject would have been opened. Individual code breaking would have been clearly reported in the patient CRF and on the envelope.

The clinical centre also received individual kit replacement envelopes. If a reserve kit needed to be used, the kit replacement envelope would be opened and the injectable solution would be prepared in such a way that the observer blind condition of the study is maintained. The date and the reason for kit replacement envelope opening would be recorded on the envelope.

No breaking of any individual randomisation code occurred during the study and the reserve kit number K050 was used for the subject with randomisation number 046, who was enrolled in addition to the originally scheduled 45 patients (2).

11 EVALUATION PARAMETERS

11.1 Study variables

11.1.1 Primary variables

Time to regression of spinal block (T_{ea}), defined as the time when Bromage score returns to 0 and sensitive perception returns to S1.

11.1.2 Secondary variables

11.1.2.1 Efficacy variables

- Time to onset of sensory block (T_{sb})
- Time to onset of motor block (T_{mb})
- Time to readiness for surgery (T_{rs}), defined as loss of pinprick sensation at the required metameric level ≥ T12 with a modified Bromage score ≥ 2
- Time to regression of motor block (Bromage score = 0; T_{rmb})
- Time to unassisted deambulation (T_{ua})
- Time to regression of sensory block to S1 (T_{S1})
- Sensory block metameric level (SBML, assessed until resolution of sensory block to S1)
- Maximum level of sensory block (SB_{max})
- Time to maximum level of sensory block (T_{SBmax})
- Time to regression of two dermatomers with respect to the maximum level of sensory block (T_{rd})
- Time to eligibility for home discharge (T_{hd})
- Time to first spontaneous urine voiding (T_{uv})
- Time to administration of rescue anaesthesia or rescue analgesia (T_{ra})
- Time to first post-operative analgesia (T_{pa})
- Proportion of patients achieving an effective anaesthesia
- Quality of spinal block

11.1.2.2 Pharmacokinetic variables

- Plasma concentrations of chloroprocaine and CABA at baseline (i.e. before spinal puncture) and at 5, 10, 30 and 60 min after spinal puncture
- Urine excretion of CABA from spinal puncture to time of first urine voiding

11.1.2.3 Safety variables

- Treatment-emergent adverse events throughout the study

- Incidence of TNS at 24 h (day 2) and 6±1 days (day 7±1) after spinal puncture (Tsp)
- Vital signs (BP, HR and SpO_2), ECG
- Pain assessment at the site of injection and at the site of surgery performed immediately after regression of spinal block, at discharge (final visit/ETV), 24 h (day 2) and 6±1 days (day 7±1) after spinal puncture

11.2 Efficacy assessments

Sensory and motor block assessment procedures and evaluations are detailed in section 7.2 of the study protocol (1).

Efficacy assessments are based on the following variables:

Parameter	**Description**
Time (min) to onset of sensory block (T_{sb})	Time period from spinal injection (T_{sp}; time 0 h) to achievement of sensory block (see section 7.2 of the study protocol [1]).
Time (min) to onset of motor block (T_{mb})	Time period from spinal injection (T_{sp}; time 0 h) to achievement of motor block (see section 7.2 of the study protocol [1]).
Time (min) to readiness for surgery (T_{rs})	Time period from completion of spinal injection (T_{sp}; time 0 h) to achievement of sensory and motor block adequate for surgery, i.e. loss of Pinprick sensation and Bromage's score ≥ 2 at the required metameric level ≥ T12
Time (h) to regression of spinal block (T_{ea})	Time period from spinal injection (T_{sp}; time 0 h) to the time when the Bromage score returns to 0 and sensitive perception returns to S1
Time (h) to regression of sensory block to S1 (T_{S1})	Time period from spinal injection (T_{sp}; time 0 h) to the time when sensitive perception has returned to S1
Time (h) to regression of motor block (T_{rmb})	Time period from spinal injection (T_{sp}; time 0 h) to the time when the Bromage score has returned to 0
Time (h) to unassisted ambulation (T_{ua})	Time period from spinal injection (T_{sp}; time 0 h) to the time when the patient can walk unassisted
Sensory block metameric level (SBML)	Metameric level of sensory block assessed from spinal injection (T_{sp}; time 0 h) until regression of sensory block to S1
Maximum level of sensory block (SB_{max})	Maximum metameric level of sensory block (decreased or absent sensation) achieved
Time (min) to maximum level of sensory block (T_{SBmax})	Time period from spinal injection (Tsp; time 0 h) to the time when the maximum metameric level of sensory block is achieved (consider the time of the first of the two consecutive observations with the same level of sensory block)

Parameter	Description
Time (h) to regression of two dermatomers with respect to the maximum level of sensory block (T_{rd})	Time period from spinal injection (T_{sp}; time 0 h) to the time when the sensory block decrease of two dermatomers with respect to the maximum level of sensory block
Time (h) to eligibility for home discharge (T_{hd})	Time period from spinal injection (T_{sp}; time 0 h) to the time when the criteria from discharge are met, even if according to the hospital procedures the patient is discharged at a later time
Time (h) to first spontaneous urine voiding (T_{uv})	Time period from spinal injection (T_{sp}; time 0 h) to the first time when the patient can pass urine unassisted
Time (h) to administration of rescue anaesthesia or rescue analgesia (T_{ra})	Time from spinal injection(T_{sp}; time 0 h) to administration of first rescue anaesthesia or analgesia (if applicable)
Time (h) to first post-operative analgesia (T_{pa})	Time from spinal injection (T_{sp}; time 0 h) to first post-operative analgesia

11.3 Pharmacokinetic assessments

- Plasma concentrations of chloroprocaine at pre-dose and at 5, 10, 30 and 60 min after spinal injection for the three dose levels (D1, D2 and D3)
- Plasma concentrations of CABA at pre-dose and at 5, 10, 30 and 60 min after spinal injection for the three dose levels (D1, D2 and D3)
- Urinary excretion of CABA, as percentage of administered chloroprocaine dose for the three dose levels (D1, D2 and D3)

11.4 Safety assessments

Safety and general tolerability of the investigational anaesthetic will be based on TEAEs, TNS, physical examinations, vital signs and ECG.

In particular, ECG (if foreseen by the standard hospital procedures), blood pressure, heart rate and SpO_2 will be monitored as detailed in sections 7.1.1 and 7.1.2 of the study protocol (1).

Occurrence of clinically relevant hypotension or bradycardia will be monitored throughout the study and, if observed, treated according to the hospitals' standard procedures.

Patients will be questioned about the occurrence of treatment-emergent adverse events (TEAEs). Particular attention will be given to TNS symptoms. Further details on the AE assessments are given in section 7.1.4 of the study protocol (1).

12 STATISTICAL METHODS

The data documented in this study and the parameters measured will be evaluated and compared using classic descriptive statistics, i.e. geometric mean (PK data only), arithmetic mean, SD, CV (%), minimum, median and maximum values for quantitative variables, and frequencies for qualitative variables.

Not available data will be evaluated as "missing values". The statistical analysis of demographic and safety data will be performed using SAS® version 9.3 (TS1M1) (4).
The PK analysis will be performed using SAS® version 9.3 (TS1M1) (4) and the figures will be generated using Phoenix WinNonlin® version 6.3 (5).

12.1 Analysis sets

12.1.1 Definitions

A subject will be defined as screened after the signature of the informed consent, regardless of the completion of all the screening procedures.

A subject will be defined as eligible if he/she respects all the inclusion/exclusion criteria. Otherwise he/she will be defined as a screen failure.

A subject will be defined as enrolled in the study if he/she is included into the treatment phase of the study. The enrolment will be performed through randomised allocation to a dose group.

A subject will be defined as randomised in the study when he/she is assigned to a randomised dose group.

- Enrolled set: all enrolled subjects. This analysis set will be used for demographic, baseline and background characteristics.
- Full Analysis Set (FAS): all randomised patients who fulfil the study protocol requirements in terms of study anaesthetics administration. Missing values of time to complete spinal block regression (T_{ea}) will be replaced with the highest T_{ea} detected in the corresponding treatment group. This analysis set will be used for sensitivity analysis.
- Per Protocol set (PP): all randomised patients who fulfil the study protocol requirements in terms of anaesthetic administration and primary efficacy evaluation, with no major deviations that could affect the primary efficacy results. This analysis set will be used for the primary efficacy analysis.
- PK Set 1 (PK 1): the PK set 1 will include all randomised patients who fulfil the study protocol requirements in terms of anaesthetic administration and have at least one post-dose blood PK sample collected.
- PK Set 2 (PK 2): the PK set 2 will include all randomised patients who fulfil the study protocol requirements in terms of anaesthetic administration and have the urine for PK analysis collected.

- Safety set: all patients who receive at least one dose of the investigational medicinal product. This analysis set will be used for the safety analyses.

Each subject will be coded by the CRO Biometry Unit as valid or not valid for the Enrolled set, FAS, PP set, PK set 1, PK set 2 and Safety set. Subjects will be evaluated according to the treatment they actually receive (Enrolled set, FAS, PP set, PK set 1, PK set 2 and Safety set).

12.1.2 Reasons for exclusion from the Full Analysis Set

Reasons for the exclusion from the Full Analysis Set are the following:

- failure to be administered the investigational product
- lack of any primary efficacy data post enrolment
- failure to satisfy major inclusion/exclusion criteria (eligibility violations). Subjects who fail to satisfy an inclusion/exclusion criterion may be excluded from the analysis without the possibility of introducing bias only under the following circumstances:
  - the inclusion/exclusion criterion was measured prior to enrolment
  - the detection of the relevant eligibility violations can be made completely objectively
  - all subjects receive equal scrutiny for eligibility violations (blind review)
  - all detected violations of the particular inclusion/exclusion criterion are excluded

12.1.3 Reasons for exclusion from the Per Protocol set

Reasons for the exclusion from the Per Protocol set include the following:

- lack of compliance to the IMP
- exposure to an IMP different from the one assigned to the subject
- missing primary efficacy data
- more than 20% of the actual block assessment times outside the recommended ranges (see section 7.2 of the study protocol [1])
- failure to satisfy any inclusion/exclusion criteria (eligibility violations)

12.1.4 Reasons for exclusion from the PK sets

Reasons for the exclusion from the PK sets include the following:

- lack of compliance to the IMP
- exposure to an IMP different from the one assigned to the subject
- missing of any post-dose blood sample (PK set 1)
- missing of urine collection for PK analysis (PK set 2)
- failure to satisfy any inclusion/exclusion criteria (eligibility violations)

12.2 Sample size and power considerations

To calculate the required study sample size, results from a previous study with spinal injection of Chloroprocaine HCl 1% (6) were taken into consideration and normal distribution of data was assumed. Sample size was calculated using n-Query Advisor 7.0. When the sample size in each of the 3 dose groups is 13, a one-way analysis of variance will have 80% power to detect at the 0.050 level a difference in time to complete spinal block regression (T_{ea}) means characterized by a variance of means, $V=\Sigma(\mu i - \mu)^2 / G$ (where G=3) of 249.962, assuming that the common standard deviation is 30.011. To be more conservative and to take into account possible deviations from normality, the sample size is increased of about 15%. At least fifteen (15) patients per dose group have to be enrolled in order to have 15 administered patients per dose group.

12.3 Handling of missing data

12.3.1 Missing values of efficacy assessments

For the analysis on the Full Analysis Set, missing values of time to complete spinal block regression (T_{ea}) will be replaced with the highest T_{ea} detected in the corresponding dose level group.

For the analysis on the Per Protocol Set and on the Full Analysis Set, any other missing values of the secondary efficacy assessments will not be replaced and will be treated as missing values.

12.3.2 Missing values of pharmacokinetic assessments

Missing values of the pharmacokinetic assessments will not be replaced and will be treated as missing data in the statistical analysis.

12.3.3 Missing values of safety assessments

Missing values of the safety assessments will not be replaced and will be treated as missing data in the statistical analysis.

12.4 Demographic, baseline and background characteristics

Continuous variables will be summarised by dose level group using classic descriptive statistics (i.e. mean, SD, CV%, min, median and max) and categorical variables will be summarised by dose level group using tables of frequencies.

12.4.1 Subjects' disposition

The disposition of all subjects enrolled in the study will be listed (Listing 16.2.4.1) and summarised by dose level and overall (Table 14.1.1.1). The number and proportion of subjects completing the study, the number and proportion of withdrawals and the reasons for withdrawal will be presented.

12.4.2 Analysis sets

The subjects included in each analysis set will be listed (Listing 16.2.4.2) and summarised by dose level and overall (Table 14.1.1.2). Reason for exclusion will be listed.

12.4.3 Subjects excluded from the efficacy and/or PK and/or Safety analysis

All subjects excluded from the efficacy and/or PK and/or Safety analysis will be listed (Listing 16.2.3.1) and the reasons for exclusion will be reported.

12.4.4 Inclusion/exclusion criteria not met

All the inclusion/exclusion criteria not met will be listed (Listing 16.2.4.4) and summarised by dose level and overall (Table 14.1.1.4) . The number and proportion of subjects for each criterion not met will be reported.

12.4.5 Protocol deviations

All the protocol deviations reported during the clinical trial will be listed (Listing 16.2.2.1) and summarised by dose level and overall (Table 14.1.1.5). The number and proportion of subjects for each deviation will be reported.

12.4.6 Discontinued subjects

All subjects who discontinued the clinical trial (if any) will be listed (Listing 16.2.1.1). The dose level of IMP administered, sex, age, last visit performed before discontinuation, time elapsed from IMP spinal injection (days), date of premature discontinuation and primary reason for subject premature discontinuation will be reported.

12.4.7 Demography

Demographic data will be listed (Listing 16.2.4.3) and summarised by dose level and overall (Table 14.1.1.3). The number and proportion of subjects in each category for categorical variables (e.g. race) and descriptive statistics (mean, SD, CV%, minimum, median and maximum) for continous variables (e.g. age, weight) will be presented.

12.4.8 Medical and surgical history

All the diseases of medical history and the surgeries of all subjects enrolled in the study will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 18.1, listed (Listing 16.2.10.2) and summarised (Table 14.1.1.6). The number and proportion of subjects for each System Organ Class (SOC) and Preferred Term (PT) will be presented.

12.4.9 Physical examination

Date of the physical examination, ASA physical status, overall investigator's interpretation (as normal [N], abnormal not clinically significant [NCS] or abnormal clinically significant [CS]) and CS findings/illnesses (if any) will be listed (Listing 16.2.10.2).

12.4.10 Prior and concomitant medications

Prior and concomitant medications/therapies will be listed (Listing 16.2.10.3) and summarised (Table 14.1.1.7) as number and proportion of subjects being treated with any type of medication/therapy classified according to the standardised product name recorded in the World Health Organization (WHO) Drug Dictionary Enhanced (WHODDE version September 1, 2015) and to the Anatomical Therapeutic Chemical (ATC) classification system.

12.4.11 Subjects study visits

The dates of all subjects study visits will be listed (Listing 16.2.10.4).

12.4.12 Pregnancy test

The date/time of urine collection for pregnancy test and the test' result will be listed (Listing 16.2.10.5).

12.5 Analysis of efficacy parameters

Continuous variables will be summarised by dose level group using classic descriptive statistics (i.e. mean, SD, CV%, min, median and max) and categorical variables will be summarised by dose level group using tables of frequencies.

12.5.1 Surgical procedure

The type of surgery, the required metameric level of sensory block, the date/time of surgery start and end, the intake of any rescue anaesthesia or rescue analgesia administered before or during the surgical procedure and whether or not a general anaesthesia was required to complete surgery will be listed (Listing 16.2.6.1).

12.5.2 Sensory and motor block assessment

The scheduled assessment time, the assessment date and time, the metameric level of sensory block and the Bromage score will be listed (Listing 16.2.6.2).

12.5.3 Time to events and maximum level of sensory block

The time to regression of spinal block (T_{ea}), time to onset of sensory block (T_{sb}), time to onset of motor block (T_{mb}), time to readiness for surgery (T_{rs}), time to regression of sensory block to S1 (T_{S1}), time to regression of motor block (T_{rmb}), time to unassisted ambulation (T_{ua}), time to maximum level of sensory block (T_{SBmax}), time to regression of two dermatomers with respect to the maximum level of sensory block (T_{rd}), time to eligibility for home discharge (T_{hd}), time to first spontaneous urine voiding (T_{uv}), time to administration of rescue anaesthesia or rescue analgesia (T_{ra}) and time to first post-operative analgesia (T_{pa}) will be listed (Listing 16.2.6.3) and will be summarised by dose level group and overall using descriptive statistics (Table 14.2.1.1, Table 14.2.1.2).

The maximum level of sensory block (SB_{max}) will be listed (Listing 16.2.6.3) and will be summarised by dose level group and overall using tables of frequency (Table 14.2.1.3, Table 14.2.1.4).

Due to the small sample size, collected data will be compared using nonparametric tests. T_{ea}, T_{sb}, T_{mb}, T_{rs}, T_{S1}, T_{rmb}, T_{ua}, SB_{max}, T_{SBmax}, T_{rd}, T_{hd}, T_{uv}, T_{ra} and T_{pa} will be analysed using the Kruskal-Wallis test. Pairwise comparisons between dose level groups will be performed using the Wilcoxon rank-sum test (Table 14.2.2.1, Table 14.2.2.2, Table 14.2.2.3, Table 14.2.2.4). Comparisons will be performed according to the following hierarchical order:

1. Overall comparison
2. D1 (30 mg) vs. D3 (50 mg) comparison
3. D2 (40 mg) vs. D3 (50 mg) comparison
4. D1 (30 mg) vs. D2 (40 mg) comparison

Due to the hierarchical testing procedure, no formal adjustment of the alpha level is necessary (7). However, if a null hypothesis of a comparison cannot be rejected, all the null hypotheses of the subsequent comparisons cannot be rejected.

12.5.4 Effectiveness of anaesthesia and quality of spinal block

The date and time of assessment and the evaluations of effectiveness of anaesthesia and quality of spinal block will be listed (Listing 16.2.6.4) and will be summarised by dose level group and overall using tables of frequencies (Table 14.2.1.5, Table 14.2.1.6, Table 14.2.1.7, Table 14.2.1.8).

12.6 Analysis of pharmacokinetic parameters

The date and time of blood samples collection, the plasma concentrations of chloroprocaine and CABA, the date and time of urine sample collection and the urinary excretion of CABA will be listed (Listing 16.2.5.3, Listing 16.2.5.4).

A descriptive PK will be presented. The results will be displayed and summarised in tables (Table 14.2.3.1, Table 14.2.3.2) and figures (Figure 16.2.5.j, Figure 14.2.3.1, Figure 14.2.3.2). Individual and mean curves (+SD at sampling times), indicating inter-subject variability, will be plotted. Data below the lower quantification limit (BLQL) will be considered as 0 in the calculations and presented as BLQL in listings and tables. As a consequence of BLQL (i.e. 0) values, calculated geometric means (if requested) could be null. For this reason, in the presence of any null value, the geometric mean will be reported as not calculated (NC). PK analysis will be performed using SAS® version 9.3 (TS1M1) (4) and the figures will be generated using Phoenix WinNonlin® version 6.3 (5).

Urinary excretion of CABA will be calculated as the amount of metabolite excreted as a percentage of the administered dose (molar ratio).

12.7 Safety and tolerability evaluation

Continuous variables will be summarised by dose level group using classic descriptive statistics (i.e. mean, SD, CV%, min, median and max) and categorical variables will be summarised by dose level group using tables of frequencies.

12.7.1 Adverse events

A summary of AE definition, classification and management is reported in the section 11 of the study protocol (1).

Adverse events (AEs) will be coded by System Organ Class (SOC) and Preferred Term (PT), using the Medical Dictionary for Regulatory Activities (MedDRA) version 18.1.

AEs will be classified as pre-treatment AEs (PTAEs) and TEAEs according to the period of their occurrence, as follows:

- PTAEs: all AEs occurring before the IMP spinal injection and not worsening after the IMP spinal injection
- TEAEs: all AEs occurring or worsening after the IMP spinal injection

Individual TEAEs and PTAEs will be listed in two different subject data listings (Listing 16.2.7.1, Listing 16.2.7.2).

No summary table will be provided for PTAEs.

TEAEs will be summarised by dose level group and overall using frequency tables. The number and proportion of subjects with any TEAE, the number of TEAEs, the number and proportion of subjects with any TEAE by severity, the number of TEAEs by severity, the number and proportion of subjects with any TEAE related to the IMP, the number of TEAEs related to the IMP will be presented (Table 14.3.1.1, Table 14.3.1.2, Table 14.3.1.3, Table 14.3.1.4).

Should any serious TEAE occur, serious TEAEs will be summarised using frequency tables. The number and proportion of subjects with any serious TEAE, the number of serious TEAEs, the number and proportion of subjects with any serious TEAE related to the IMP and the number of serious TEAEs related to the IMP would be presented (Table 14.3.1.5, Table 14.3.1.6).

Additionally, all TEAEs leading to death, serious TEAEs and TEAEs leading to discontinuation will be listed separately, if applicable (Table 14.3.2.1).

12.7.2 Vital signs

For screening, baseline and discharge (i.e. final/early termination visit) assessments of haemodynamic variables and for any other assessment judged clinical significant, the date and time of vital signs assessment and the values of Systolic Blood Pressure, Diastolic Blood Pressure, Heart Rate and Oxygen Saturation will be listed (Listing 16.2.9.1).

Screening, baseline and discharge (i.e. final/early termination visit) values of Systolic Blood Pressure, Diastolic Blood Pressure, Heart Rate and Oxygen Saturation will be summarised by dose level group and overall using descriptive statistics (Table 14.3.5.1).

12.7.3 ECG

For any ECG assessment judged clinical significant, the date and time of ECG recording, overall investigator's interpretation (as normal, abnormal not clinically significant [NCS] or abnormal clinically significant [CS]) and the values Heart Rate, PR Interval, QRS Duration and QT Interval parameters will be listed (Listing 16.2.9.2).

12.7.4 Pain assessment at the site of injection and at the site of surgery

Pain assessment at the site of injection and at the site of surgery immediately after regression of spinal block, at discharge (final visit/ETV), 24 h (day 2) and 6±1 days (day 7±1) after spinal injection will be listed (Listing 16.2.9.3) and will be summarised by dose level group and overall using frequency tables (Table 14.3.5.2).

12.7.5 Incidence of TNS at 24 h (day 2) and 6 days±1 (day 7±1) after spinal injection (T_{sp})

The incidence of TNS at 24 h (day 2) and 6±1 days (day 7±1) after spinal injection (T_{sp}) will be listed (Listing 16.2.9.4) and will be summarised by dose level group and overall using tables of frequency (Table 14.3.5.3).

12.7.6 Modified Aldrete's scoring scale

The assessments of the modified Aldrete's scoring scale will be listed (Listing 16.2.9.5).

12.7.7 Spinal injection

The date/time of spinal injection, the anatomical location of spinal injection, the identifier of the kit used and whether or not the planned volume was administered as per protocol will be listed (Listing 16.2.5.1).

12.7.8 Sedation and premedication

The administration of i.v. midazolam, the date and time of injection and the injected dose (if applicable), the administration of Ringer's solution, the date and time of infusion start and end and the infused volume (if applicable) will be listed (Listing 16.2.5.2).

13 REFERENCES

1. Study Protocol CRO-14-122 / CHL.1/02-2014. Spinal anaesthesia with Chloroprocaine HCl 1% for elective lower limb procedures of short duration: a prospective, randomised, observer-blind study in adult patients. Final version 2.0, 28JAN2015
2. Study Protocol CRO-14-122 / CHL.1/02-2014. Spinal anaesthesia with Chloroprocaine HCl 1% for elective lower limb procedures of short duration: a prospective, randomised, observer-blind study in adult patients. Amendment Nr. 3, Final version 1.0, 03NOV2015
3. U.S. Department of Health and Human Services and U.S. Department of Agriculture, Nutrition and your health: Dietary Guidelines for Americans, 2010
4. SAS/STAT® 9.3 User's Guide
5. WinNonlin® Getting Started Guide, Pharsight Corporation
6. Casati A, Danelli G, Berti M, Fioro A, Fanelli A, Benassi C, Petronella G, Fanelli G. Intrathecal 2-chloroprocaine for lower limb outpatient surgery: a prospective, randomized, double-blind, clinical evaluation. Anesth Analg. 2006 Jul;103(1):234-8, table of contents
7. EMA CPMP/EWP/908/99 guideline "Points to consider on multiplicity issues in clinical trials", 19 September 2002

14 APPENDICES

Appendix 1. Section 14 - Tables and Figures Shells

Appendix 2. Section 16.2 - Individual Subject Data Listings and Figures Shells

Section 14 - Tables and Figures Shells

Section 14 - Tables and Figures Shells

Table 14.1.1.1 - Subjects' disposition (Enrolled set)

	Enrolled Set Chloroprocaine 1% 30 mg N=XX n (%)	40 mg N=XX n (%)	50 mg N=XX n (%)	Overall N=XX n (%)
Randomised	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Discontinued before treatment	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Treated	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Completed	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Discontinued	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Reason A	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Reason B	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the enrolled set
Source: Listing 16.2.4.1 - Subjects' disposition
Program: Tables\c122-ds-tbl.sas

Table 14.1.1.2 - Analysis sets (Enrolled set)

	Enrolled Set Chloroprocaine 1%			
	30 mg N=XX n (%)	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Safety Set	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Full Analysis Set	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Per Protocol Set	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
PK Set 1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
PK Set 2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the enrolled set
Source: Listing 16.2.4.2 - Analysis sets
Program: Tables\c122-ds-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

			Enrolled Set Chloroprocaine 1%			
		Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Race	American Indian or Alaska Native	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Asian	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Native Hawaiian or Other Pacific Islander	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Black or African American	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	White	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Other	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age (years)		N	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the enrolled set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

		Enrolled Set Chloroprocaine 1%			
	Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Height (cm)	N	nn	nn	nn	nn
	Mean	xxx.x	xxx.x	xxx.x	xxx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xxx	xxx	xxx	xxx
	Median	xxx.x	xxx.x	xxx.x	xxx.x
	Max	xxx	xxx	xxx	xxx
Weight (kg)	N	nn	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the enrolled set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

		Enrolled Set Chloroprocaine 1%			
	Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Body Mass Index (kg/m^2)	N	nn	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the enrolled set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

			Safety Set Chloroprocaine 1%			
		Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Race	American Indian or Alaska Native	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Asian	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Native Hawaiian or Other Pacific Islander	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Black or African American	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	White	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Other	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age (years)		N	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

		Safety Set Chloroprocaine 1%			
	Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Height (cm)	N	nn	nn	nn	nn
	Mean	xxx.x	xxx.x	xxx.x	xxx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xxx	xxx	xxx	xxx
	Median	xxx.x	xxx.x	xxx.x	xxx.x
	Max	xxx	xxx	xxx	xxx
Weight (kg)	N	nn	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

		Safety Set Chloroprocaine 1%			
	Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Body Mass Index (kg/m^2)	N	nn	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

			Full Analysis Set Chloroprocaine 1%			
		Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Race	American Indian or Alaska Native	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Asian	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Native Hawaiian or Other Pacific Islander	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Black or African American	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	White	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Other	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age (years)		N	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the full analysis set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

		Full Analysis Set Chloroprocaine 1%			
	Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Height (cm)	N	nn	nn	nn	nn
	Mean	xxx.x	xxx.x	xxx.x	xxx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xxx	xxx	xxx	xxx
	Median	xxx.x	xxx.x	xxx.x	xxx.x
	Max	xxx	xxx	xxx	xxx
Weight (kg)	N	nn	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the full analysis set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

		Full Analysis Set Chloroprocaine 1%			
	Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Body Mass Index (kg/m^2)	N	nn	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the full analysis set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

			Per Protocol Set Chloroprocaine 1%			
		Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Sex	Female	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Male	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Race	American Indian or Alaska Native	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Asian	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Native Hawaiian or Other Pacific Islander	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Black or African American	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	White	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Other	n (%)	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Age (years)		N	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

		Per Protocol Set Chloroprocaine 1%			
	Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Height (cm)	N	nn	nn	nn	nn
	Mean	xxx.x	xxx.x	xxx.x	xxx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xxx	xxx	xxx	xxx
	Median	xxx.x	xxx.x	xxx.x	xxx.x
	Max	xxx	xxx	xxx	xxx
Weight (kg)	N	nn	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.3 - Demography (Enrolled set, Safety set, Full analysis set and Per protocol set)

		Per Protocol Set Chloroprocaine 1%			
	Statistics	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Body Mass Index (kg/m^2)	N	nn	nn	nn	nn
	Mean	xx.xx	xx.xx	xx.xx	xx.xx
	SD	xx.xx	xx.xx	xx.xx	xx.xx
	CV%	xx.xx	xx.xx	xx.xx	xx.xx
	Min	xx.x	xx.x	xx.x	xx.x
	Median	xx.xx	xx.xx	xx.xx	xx.xx
	Max	xx.x	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Source: Listing 16.2.4.3 - Demography
Program: Tables\c122-dm-tbl.sas

Table 14.1.1.4 - Inclusion/Exclusion criteria not met (Enrolled set)

	Enrolled Set Chloroprocaine 1%			
	30 mg N=XX n (%)	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Number of subjects who did not meet any inclusion/exclusion criterion	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Inclusion criterion 2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...	...
Exclusion	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Exclusion criterion 2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the enrolled set
Source: Listing 16.2.4.4 - Inclusion/Exclusion criteria not met
Program: Tables\c122-ie-tbl.sas

Table 14.1.1.5 - Protocol deviations (Enrolled set, Full analysis set and Per protocol set)

	Enrolled Set Chloroprocaine 1% 30 mg N=XX n (%)	40 mg N=XX n (%)	50 mg N=XX n (%)	Overall N=XX n (%)
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation Coded Term A	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation Coded Term B	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...	...
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation Coded Term C	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation Coded Term D	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the enrolled set
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\c122-dv-tbl.sas

Table 14.1.1.5 - Protocol deviations (Enrolled set, Full analysis set and Per protocol set)

	Full Analysis Set Chloroprocaine 1%			
	30 mg N=XX n (%)	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Major	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation Coded Term A	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation Coded Term B	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...	...
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation Coded Term C	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation Coded Term D	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the full analysis set
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\c122-dv-tbl.sas

Table 14.1.1.5 - Protocol deviations (Enrolled set, Full analysis set and Per protocol set)

	Per Protocol Set Chloroprocaine 1% 30 mg N=XX n (%)	 40 mg N=XX n (%)	 50 mg N=XX n (%)	 Overall N=XX n (%)
Number of subjects with any protocol deviation	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Minor	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation Coded Term C	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Deviation Coded Term D	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Source: Listing 16.2.2.1 - Protocol deviations
Program: Tables\c122-dv-tbl.sas

Table 14.1.1.6 - Medical and surgical history (Safety set)

	Safety Set Chloroprocaine 1%			
System Organ Class [1] **Preferred Term [1]**	**30 mg** **N=XX** **n (%) [n MH/SH]**	**40 mg** **N=XX** **n (%) [n MH/SH]**	**40 mg** **N=XX** **n (%) [n MH/SH]**	**Overall** **N=XX** **n (%) [n MH/SH]**
Number of subjects with any disease or surgery	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
System Organ Class A	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Preferred Term A	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Note 1: MedDRA version 18.1
Source: Listing 16.2.10.1 - Medical and surgical history
Program: Tables\c122-mh-tbl.sas

Table 14.1.1.7 - Prior and concomitant medications (Safety set)

Prior or Concomitant ATC level 4 [1] Standardised name [1]	Safety Set Chloroprocaine 1% 30 mg N=XX n (%) [n CM]	40 mg N=XX n (%) [n CM]	50 mg N=XX n (%) [n CM]	Overall N=XX n (%) [n CM]
Number of patients with any prior or concomitant medication	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Prior	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
ATC level 4 Term A	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Standardised name A	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Standardised name B	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
...	...	...	...	...
Concomitant	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
ATC level 4 Term A	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Standardised name A	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Standardised name B	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Note 1: WHODDE September 1, 2015
Source: Listing 16.2.10.3 - Prior and concomitant medications
Program: Tables\c122-cm-tbl.sas

Table 14.2.1.1 - Time to events (Per protocol set)

		Per Protocol Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Regression of Spinal Block (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Onset of Sensory Block (min)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.1 - Time to events (Per protocol set)

		Per Protocol Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Onset of Motor Block (min)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Readiness for Surgery (min)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.1 - Time to events (Per protocol set)

		Per Protocol Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Regression of Sensory Block (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Regression of Motor Block h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.1 - Time to events (Per protocol set)

		Per Protocol Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Unassisted Ambulation (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Maximum Level of Sensory Block (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.1 - Time to events (Per protocol set)

		Per Protocol Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Regression of Two Dermatomers (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Eligibility for Home Discharge (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.1 - Time to events (Per protocol set)

		Per Protocol Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
First Spontaneous Urine Voiding (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Rescue Anaesthesia/Analgesia (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.1 - Time to events (Per protocol set)

		Per Protocol Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
First Post-Operative Analgesia (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.2 - Time to events (Full analysis set)

		Full Analysis Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Regression of Spinal Block (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Onset of Sensory Block (min)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.2 - Time to events (Full analysis set)

		Full Analysis Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Onset of Motor Block (min)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Readiness for Surgery (min)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.2 - Time to events (Full analysis set)

		Full Analysis Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Regression of Sensory Block (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Regression of Motor Block h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.2 - Time to events (Full analysis set)

		Full Analysis Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Unassisted Ambulation (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Maximum Level of Sensory Block (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.2 - Time to events (Full analysis set)

		Full Analysis Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Regression of Two Dermatomers (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Eligibility for Home Discharge (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.2 - Time to events (Full analysis set)

		Full Analysis Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
First Spontaneous Urine Voiding (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx
Rescue Anaesthesia/Analgesia (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.2 - Time to events (Full analysis set)

		Full Analysis Set Chloroprocaine 1%			
Time to	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
First Post-Operative Analgesia (h)	N	nn	nn	nn	nn
	Mean	xx.x	xx.x	xx.x	xx.x
	SD	xx.x	xx.x	xx.x	xx.x
	CV%	xx.x	xx.x	xx.x	xx.x
	Min	xx	xx	xx	xx
	Median	xx.x	xx.x	xx.x	xx.x
	Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.3 - Maximum level of sensory block (Per protocol set)

		Per Protocol Set Chloroprocaine 1%			
	Metameric Level	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Maximum Level of Sensory Block	T1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	T2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	T3	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	T4	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.4 - Maximum level of sensory block (Full analysis set)

		Full Analysis Set Chloroprocaine 1%			
	Metameric Level	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Maximum Level of Sensory Block	T1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	T2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	T3	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	T4	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the full analysis set
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.5 - Effectiveness of anaesthesia (Per protocol set)

		Per Protocol Set Chloroprocaine 1% 30 mg N=XX n (%)	40 mg N=XX n (%)	50 mg N=XX n (%)	Overall N=XX n (%)
Achievement of an Effective Anaesthesia	Y	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	N	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Source: Listing 16.2.6.4 - Effectiveness of anaesthesia and quality of spinal block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.6 - Effectiveness of anaesthesia (Full analysis set)

		Full Analysis Set Chloroprocaine 1%			
		30 mg N=XX n (%)	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Achievement of an Effective Anaesthesia	Y	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	N	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the full analysis set
Source: Listing 16.2.6.4 - Effectiveness of anaesthesia and quality of spinal block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.7 - Quality of spinal block (Per protocol set)

		Per Protocol Set Chloroprocaine 1% 30 mg N=XX n (%)	40 mg N=XX n (%)	50 mg N=XX n (%)	Overall N=XX n (%)
Quality of Spinal Block	Adequate Spinal Block	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Inadequate Spinal Block	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Failed Spinal Block	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Source: Listing 16.2.6.4 - Effectiveness of anaesthesia and quality of spinal block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.1.8 - Quality of spinal block (Full analysis set)

		Full Analysis Set Chloroprocaine 1% 30 mg N=XX n (%)	40 mg N=XX n (%)	50 mg N=XX n (%)	Overall N=XX n (%)
Quality of Spinal Block	Adequate Spinal Block	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Inadequate Spinal Block	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
	Failed Spinal Block	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the full analysis set
Source: Listing 16.2.6.4 - Effectiveness of anaesthesia and quality of spinal block
Program: Tables\c122-qs-01-tbl.sas

Table 14.2.2.1 - Comparison of time to events (Per protocol set)

			Per Protocol Set	
Time to	**Comparison**	**Test**	**Statistic**	**p-value [1]**
Regression of Spinal Block (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Onset of Sensory Block (min)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Onset of Motor Block (min)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Readiness for Surgery (min)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx

Note: Subjects are analysed according to the dose level of the product they actually received
Note 1: p-values of Wilcoxon Rank-Sum test were calculated using t approximation
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-02-tbl.sas

Table 14.2.2.1 - Comparison of time to events (Per protocol set)

			Per Protocol Set	
Time to	**Comparison**	**Test**	**Statistic**	**p-value [1]**
Regression of Sensory Block (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Regression of Motor Block h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Unassisted Ambulation (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Maximum Level of Sensory Block (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx

Note: Subjects are analysed according to the dose level of the product they actually received
Note 1: p-values of Wilcoxon Rank-Sum test were calculated using t approximation
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-02-tbl.sas

Table 14.2.2.1 - Comparison of time to events (Per protocol set)

			Per Protocol Set	
Time to	**Comparison**	**Test**	**Statistic**	**p-value [1]**
Regression of Two Dermatomers (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Eligibility for Home Discharge (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
First Spontaneous Urine Voiding (h	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Rescue Anaesthesia/Analgesia (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx

Note: Subjects are analysed according to the dose level of the product they actually received
Note 1: p-values of Wilcoxon Rank-Sum test were calculated using t approximation
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-02-tbl.sas

Table 14.2.2.1 - Comparison of time to events (Per protocol set)

			Per Protocol Set	
Time to	**Comparison**	**Test**	**Statistic**	**p-value [1]**
First Post-Operative Analgesia (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx

Note: Subjects are analysed according to the dose level of the product they actually received
Note 1: p-values of Wilcoxon Rank-Sum test were calculated using t approximation
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-02-tbl.sas

Table 14.2.2.2 - Comparison of time to events (Full analysis set)

			Full Analysis Set	
Time to	**Comparison**	**Test**	**Statistic**	**p-value [1]**
Regression of Spinal Block (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Onset of Sensory Block (min)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Onset of Motor Block (min)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Readiness for Surgery (min)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx

Note: Subjects are analysed according to the dose level of the product they actually received
Note 1: p-values of Wilcoxon Rank-Sum test were calculated using t approximation
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-02-tbl.sas

Table 14.2.2.2 - Comparison of time to events (Full analysis set)

			Full Analysis Set	
Time to	**Comparison**	**Test**	**Statistic**	**p-value [1]**
Regression of Sensory Block (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Regression of Motor Block h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Unassisted Ambulation (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Maximum Level of Sensory Block (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx

Note: Subjects are analysed according to the dose level of the product they actually received
Note 1: p-values of Wilcoxon Rank-Sum test were calculated using t approximation
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-02-tbl.sas

Table 14.2.2.2 - Comparison of time to events (Full analysis set)

			Full Analysis Set	
Time to	**Comparison**	**Test**	**Statistic**	**p-value [1]**
Regression of Two Dermatomers (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Eligibility for Home Discharge (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
First Spontaneous Urine Voiding (h	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
Rescue Anaesthesia/Analgesia (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx

Note: Subjects are analysed according to the dose level of the product they actually received
Note 1: p-values of Wilcoxon Rank-Sum test were calculated using t approximation
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-02-tbl.sas

Table 14.2.2.2 - Comparison of time to events (Full analysis set)

			Full Analysis Set	
Time to	**Comparison**	**Test**	**Statistic**	**p-value [1]**
First Post-Operative Analgesia (h)	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx

Note: Subjects are analysed according to the dose level of the product they actually received
Note 1: p-values of Wilcoxon Rank-Sum test were calculated using t approximation
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-02-tbl.sas

Table 14.2.2.3 - Comparison of maximum level of sensory block (Per protocol set)

			Per Protocol Set	
	Comparison	**Test**	**Statistic**	**p-value [1]**
Maximum Level of Sensory Block	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx

Note: Subjects are analysed according to the dose level of the product they actually received
Note 1: p-values of Wilcoxon Rank-Sum test were calculated using t approximation
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-02-tbl.sas

Table 14.2.2.4 - Comparison of maximum level of sensory block (Full analysis set)

			Full Analysis Set	
	Comparison	**Test**	**Statistic**	**p-value [1]**
Maximum Level of Sensory Block	Chloroprocaine 1% 30 mg vs. 40 mg vs. 50 mg	Kruskal-Wallis	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 40 mg vs. 50 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx
	Chloroprocaine 1% 30 mg vs. 40 mg	Wilcoxon Rank-Sum	xxxx.x	x.xxxx

Note: Subjects are analysed according to the dose level of the product they actually received
Note 1: p-values of Wilcoxon Rank-Sum test were calculated using t approximation
Source: Listing 16.2.6.3 - Time to events and maximum level of sensory block
Program: Tables\c122-qs-02-tbl.sas

Table 14.2.3.1 - Plasma concentrations (PK set 1)

			PK Set 1 Chloroprocaine 1%			
	Time Point	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Chloroprocaine Plasma Concentration (ng/mL)	Pre-dose (0)	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx
Chloroprocaine Plasma Concentration (ng/mL)	5 min after spinal injection	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.5.3 - PK blood samples collection and plasma concentrations
Program: Tables\c122-pc-tbl.sas

Table 14.2.3.1 - Plasma concentrations (PK set 1)

			PK Set 1 Chloroprocaine 1%			
	Time Point	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Chloroprocaine Plasma Concentration (ng/mL)	10 min after spinal injection	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx
Chloroprocaine Plasma Concentration (ng/mL)	30 min after spinal injection	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.5.3 - PK blood samples collection and plasma concentrations
Program: Tables\c122-pc-tbl.sas

Table 14.2.3.1 - Plasma concentrations (PK set 1)

			PK Set 1 Chloroprocaine 1%			
	Time Point	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Chloroprocaine Plasma Concentration (ng/mL)	60 min after spinal injection	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx
CABA Plasma Concentration (ng/mL)	Pre-dose (0)	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.5.3 - PK blood samples collection and plasma concentrations
Program: Tables\c122-pc-tbl.sas

Table 14.2.3.1 - Plasma concentrations (PK set 1)

			PK Set 1 Chloroprocaine 1%			
	Time Point	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
CABA Plasma Concentration (ng/mL)	5 min after spinal injection	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx
CABA Plasma Concentration (ng/mL)	10 min after spinal injection	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.5.3 - PK blood samples collection and plasma concentrations
Program: Tables\c122-pc-tbl.sas

Table 14.2.3.1 - Plasma concentrations (PK set 1)

			PK Set 1 Chloroprocaine 1%			
	Time Point	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
CABA Plasma Concentration (ng/mL)	30 min after spinal injection	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx
CABA Plasma Concentration (ng/mL)	60 min after spinal injection	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.5.3 - PK blood samples collection and plasma concentrations
Program: Tables\c122-pc-tbl.sas

Table 14.2.3.2 - Urinary concentration and excretion (PK set 2)

			PK Set 2 Chloroprocaine 1%			
	Time Point	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
CABA Urinary Concentration (ng/mL)	First Spontaneous Urine Voiding	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx
CABA Urinary Excretion (%)	First Spontaneous Urine Voiding	N	nn	nn	nn	nn
		Geo.Mean	xx.x	xx.x	xx.x	xx.x
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.5.4 - PK urine sample collection, urinary concentration and urinary excretion
Program: Tables\c122-pc-tbl.sas

Table 14.3.1.1 - Global incidence of treatment emergent adverse events (Safety set)

	Safety Set Chloroprocaine 1% 30 mg N=XX n (%) [n AE]	40 mg N=XX n (%) [n AE]	50 mg N=XX n (%) [n AE]	Overall N=XX n (%) [n AE]
Treatment Emergent Adverse Events	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Related	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Not related	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Mild	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Moderate	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Severe	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Leading to discontinuation	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Serious Treatment Emergent Adverse Events	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Related	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Not related	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Leading to discontinuation	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Life-threatening	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Leading to death	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c122-ae-01-tbl.sas

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

	Safety Set Chloroprocaine 1%			
System Organ Class [1] **Preferred Term [1]**	**30 mg** **N=XX** **n (%) [n AE]**	**40 mg** **N=XX** **n (%) [n AE]**	**50 mg** **N=XX** **n (%) [n AE]**	**Overall** **N=XX** **n (%) [n AE]**
Treatment Emergent Adverse Events	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Injury, poisoning and procedural complications	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Procedural pain	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Injection site pain	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Note 1: MedDRA version 18.1
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c122-ae-02-tbl.sas

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

	Safety Set Chloroprocaine 1%											
	30 mg N=XX			40 mg N=XX			50 mg 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]**	**Mild n (%) [n AE]**	**Moderate n (%) [n AE]**	**Severe n (%) [n AE]**
Treatment Emergent Adverse Events	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Injury, poisoning and procedural complications	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Procedural pain	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Injection site pain	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
...	...	...	...	...	...	...	...	...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Note 1: MedDRA version 18.1
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c122-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)

	Safety Set Chloroprocaine 1%			
System Organ Class [1] **Preferred Term [1]**	**30 mg** **N=XX** **n (%) [n AE]**	**40 mg** **N=XX** **n (%) [n AE]**	**50 mg** **N=XX** **n (%) [n AE]**	**Overall** **N=XX** **n (%) [n AE]**
Treatment Emergent Adverse Events related to study IMP	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Injury, poisoning and procedural complications	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Procedural pain	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Injection site pain	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Note 1: MedDRA version 18.1
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c122-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)

	Safety Set Chloroprocaine 1%			
System Organ Class [1] **Preferred Term [1]**	**30 mg** **N=XX** **n (%) [n AE]**	**40 mg** **N=XX** **n (%) [n AE]**	**50 mg** **N=XX** **n (%) [n AE]**	**Overall** **N=XX** **n (%) [n AE]**
Serious Treatment Emergent Adverse Events	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Injury, poisoning and procedural complications	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Procedural pain	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Injection site pain	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Note 1: MedDRA version 18.1
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c122-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)

	Safety Set Chloroprocaine 1%			
System Organ Class [1] **Preferred Term [1]**	**30 mg** **N=XX** **n (%) [n AE]**	**40 mg** **N=XX** **n (%) [n AE]**	**50 mg** **N=XX** **n (%) [n AE]**	**Overall** **N=XX** **n (%) [n AE]**
Serious Treatment Emergent Adverse Events related to study IMP	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Injury, poisoning and procedural complications	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Procedural pain	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
Injection site pain	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]	nn (xx.x) [nn]
...	...	...	...	...

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the safety set
Note 1: MedDRA version 18.1
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c122-ae-02-tbl.sas

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

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	AE Nr / FU Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start or Follow-up Date/time / Start or Follow-up Day / End Date/time / End Day / Duration	IMP injection Date/time / Day / Time from IMP injection	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other action taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day j / Ongoing / --- / ---	ddMMMyyyy hh:mm / Day j / xx h xx min	Y / Moderate / Not related / Weather condition	Recovering/resolving / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c122-ae-03-tbl.sas

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

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	AE Nr / FU Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start or Follow-up Date/time / Start or Follow-up Day / End Date/time / End Day / Duration	IMP injection Date/time / Day / Time from IMP injection	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other action taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day j / Ongoing / --- / ---	ddMMMyyyy hh:mm / Day j / xx h xx min	Y / Moderate / Not related / Weather condition	Recovering/resolving / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c122-ae-03-tbl.sas

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

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	AE Nr / FU Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start or Follow-up Date/time / Start or Follow-up Day / End Date/time / End Day / Duration	IMP injection Date/time / Day / Time from IMP injection	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other action taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day j / Ongoing / --- / ---	ddMMMyyyy hh:mm / Day j / xx h xx min	Y / Moderate / Not related / Weather condition	Recovering/resolving / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Source: Listing 16.2.7.1 - Treatment-emergent adverse events
Program: Tables\c122-ae-03-tbl.sas

Table 14.2.3.1 - Vital signs (Safety set)

			Safety Set Chloroprocaine 1%			
Parameter	**Time Point**	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Systolic Blood Pressure (mmHg)	Screening	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
Systolic Blood Pressure (mmHg)	Baseline	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.9.1 - Vital signs
Program: Tables\c122-vs-tbl.sas

Table 14.2.3.1 - Vital signs (Safety set)

			Safety Set Chloroprocaine 1%			
Parameter	**Time Point**	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Systolic Blood Pressure (mmHg)	Discharge	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
Diastolic Blood Pressure (mmHg)	Screening	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.9.1 - Vital signs
Program: Tables\c122-vs-tbl.sas

Table 14.2.3.1 - Vital signs (Safety set)

			Safety Set Chloroprocaine 1%			
Parameter	**Time Point**	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Diastolic Blood Pressure (mmHg)	Baseline	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx
Diastolic Blood Pressure (mmHg)	Discharge	N	nn	nn	nn	nn
		Mean	xxx.x	xxx.x	xxx.x	xxx.x
		SD	xxx.x	xxx.x	xxx.x	xxx.x
		CV%	xxx.x	xxx.x	xxx.x	xxx.x
		Min	xxx	xxx	xxx	xxx
		Median	xxx.x	xxx.x	xxx.x	xxx.x
		Max	xxx	xxx	xxx	xxx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.9.1 - Vital signs
Program: Tables\c122-vs-tbl.sas

Table 14.2.3.1 - Vital signs (Safety set)

			Safety Set Chloroprocaine 1%			
Parameter	**Time Point**	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Heart Rate (beats/min)	Screening	N	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx
Heart Rate (beats/min)	Baseline	N	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.9.1 - Vital signs
Program: Tables\c122-vs-tbl.sas

Table 14.2.3.1 - Vital signs (Safety set)

			Safety Set Chloroprocaine 1%			
Parameter	**Time Point**	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Heart Rate (beats/min)	Discharge	N	nn	nn	nn	nn
		Mean	xx.x	xx.x	xx.x	xx.x
		SD	xx.x	xx.x	xx.x	xx.x
		CV%	xx.x	xx.x	xx.x	xx.x
		Min	xx	xx	xx	xx
		Median	xx.x	xx.x	xx.x	xx.x
		Max	xx	xx	xx	xx
Oxygen Saturation (%)	Screening	N	nn	nn	nn	nn
		Mean	xx.xx	xx.xx	xx.xx	xx.xx
		SD	xx.xx	xx.xx	xx.xx	xx.xx
		CV%	xx.xx	xx.xx	xx.xx	xx.xx
		Max	xx.x	xx.x	xx.x	xx.x
		Median	xx.xx	xx.xx	xx.xx	xx.xx
		Max	xx.x	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.9.1 - Vital signs
Program: Tables\c122-vs-tbl.sas

Table 14.2.3.1 - Vital signs (Safety set)

			Safety Set Chloroprocaine 1%			
Parameter	**Time Point**	**Statistics**	**30 mg N=XX**	**40 mg N=XX**	**50 mg N=XX**	**Overall N=XX**
Oxygen Saturation (%)	Baseline	N	nn	nn	nn	nn
		Mean	xx.xx	xx.xx	xx.xx	xx.xx
		SD	xx.xx	xx.xx	xx.xx	xx.xx
		CV%	xx.xx	xx.xx	xx.xx	xx.xx
		Max	xx.x	xx.x	xx.x	xx.x
		Median	xx.xx	xx.xx	xx.xx	xx.xx
		Max	xx.x	xx.x	xx.x	xx.x
Oxygen Saturation (%)	Discharge	N	nn	nn	nn	nn
		Mean	xx.xx	xx.xx	xx.xx	xx.xx
		SD	xx.xx	xx.xx	xx.xx	xx.xx
		CV%	xx.xx	xx.xx	xx.xx	xx.xx
		Max	xx.x	xx.x	xx.x	xx.x
		Median	xx.xx	xx.xx	xx.xx	xx.xx
		Max	xx.x	xx.x	xx.x	xx.x

Note: Subjects are summarised according to the dose level of the product they actually received
Source: Listing 16.2.9.1 - Vital signs
Program: Tables\c122-vs-tbl.sas

Table 14.3.5.2 - Pain assessment at the site of injection and at the site of surgery (Safety set)

			Safety Set			
			Chloroprocaine 1%			
Parameter	**Time Point**	**Pain Assessment [1]**	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Pain at the Injection Site	Immediately after regression of spinal block	0	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		3	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		4	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		5	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		6	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		7	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		8	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		9	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		10	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Source: Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery
Program: Tables\c122-qs-03-tbl.sas

Table 14.3.5.2 - Pain assessment at the site of injection and at the site of surgery (Safety set)

			Safety Set			
			Chloroprocaine 1%			
Parameter	**Time Point**	**Pain Assessment [1]**	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Pain at the Injection Site	Discharge	0	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		3	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		4	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		5	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		6	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		7	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		8	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		9	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		10	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Source: Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery
Program: Tables\c122-qs-03-tbl.sas

Table 14.3.5.2 - Pain assessment at the site of injection and at the site of surgery (Safety set)

			Safety Set			
			Chloroprocaine 1%			
Parameter	**Time Point**	**Pain Assessment [1]**	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Pain at the Injection Site	Day 2	0	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		3	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		4	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		5	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		6	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		7	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		8	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		9	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		10	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Source: Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery
Program: Tables\c122-qs-03-tbl.sas

Table 14.3.5.2 - Pain assessment at the site of injection and at the site of surgery (Safety set)

			Safety Set			
			Chloroprocaine 1%			
Parameter	**Time Point**	**Pain Assessment [1]**	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Pain at the Injection Site	Day 7±1	0	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		3	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		4	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		5	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		6	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		7	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		8	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		9	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		10	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Source: Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery
Program: Tables\c122-qs-03-tbl.sas

Table 14.3.5.2 - Pain assessment at the site of injection and at the site of surgery (Safety set)

			Safety Set			
			Chloroprocaine 1%			
Parameter	**Time Point**	**Pain Assessment [1]**	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Pain at the Surgery Site	Immediately after regression of spinal block	0	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		3	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		4	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		5	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		6	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		7	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		8	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		9	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		10	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Source: Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery
Program: Tables\c122-qs-03-tbl.sas

Table 14.3.5.2 - Pain assessment at the site of injection and at the site of surgery (Safety set)

			Safety Set			
			Chloroprocaine 1%			
Parameter	**Time Point**	**Pain Assessment [1]**	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Pain at the Surgery Site	Discharge	0	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		3	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		4	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		5	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		6	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		7	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		8	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		9	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		10	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Source: Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery
Program: Tables\c122-qs-03-tbl.sas

Table 14.3.5.2 - Pain assessment at the site of injection and at the site of surgery (Safety set)

			Safety Set			
			Chloroprocaine 1%			
Parameter	**Time Point**	**Pain Assessment [1]**	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Pain at the Surgery Site	Day 2	0	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		3	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		4	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		5	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		6	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		7	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		8	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		9	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		10	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Source: Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery
Program: Tables\c122-qs-03-tbl.sas

Table 14.3.5.2 - Pain assessment at the site of injection and at the site of surgery (Safety set)

			Safety Set			
			Chloroprocaine 1%			
Parameter	**Time Point**	**Pain Assessment [1]**	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Pain at the Surgery Site	Day 7±1	0	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		1	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		2	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		3	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		4	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		5	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		6	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		7	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		8	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		9	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		10	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Source: Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery
Program: Tables\c122-qs-03-tbl.sas

Table 14.3.5.3 - Transient neurological symptoms (Safety set)

			Safety Set Chloroprocaine 1%			
	Time Point	**Assessment**	**30 mg N=XX n (%)**	**40 mg N=XX n (%)**	**50 mg N=XX n (%)**	**Overall N=XX n (%)**
Transient Neurological Symptoms	Day 2	Y	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		N	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
Transient Neurological Symptoms	Day 7±1	Y	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)
		N	nn (xx.x)	nn (xx.x)	nn (xx.x)	nn (xx.x)

Note: Subjects are summarised according to the dose level of the product they actually received
The denominator for calculating the proportions is the number of subjects in each dose level and overall in the per protocol set
Source: Listing 16.2.9.4 - Transient neurological symptoms
Program: Tables\c122-qs-03-tbl.sas

Figure 14.2.3.1 - Mean plasma concentration curves of Chloroprocaine (PK set 1)

Mean plasma concentration curves of Chloroprocaine (linear scale and logarithmic/linear scale)

Figure 14.2.3.2 - Mean plasma concentration curves of CABA (PK set 1)

Mean plasma concentration curves of CABA (linear scale and logarithmic/linear scale)

Section 16.2 - Individual Subject Data Listings and Figures Shells

Listing 16.2.1.1 - Discontinued Subjects

Subject ID	IMP administered	Sex	Age (years)	Last visit	Time elapsed from IMP spinal injection (days)	Date of premature discontinuation	Primary reason for subject premature discontinuation
Sjjj/nnn	Chloroprocaine 1% - 30 mg	M	xx	Visit A	x	ddMMMyyyy	Reason A
Sjjj/nnn	Chloroprocaine 1% - 40 mg	F	xx	Visit B	x	ddMMMyyyy	Reason B
Sjjj/nnn	Chloroprocaine 1% - 50 mg	F	xx	Visit C	x	ddMMMyyyy	Reason C
Sjjj/nnn	Not Treated	F	xx	Visit C	x	ddMMMyyyy	Reason D
Sjjj/nnn	...	..	..	...	..	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.2.1 - Protocol deviations

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Deviation Number	Deviation Category	Deviation Coded Term	Deviation Description
Sjjj/nnn	1	Major	Coded Term A	Description A
Sjjj/nnn	2	Minor	Coded Term B	Description B
Sxxx/ppp	1	Major	Coded Term A	Description A
Sxxx/ppp	2	Minor	Coded Term B	Description B
Sxxx/ppp		...	...	...

Note: Only subjects with protocol deviations are listed. Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-dv-lst.sas

Listing 16.2.2.1 - Protocol deviations

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Deviation Number	Deviation Category	Deviation Coded Term	Deviation Description
Sjjj/nnn	1	Major	Coded Term A	Description A
Sjjj/nnn	2	Minor	Coded Term B	Description B
Sxxx/ppp	1	Major	Coded Term A	Description A
Sxxx/ppp	2	Minor	Coded Term B	Description B
Sxxx/ppp		...	...	...

Note: Only subjects with protocol deviations are listed. Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-dv-lst.sas

Listing 16.2.2.1 - Protocol deviations

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Deviation Number	Deviation Category	Deviation Coded Term	Deviation Description
Sjjj/nnn	1	Major	Coded Term A	Description A
Sjjj/nnn	2	Minor	Coded Term B	Description B
Sxxx/ppp	1	Major	Coded Term A	Description A
Sxxx/ppp	2	Minor	Coded Term B	Description B
Sxxx/ppp		...	...	...

Note: Only subjects with protocol deviations are listed. Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-dv-lst.sas

Listing 16.2.2.1 - Protocol deviations

Investigational Medicinal Product: Not Assigned

Subject ID	Deviation Number	Deviation Category	Deviation Coded Term	Deviation Description
Sjjj/nnn	1	Major	Coded Term A	Description A
Sjjj/nnn	2	Minor	Coded Term B	Description B
Sxxx/ppp	1	Major	Coded Term A	Description A
Sxxx/ppp	2	Minor	Coded Term B	Description B
Sxxx/ppp		...	...	...

Note: Only subjects with protocol deviations are listed. Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-dv-lst.sas

Listing 16.2.2.1 - Protocol deviations

Investigational Medicinal Product: Not Treated

Subject ID	Deviation Number	Deviation Category	Deviation Coded Term	Deviation Description
Sjjj/nnn	1	Major	Coded Term A	Description A
Sjjj/nnn	2	Minor	Coded Term B	Description B
Sxxx/ppp	1	Major	Coded Term A	Description A
Sxxx/ppp	2	Minor	Coded Term B	Description B
Sxxx/ppp		...	...	...

Note: Only subjects with protocol deviations are listed. Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-dv-lst.sas

Listing 16.2.3.1 - Subjects excluded from the efficacy and/or PK and/or safety analysis

Subject ID	Investigational Medicinal Product	Sex	Age (years)	Enrolled Set	Randomised	Safety Set	Full Analysis Set	Per Protocol Set	PK Set 1	PK Set 2	Reason for the exclusion
Sjjj	Not Assigned	M	xx	N	N	N	N	N	N	N	Reason D
Sjjj/nnn	Chloroprocaine 1% - 30 mg	M	xx	Y	Y	Y	Y	N	Y	N	Reason A
Sjjj/nnn	Chloroprocaine 1% - 40 mg	M	xx	Y	Y	Y	Y	Y	N	Y	Reason B
Sjjj/nnn	Chloroprocaine 1% - 50 mg	M	xx	Y	Y	N	N	N	N	Y	Reason C
Sjjj/nnn	Not Treated	F	xx	Y	Y	N	N	N	N	N	Reason E
Sjjj/nnn	...	..	..	..	.	..	.	.	..	..	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Date of Informed Consent	Date of Screening	Date of Randomisation	Date of Spinal Injection	Completed or Discontinued	Date of Study Completion or Discontinuation	Date of End of Partecipation	Comments Reason for discontinuation
Sjjj/nnn	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Discontinued	ddMMMyyyy	ddMMMyyyy	Reason A
Sjjj/nnn	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Completed	ddMMMyyyy	ddMMMyyyy	
Sjjj/nnn	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Date of Informed Consent	Date of Screening	Date of Randomisation	Date of Spinal Injection	Completed or Discontinued	Date of Study Completion or Discontinuation	Date of End of Partecipation	Comments Reason for discontinuation
Sjjj/nnn	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Discontinued	ddMMMyyyy	ddMMMyyyy	Reason B
Sjjj/nnn	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Completed	ddMMMyyyy	ddMMMyyyy	
Sjjj/nnn	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Date of Informed Consent	Date of Screening	Date of Randomisation	Date of Spinal Injection	Completed or Discontinued	Date of Study Completion or Discontinuation	Date of End of Partecipation	Comments Reason for discontinuation
Sjjj/nnn	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Discontinued	ddMMMyyyy	ddMMMyyyy	Reason C
Sjjj/nnn	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy	Completed	ddMMMyyyy	ddMMMyyyy	
Sjjj/nnn	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Investigational Medicinal Product: Not Assigned

Subject ID	Date of Informed Consent	Date of Screening	Date of Randomisation	Date of Spinal Injection	Completed or Discontinued	Date of Study Completion or Discontinuation	Date of End of Partecipation	Comments Reason for discontinuation
Sjjj	ddMMMyyyy	ddMMMyyyy			---			Reason D
Sjjj	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.1 - Subjects' disposition

Investigational Medicinal Product: Not Treated

Subject ID	Date of Informed Consent	Date of Screening	Date of Randomisation	Date of Spinal Injection	Completed or Discontinued	Date of Study Completion or Discontinuation	Date of End of Partecipation	Comments Reason for discontinuation
Sjjj/nnn	ddMMMyyyy	ddMMMyyyy	ddMMMyyyy		Discontinued	ddMMMyyyy	ddMMMyyyy	Reason E
Sjjj/nnn	...	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.2 - Analysis sets

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Enrolled Set	Randomised	Safety Set	Full Analysis Set	Per Protocol Set	PK Set 1	PK Set 2	Reason for the exclusion
Sjjj/nnn	Y	Y	Y	Y	N	Y	N	Reason A
Sjjj/nnn	..	.	..	.	.	..	..	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.2 - Analysis sets

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Enrolled Set	Randomised	Safety Set	Full Analysis Set	Per Protocol Set	PK Set 1	PK Set 2	Reason for the exclusion
Sjjj/nnn	Y	Y	Y	Y	Y	N	Y	Reason B
Sjjj/nnn	..	.	..	.	.	..	..	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.2 - Analysis sets

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Enrolled Set	Randomised	Safety Set	Full Analysis Set	Per Protocol Set	PK Set 1	PK Set 2	Reason for the exclusion
Sjjj/nnn	Y	Y	N	N	N	N	Y	Reason C
Sjjj/nnn	..	.	..	.	.	..	..	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.2 - Analysis sets

Investigational Medicinal Product: Not Assigned

Subject ID	Enrolled Set	Randomised	Safety Set	Full Analysis Set	Per Protocol Set	PK Set 1	PK Set 2	Reason for the exclusion
Sjjj	N	N	N	N	N	N	N	Reason D
Sjjj	..	.	..	.	.	..	..	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.2 - Analysis sets

Investigational Medicinal Product: Not Treated

Subject ID	Enrolled Set	Randomised	Safety Set	Full Analysis Set	Per Protocol Set	PK Set 1	PK Set 2	Reason for the exclusion
Sjjj/nnn	Y	Y	N	N	N	N	N	Reason E
Sjjj/nnn	..	.	..	.	.	..	..	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ds-lst.sas

Listing 16.2.4.3 - Demography

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Sex	Race	Age (years)	Height (cm)	Weight (kg)	Body Mass Index (kg/m^2)
Sjjj/nnn	M	Race A	xx	xxx	xx.x	xx.x
Sxxx/ppp	F	Race B	xx	xxx	xx.x	xx.x
Szzz/ttt	..	...	..	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-dm-lst.sas

Listing 16.2.4.3 - Demography

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Sex	Race	Age (years)	Height (cm)	Weight (kg)	Body Mass Index (kg/m^2)
Sjjj/nnn	M	Race A	xx	xxx	xx.x	xx.x
Sxxx/ppp	F	Race B	xx	xxx	xx.x	xx.x
Szzz/ttt	..	...	..	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-dm-lst.sas

Listing 16.2.4.3 - Demography

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Sex	Race	Age (years)	Height (cm)	Weight (kg)	Body Mass Index (kg/m^2)
Sjjj/nnn	M	Race A	xx	xxx	xx.x	xx.x
Sxxx/ppp	F	Race B	xx	xxx	xx.x	xx.x
Szzz/ttt	..	...	..	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-dm-lst.sas

Listing 16.2.4.3 - Demography

Investigational Medicinal Product: Not Assigned

Subject ID	Sex	Race	Age (years)	Height (cm)	Weight (kg)	Body Mass Index (kg/m^2)
Sjjj	M	Race A	xx	xxx	xx.x	xx.x
Sxxx	F	Race B	xx	xxx	xx.x	xx.x
Szzz	..	...	..	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-dm-lst.sas

Listing 16.2.4.3 - Demography

Investigational Medicinal Product: Not Treated

Subject ID	Sex	Race	Age (years)	Height (cm)	Weight (kg)	Body Mass Index (kg/m^2)
Sjjj/nnn	M	Race A	xx	xxx	xx.x	xx.x
Sxxx/ppp	F	Race B	xx	xxx	xx.x	xx.x
Szzz/ttt	..	...	..	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-dm-lst.sas

Listing 16.2.4.4 - Inclusion/Exclusion criteria not met

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Patient ID	Time point	Assessment Date	Inclusion/ Exclusion	Criterion Number	Criterion
Sjjj/nnn	Screening	ddMMMyyyy	Exclusion	1	Physical findings: clinically significant abnormal physical findings ...
...	...	...	...		...

Note: Subjects are listed according to the dose level of the product they were assigned to
Program: Listings\c122-ie-lst.sas

Listing 16.2.4.4 - Inclusion/Exclusion criteria not met

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Patient ID	Time point	Assessment Date	Inclusion/ Exclusion	Criterion Number	Criterion
Sjjj/nnn	Screening	ddMMMyyyy	Exclusion	1	Physical findings: clinically significant abnormal physical findings ...
...	...	...	...		...

Note: Subjects are listed according to the dose level of the product they were assigned to
Program: Listings\c122-ie-lst.sas

Listing 16.2.4.4 - Inclusion/Exclusion criteria not met

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Patient ID	Time point	Assessment Date	Inclusion/ Exclusion	Criterion Number	Criterion
Sjjj/nnn	Screening	ddMMMyyyy	Exclusion	1	Physical findings: clinically significant abnormal physical findings ...
...	...	...	...		...

Note: Subjects are listed according to the dose level of the product they were assigned to
Program: Listings\c122-ie-lst.sas

Listing 16.2.4.4 - Inclusion/Exclusion criteria not met

Investigational Medicinal Product: Not Assigned

Patient ID	Time point	Assessment Date	Inclusion/ Exclusion	Criterion Number	Criterion
Sjjj/nnn	Screening	ddMMMyyyy	Exclusion	1	Physical findings: clinically significant abnormal physical findings ...
...	...	...	...		...

Note: Subjects are listed according to the dose level of the product they were assigned to
Program: Listings\c122-ie-lst.sas

Listing 16.2.4.4 - Inclusion/Exclusion criteria not met

Investigational Medicinal Product: Not Treated

Patient ID	Time point	Assessment Date	Inclusion/ Exclusion	Criterion Number	Criterion
Sjjj/nnn	Screening	ddMMMyyyy	Exclusion	1	Physical findings: clinically significant abnormal physical findings ...
...	...	...	...		...

Note: Subjects are listed according to the dose level of the product they were assigned to
Program: Listings\c122-ie-lst.sas

Listing 16.2.5.1 - IMP spinal injection

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Anatomical location of the spinal injection	Kit Identifier	Injection Date/time	Was the planned volume administered as per protocol?	Comments
Sjjj/nnn	L3/L4	Knnn	ddMMMyyyy hh:mm	Y	...
Skkk/ttt	L4/L5	Kttt	ddMMMyyyy hh:mm	Y	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ex-lst.sas

Listing 16.2.5.1 - IMP spinal injection

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Anatomical location of the spinal injection	Kit Identifier	Injection Date/time	Was the planned volume administered as per protocol?	Comments
Sjjj/nnn	L3/L4	Knnn	ddMMMyyyy hh:mm	Y	...
Skkk/ttt	L4/L5	Kttt	ddMMMyyyy hh:mm	Y	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ex-lst.sas

Listing 16.2.5.1 - IMP spinal injection

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Anatomical location of the spinal injection	Kit Identifier	Injection Date/time	Was the planned volume administered as per protocol?	Comments
Sjjj/nnn	L3/L4	Knnn	ddMMMyyyy hh:mm	Y	...
Skkk/ttt	L4/L5	Kttt	ddMMMyyyy hh:mm	Y	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ex-lst.sas

Listing 16.2.5.1 - IMP spinal injection

Investigational Medicinal Product: Not Treated

Subject ID	Anatomical location of the spinal injection	Kit Identifier	Injection Date/time	Was the planned volume administered as per protocol?	Comments
Sjjj/nnn	L3/L4	Knnn	---	N	...
Skkk/ttt	L4/L5	Kttt	---	N	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ex-lst.sas

Listing 16.2.5.2 - Sedation and premedication

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Sedation with i.v. Midazolam?	Injection Date/time	Injected Dose	Premedication with Ringer's solution?	Infusion start Date/time	Infusion start End/time	Infused Volume
Sjjj/nnn	Y	ddMMMyyyy hh:mm	2 mg	Y	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	500 mL
Sjjj/nnn	..	..	..	..	..	..	..

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-cm-lst.sas

Listing 16.2.5.2 - Sedation and premedication

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Sedation with i.v. Midazolam?	Injection Date/time	Injected Dose	Premedication with Ringer's solution?	Infusion start Date/time	Infusion start End/time	Infused Volume
Sjjj/nnn	Y	ddMMMyyyy hh:mm	2 mg	Y	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	500 mL
Sjjj/nnn	..	..	..	..	..	..	..

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-cm-lst.sas

Listing 16.2.5.2 - Sedation and premedication

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Sedation with i.v. Midazolam?	Injection Date/time	Injected Dose	Premedication with Ringer's solution?	Infusion start Date/time	Infusion start End/time	Infused Volume
Sjjj/nnn	Y	ddMMMyyyy hh:mm	2 mg	Y	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	500 mL
Sjjj/nnn	..	..	..	..	..	..	..

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-cm-lst.sas

Listing 16.2.5.2 - Sedation and premedication

Investigational Medicinal Product: Not Treated

Subject ID	Sedation with i.v. Midazolam?	Injection Date/time	Injected Dose	Premedication with Ringer's solution?	Infusion start Date/time	Infusion start End/time	Infused Volume
Sjjj/nnn	Y	ddMMMyyyy hh:mm	2 mg	Y	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	500 mL
Sjjj/nnn	..	..	..	..	..	..	..

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-cm-lst.sas

Listing 16.2.5.3 - PK blood samples collection and plasma concentrations

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	IMP Injection Date/time	Sample Number	Time Point	Collection Date/time	Time from IMP Injection	Chloroprocaine Plasma Concentration (ng/mL)	CABA Plasma Concentration (ng/mL)
Sjjj/nnn	ddMMMyyyy hh:mm	1	Pre-dose (0) - Within 60 min before IMP administration	ddMMMyyyy hh:mm	-xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	2	5 min after spinal injection	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	3	10 min after spinal injection	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	4	30 min after spinal injection ± 1 min	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	5	60 min after spinal injection ± 3 min	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Skkk/ttt	...	..	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pc-lst.sas

Listing 16.2.5.3 - PK blood samples collection and plasma concentrations

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	IMP Injection Date/time	Sample Number	Time Point	Collection Date/time	Time from IMP Injection	Chloroprocaine Plasma Concentration (ng/mL)	CABA Plasma Concentration (ng/mL)
Sjjj/nnn	ddMMMyyyy hh:mm	1	Pre-dose (0) - Within 60 min before IMP administration	ddMMMyyyy hh:mm	-xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	2	5 min after spinal injection	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	3	10 min after spinal injection	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	4	30 min after spinal injection ± 1 min	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	5	60 min after spinal injection ± 3 min	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Skkk/ttt	...	..	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pc-lst.sas

Listing 16.2.5.3 - PK blood samples collection and plasma concentrations

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	IMP Injection Date/time	Sample Number	Time Point	Collection Date/time	Time from IMP Injection	Chloroprocaine Plasma Concentration (ng/mL)	CABA Plasma Concentration (ng/mL)
Sjjj/nnn	ddMMMyyyy hh:mm	1	Pre-dose (0) - Within 60 min before IMP administration	ddMMMyyyy hh:mm	-xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	2	5 min after spinal injection	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	3	10 min after spinal injection	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	4	30 min after spinal injection ± 1 min	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Sjjj/nnn	ddMMMyyyy hh:mm	5	60 min after spinal injection ± 3 min	ddMMMyyyy hh:mm	xx min	xx.xx	xx.xx
Skkk/ttt	...	..	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pc-lst.sas

Listing 16.2.5.4 - PK urine sample collection, urinary concentration and urinary excretion

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	IMP Injection Date/time	Time Point	Collection Date/time	Time from IMP Injection	Urine Volume (mL)	CABA Urinary Concentration (ng/mL)	CABA Urinary Excretion (%)
Sjjj/nnn	ddMMMyyyy hh:mm	First Spontaneous Urine Voiding	ddMMMyyyy hh:mm	zz h xx min	xxx	xx.xx	xxx.xx
Skkk/ttt	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pc-lst.sas

Listing 16.2.5.4 - PK urine sample collection, urinary concentration and urinary excretion

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	IMP Injection Date/time	Time Point	Collection Date/time	Time from IMP Injection	Urine Volume (mL)	CABA Urinary Concentration (ng/mL)	CABA Urinary Excretion (%)
Sjjj/nnn	ddMMMyyyy hh:mm	First Spontaneous Urine Voiding	ddMMMyyyy hh:mm	zz h xx min	xxx	xx.xx	xxx.xx
Skkk/ttt	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pc-lst.sas

Listing 16.2.5.4 - PK urine sample collection, urinary concentration and urinary excretion

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	IMP Injection Date/time	Time Point	Collection Date/time	Time from IMP Injection	Urine Volume (mL)	CABA Urinary Concentration (ng/mL)	CABA Urinary Excretion (%)
Sjjj/nnn	ddMMMyyyy hh:mm	First Spontaneous Urine Voiding	ddMMMyyyy hh:mm	zz h xx min	xxx	xx.xx	xxx.xx
Skkk/ttt	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pc-lst.sas

Listing 16.2.6.1 - Surgical procedure

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Type of Lower Limb Surgery / Preferred Term [1] / System Organ Class [1]	Required Metameric Level of Sensory Block	Surgery Executed?	Surgery start Date/time / Surgery end Date/time / Duration	Rescue Anaesthesia or Analgesia?	Rescue Anaesthesia or Analgesia Date/time	General Anaesthesia Required?	General Anaesthesia Date/time
Sjjj/nnn	Arthroscopic meniscectomy (right knee) / Meniscus removal / Surgical and medical procedures	T12	Y	ddMMMyyyy hh:mm ddMMMyyyy hh:mm xx min	Y	ddMMMyyyy hh:mm	Y	ddMMMyyyy hh:mm
Skkk/ttt	...	...	..	...	..	...	..	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-ce-lst.sas

Listing 16.2.6.2 - Sensory and motor block assessment

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Spinal Injection, Readiness for Surgery or Regression of Two Dermatomers Date/time	Time Point	Assessment Date/time	Elapsed Time	Metameric Level of Sensory Block	Bromage Score
Sjjj/nnn	ddMMMyyyy hh:mm	2 min after spinal injection	ddMMMyyyy hh:mm	zz h xx min	L4	0
Sjjj/nnn	ddMMMyyyy hh:mm	4 min after spinal injection	ddMMMyyyy hh:mm	zz h xx min	L1	1
Sjjj/nnn	ddMMMyyyy hh:mm	6 min after spinal injection	ddMMMyyyy hh:mm	zz h xx min	T12	2
Sjjj/nnn	ddMMMyyyy hh:mm	...	ddMMMyyyy hh:mm	zz h xx min	...	...
Sjjj/nnn	ddMMMyyyy hh:mm	5 min after readiness for surgery ± 1 min	ddMMMyyyy hh:mm	zz h xx min	T11	2
Sjjj/nnn	ddMMMyyyy hh:mm	10 min after readiness for surgery ± 1 min	ddMMMyyyy hh:mm	zz h xx min	T10	3
Sjjj/nnn	ddMMMyyyy hh:mm	15 min after readiness for surgery ± 1 min	ddMMMyyyy hh:mm	zz h xx min	T8	3
Sjjj/nnn	ddMMMyyyy hh:mm	...	ddMMMyyyy hh:mm	zz h xx min	...	...
Sjjj/nnn	ddMMMyyyy hh:mm	30 min after regression of two dermatomers ± 5 min	ddMMMyyyy hh:mm	zz h xx min	T12	3
Sjjj/nnn	ddMMMyyyy hh:mm	1 hour after regression of two dermatomers ± 5 min	ddMMMyyyy hh:mm	zz h xx min	L1	2
Sjjj/nnn	ddMMMyyyy hh:mm	1 hour and 30 min after regression of two dermatomers ± 5 min	ddMMMyyyy hh:mm	zz h xx min	L3	1
Sjjj/nnn	ddMMMyyyy hh:mm	...	ddMMMyyyy hh:mm	zz h xx min	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.6.2 - Sensory and motor block assessment

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Spinal Injection, Readiness for Surgery or Regression of Two Dermatomers Date/time	Time Point	Assessment Date/time	Elapsed Time	Metameric Level of Sensory Block	Bromage Score
Sjjj/nnn	ddMMMyyyy hh:mm	2 min after spinal injection	ddMMMyyyy hh:mm	zz h xx min	L4	0
Sjjj/nnn	ddMMMyyyy hh:mm	4 min after spinal injection	ddMMMyyyy hh:mm	zz h xx min	L1	1
Sjjj/nnn	ddMMMyyyy hh:mm	6 min after spinal injection	ddMMMyyyy hh:mm	zz h xx min	T12	2
Sjjj/nnn	ddMMMyyyy hh:mm	...	ddMMMyyyy hh:mm	zz h xx min	...	...
Sjjj/nnn	ddMMMyyyy hh:mm	5 min after readiness for surgery ± 1 min	ddMMMyyyy hh:mm	zz h xx min	T11	2
Sjjj/nnn	ddMMMyyyy hh:mm	10 min after readiness for surgery ± 1 min	ddMMMyyyy hh:mm	zz h xx min	T10	3
Sjjj/nnn	ddMMMyyyy hh:mm	15 min after readiness for surgery ± 1 min	ddMMMyyyy hh:mm	zz h xx min	T8	3
Sjjj/nnn	ddMMMyyyy hh:mm	...	ddMMMyyyy hh:mm	zz h xx min	...	...
Sjjj/nnn	ddMMMyyyy hh:mm	30 min after regression of two dermatomers ± 5 min	ddMMMyyyy hh:mm	zz h xx min	T12	3
Sjjj/nnn	ddMMMyyyy hh:mm	1 hour after regression of two dermatomers ± 5 min	ddMMMyyyy hh:mm	zz h xx min	L1	2
Sjjj/nnn	ddMMMyyyy hh:mm	1 hour and 30 min after regression of two dermatomers ± 5 min	ddMMMyyyy hh:mm	zz h xx min	L3	1
Sjjj/nnn	ddMMMyyyy hh:mm	...	ddMMMyyyy hh:mm	zz h xx min	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.6.2 - Sensory and motor block assessment

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Spinal Injection, Readiness for Surgery or Regression of Two Dermatomers Date/time	Time Point	Assessment Date/time	Elapsed Time	Metameric Level of Sensory Block	Bromage Score
Sjjj/nnn	ddMMMyyyy hh:mm	2 min after spinal injection	ddMMMyyyy hh:mm	zz h xx min	L4	0
Sjjj/nnn	ddMMMyyyy hh:mm	4 min after spinal injection	ddMMMyyyy hh:mm	zz h xx min	L1	1
Sjjj/nnn	ddMMMyyyy hh:mm	6 min after spinal injection	ddMMMyyyy hh:mm	zz h xx min	T12	2
Sjjj/nnn	ddMMMyyyy hh:mm	...	ddMMMyyyy hh:mm	zz h xx min	...	...
Sjjj/nnn	ddMMMyyyy hh:mm	5 min after readiness for surgery ± 1 min	ddMMMyyyy hh:mm	zz h xx min	T11	2
Sjjj/nnn	ddMMMyyyy hh:mm	10 min after readiness for surgery ± 1 min	ddMMMyyyy hh:mm	zz h xx min	T10	3
Sjjj/nnn	ddMMMyyyy hh:mm	15 min after readiness for surgery ± 1 min	ddMMMyyyy hh:mm	zz h xx min	T8	3
Sjjj/nnn	ddMMMyyyy hh:mm	...	ddMMMyyyy hh:mm	zz h xx min	...	...
Sjjj/nnn	ddMMMyyyy hh:mm	30 min after regression of two dermatomers ± 5 min	ddMMMyyyy hh:mm	zz h xx min	T12	3
Sjjj/nnn	ddMMMyyyy hh:mm	1 hour after regression of two dermatomers ± 5 min	ddMMMyyyy hh:mm	zz h xx min	L1	2
Sjjj/nnn	ddMMMyyyy hh:mm	1 hour and 30 min after regression of two dermatomers ± 5 min	ddMMMyyyy hh:mm	zz h xx min	L3	1
Sjjj/nnn	ddMMMyyyy hh:mm	...	ddMMMyyyy hh:mm	zz h xx min	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.6.3 - Time to events and maximum level of sensory block

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Spinal Injection Date/time	Event	Event Date/time	Time to Event	Metameric Level
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Spinal Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Onset of Sensory Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Onset of Motor Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Readiness for Surgery	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Sensory Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Motor Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Unassisted Ambulation	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Maximum Level of Sensory Block	ddMMMyyyy hh:mm	yy h xx min	T8
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Two Dermatomers	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Eligibility for Home Discharge	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	First Spontaneous Urine Voiding	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Rescue Anaesthesia/Analgesia	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	First Post-Operative Analgesia	ddMMMyyyy hh:mm	yy h xx min	
Skkk/ttt	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.6.3 - Time to events and maximum level of sensory block

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Spinal Injection Date/time	Event	Event Date/time	Time to Event	Metameric Level
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Spinal Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Onset of Sensory Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Onset of Motor Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Readiness for Surgery	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Sensory Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Motor Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Unassisted Ambulation	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Maximum Level of Sensory Block	ddMMMyyyy hh:mm	yy h xx min	T8
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Two Dermatomers	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Eligibility for Home Discharge	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	First Spontaneous Urine Voiding	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Rescue Anaesthesia/Analgesia	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	First Post-Operative Analgesia	ddMMMyyyy hh:mm	yy h xx min	
Skkk/ttt	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.6.3 - Time to events and maximum level of sensory block

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Spinal Injection Date/time	Event	Event Date/time	Time to Event	Metameric Level
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Spinal Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Onset of Sensory Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Onset of Motor Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Readiness for Surgery	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Sensory Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Motor Block	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Unassisted Ambulation	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Maximum Level of Sensory Block	ddMMMyyyy hh:mm	yy h xx min	T8
Sjjj/nnn	ddMMMyyyy hh:mm	Regression of Two Dermatomers	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Eligibility for Home Discharge	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	First Spontaneous Urine Voiding	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	Rescue Anaesthesia/Analgesia	ddMMMyyyy hh:mm	yy h xx min	
Sjjj/nnn	ddMMMyyyy hh:mm	First Post-Operative Analgesia	ddMMMyyyy hh:mm	yy h xx min	
Skkk/ttt	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.6.4 - Effectiveness of anaesthesia and quality of spinal block

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Spinal Injection Date/time	Assessment Date/time	Elapsed Time	Parameter	Assessment
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Achievement of an Effective Anaesthesia	Y
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Quality of Spinal Block	Adequate Spinal Block
Skkk/ttt	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Achievement of an Effective Anaesthesia	N
Skkk/ttt	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Quality of Spinal Block	Inadequate Spinal Block
Snnn/xxx	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.6.4 - Effectiveness of anaesthesia and quality of spinal block

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Spinal Injection Date/time	Assessment Date/time	Elapsed Time	Parameter	Assessment
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Achievement of an Effective Anaesthesia	Y
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Quality of Spinal Block	Adequate Spinal Block
Skkk/ttt	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Achievement of an Effective Anaesthesia	N
Skkk/ttt	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Quality of Spinal Block	Inadequate Spinal Block
Snnn/xxx	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.6.4 - Effectiveness of anaesthesia and quality of spinal block

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Spinal Injection Date/time	Assessment Date/time	Elapsed Time	Parameter	Assessment
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Achievement of an Effective Anaesthesia	Y
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Quality of Spinal Block	Adequate Spinal Block
Skkk/ttt	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Achievement of an Effective Anaesthesia	N
Skkk/ttt	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Quality of Spinal Block	Inadequate Spinal Block
Snnn/xxx	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	AE Nr / FU Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start or Follow-up Date/time / Start or Follow-up Day / End Date/time / End Day / Duration	IMP injection Date/time / Day / Time from IMP injection	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other action taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day j / Ongoing / --- / ---	ddMMMyyyy hh:mm / Day j / xx h xx min	N / Moderate / Not related / Weather condition	Recovering/resolving / Not applicable / ---	Y / N / ---
Sjjj/nnn	1/1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day k / ddMMMyyyy hh:mm / Day k / x h	ddMMMyyyy hh:mm / Day j / xx h xx min	N / Mild / Not related / Weather condition	Recovered/resolved / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Program: Listings\c122-ae-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	AE Nr / FU Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start or Follow-up Date/time / Start or Follow-up Day / End Date/time / End Day / Duration	IMP injection Date/time / Day / Time from IMP injection	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other action taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day j / Ongoing / --- / ---	ddMMMyyyy hh:mm / Day j / xx h xx min	N / Moderate / Not related / Weather condition	Recovering/resolving / Not applicable / ---	Y / N / ---
Sjjj/nnn	1/1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day k / ddMMMyyyy hh:mm / Day k / x h	ddMMMyyyy hh:mm / Day j / xx h xx min	N / Mild / Not related / Weather condition	Recovered/resolved / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Program: Listings\c122-ae-lst.sas

Listing 16.2.7.1 - Treatment-emergent adverse events

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	AE Nr / FU Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start or Follow-up Date/time / Start or Follow-up Day / End Date/time / End Day / Duration	IMP injection Date/time / Day / Time from IMP injection	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other action taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day j / Ongoing / --- / ---	ddMMMyyyy hh:mm / Day j / xx h xx min	N / Moderate / Not related / Weather condition	Recovering/resolving / Not applicable / ---	Y / N / ---
Sjjj/nnn	1/1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day k / ddMMMyyyy hh:mm / Day k / x h	ddMMMyyyy hh:mm / Day j / xx h xx min	N / Mild / Not related / Weather condition	Recovered/resolved / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Program: Listings\c122-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	AE Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start Date/time / End Date/time / Duration	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other Action Taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day k / ddMMMyyyy hh:mm / Day k / x h	N / Mild / Not related / Weather condition	Recovered/resolved / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Program: Listings\c122-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	AE Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start Date/time / End Date/time / Duration	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other Action Taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day k / ddMMMyyyy hh:mm / Day k / x h	N / Mild / Not related / Weather condition	Recovered/resolved / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Program: Listings\c122-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	AE Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start Date/time / End Date/time / Duration	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other Action Taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day k / ddMMMyyyy hh:mm / Day k / x h	N / Mild / Not related / Weather condition	Recovered/resolved / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Program: Listings\c122-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Investigational Medicinal Product: Not Assigned

Subject ID	AE Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start Date/time / End Date/time / Duration	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other Action Taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day k / ddMMMyyyy hh:mm / Day k / x h	N / Mild / Not related / Weather condition	Recovered/resolved / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Program: Listings\c122-ae-lst.sas

Listing 16.2.7.2 - Pre-treatment adverse events

Investigational Medicinal Product: Not Treated

Subject ID	AE Nr	Verbatim / Preferred Term [1] / System Organ Class [1]	Start Date/time / End Date/time / Duration	Seriousness / Severity / Related to IMP / Other relationship	Outcome / Action taken with IMP / Other Action Taken	Therapy required / Leading to discontinuation / Comments
Sjjj/nnn	1	Headache / Headache / Nervous system disorders	ddMMMyyyy hh:mm / Day k / ddMMMyyyy hh:mm / Day k / x h	N / Mild / Not related / Weather condition	Recovered/resolved / Not applicable / ---	Y / N / ---
Skkk/ppp	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: MedDRA version 18.1
Program: Listings\c122-ae-lst.sas

Listing 16.2.9.1 - Vital signs

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Time Point	Assessment Date/time	Parameter	Value	Normal Range	Interpretation [1]
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Skkk/xxx	...	...	...	...	>= 95 %	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-vs-lst.sas

Listing 16.2.9.1 - Vital signs

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Time Point	Assessment Date/time	Parameter	Value	Normal Range	Interpretation [1]
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Skkk/xxx	...	...	...	...	>= 95 %	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-vs-lst.sas

Listing 16.2.9.1 - Vital signs

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Time Point	Assessment Date/time	Parameter	Value	Normal Range	Interpretation [1]
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Discharge	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Skkk/xxx	...	...	...	...	>= 95 %	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-vs-lst.sas

Listing 16.2.9.1 - Vital signs

Investigational Medicinal Product: Not Assigned

Subject ID	Time Point	Assessment Date/time	Parameter	Value	Normal Range	Interpretation [1]
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Skkk/xxx	...	...	...	...	>= 95 %	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-vs-lst.sas

Listing 16.2.9.1 - Vital signs

Investigational Medicinal Product: Not Treated

Subject ID	Time Point	Assessment Date/time	Parameter	Value	Normal Range	Interpretation [1]
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Systolic Blood Pressure	xxx mmHg	100-139 mmHg	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Diastolic Blood Pressure	xxx mmHg	50-89 mmHg	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Baseline	ddMMMyyyy hh:mm	Oxygen Saturation	xxx.x %	>= 95 %	X
Skkk/xxx	...	...	...	...	>= 95 %	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-vs-lst.sas

Listing 16.2.9.2 - ECG

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Time Point	Assessment Date/time	Parameter	Value	Normal Range	Interpretation [1]
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, Not Clinically Significant	---	---
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Clinically Significant Abnormalities	xxxxx	---	---
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	PR Interval	xxx msec	100-220 msec	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	QRS Duration	xxx msec	<= 120 msec	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	QT Interval	xxx msec	<= 500 msec	X
Skkk/xxx	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-eg-lst.sas

Listing 16.2.9.2 - ECG

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Time Point	Assessment Date/time	Parameter	Value	Normal Range	Interpretation [1]
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, Not Clinically Significant	---	---
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Clinically Significant Abnormalities	xxxxx	---	---
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	PR Interval	xxx msec	100-220 msec	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	QRS Duration	xxx msec	<= 120 msec	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	QT Interval	xxx msec	<= 500 msec	X
Skkk/xxx	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-eg-lst.sas

Listing 16.2.9.2 - ECG

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Time Point	Assessment Date/time	Parameter	Value	Normal Range	Interpretation [1]
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, Not Clinically Significant	---	---
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Clinically Significant Abnormalities	xxxxx	---	---
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	PR Interval	xxx msec	100-220 msec	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	QRS Duration	xxx msec	<= 120 msec	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	QT Interval	xxx msec	<= 500 msec	X
Skkk/xxx	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-eg-lst.sas

Listing 16.2.9.2 - ECG

Investigational Medicinal Product: Not Treated

Subject ID	Time Point	Assessment Date/time	Parameter	Value	Normal Range	Interpretation [1]
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Investigator's Interpretation	Abnormal, Not Clinically Significant	---	---
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Clinically Significant Abnormalities	xxxxx	---	---
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	Heart Rate	xxx beats/min	50-90 beats/min	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	PR Interval	xxx msec	100-220 msec	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	QRS Duration	xxx msec	<= 120 msec	X
Sjjj/nnn	Unscheduled	ddMMMyyyy hh:mm	QT Interval	xxx msec	<= 500 msec	X
Skkk/xxx	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-eg-lst.sas

Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Spinal Injection Date/time	Time Point	Assessment Date/time	Elapsed Time	Parameter	Pain Assessment [1]
Sjjj/nnn	ddMMMyyyy hh:mm	Immediately after regression of spinal block	ddMMMyyyy hh:mm	yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Discharge	ddMMMyyyy hh:mm	yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	yy days yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Immediately after regression of spinal block	ddMMMyyyy hh:mm	yy h xx min	Pain at the Surgery Site	7
Sjjj/nnn	ddMMMyyyy hh:mm	Discharge	ddMMMyyyy hh:mm	yy h xx min	Pain at the Surgery Site	7
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Pain at the Surgery Site	7
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	yy days yy h xx min	Pain at the Surgery Site	7
Snnn/xxx	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Program: Listings\c122-qs-lst.sas

Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Spinal Injection Date/time	Time Point	Assessment Date/time	Elapsed Time	Parameter	Pain Assessment [1]
Sjjj/nnn	ddMMMyyyy hh:mm	Immediately after regression of spinal block	ddMMMyyyy hh:mm	yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Discharge	ddMMMyyyy hh:mm	yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	yy days yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Immediately after regression of spinal block	ddMMMyyyy hh:mm	yy h xx min	Pain at the Surgery Site	7
Sjjj/nnn	ddMMMyyyy hh:mm	Discharge	ddMMMyyyy hh:mm	yy h xx min	Pain at the Surgery Site	7
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Pain at the Surgery Site	7
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	yy days yy h xx min	Pain at the Surgery Site	7
Snnn/xxx	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Program: Listings\c122-qs-lst.sas

Listing 16.2.9.3 - Pain assessment at the site of injection and at the site of surgery

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Spinal Injection Date/time	Time Point	Assessment Date/time	Elapsed Time	Parameter	Pain Assessment [1]
Sjjj/nnn	ddMMMyyyy hh:mm	Immediately after regression of spinal block	ddMMMyyyy hh:mm	yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Discharge	ddMMMyyyy hh:mm	yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	yy days yy h xx min	Pain at the Injection Site	5
Sjjj/nnn	ddMMMyyyy hh:mm	Immediately after regression of spinal block	ddMMMyyyy hh:mm	yy h xx min	Pain at the Surgery Site	7
Sjjj/nnn	ddMMMyyyy hh:mm	Discharge	ddMMMyyyy hh:mm	yy h xx min	Pain at the Surgery Site	7
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Pain at the Surgery Site	7
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	yy days yy h xx min	Pain at the Surgery Site	7
Snnn/xxx	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: Pain was assessed according to a numerical rating scale ranging from 0 (no pain) to 10 (worst imaginable pain)
Program: Listings\c122-qs-lst.sas

Listing 16.2.9.4 - Transient neurological symptoms

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Spinal Injection Date/time	Time Point	Questionnaire Date/time	Elapsed Time	Parameter	Assessment
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Transient Neurological Symptoms	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Was the Patient Feeling Good?	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Reported Problems	Nausea/Vomiting
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Unusual Sensations?	Y
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Symptoms	Burning, Tingling
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Location of Symptoms	Thighs anterior, Lower limbs
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Laterality of Symptoms	Bilateral
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Previous Experience of Such Symptoms?	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	zz days yy h xx min	Transient Neurological Symptoms	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	zz days yy h xx min	Was the Patient Feeling Good?	Y
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	zz days yy h xx min	Unusual Sensations?	N

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.9.4 - Transient neurological symptoms

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Spinal Injection Date/time	Time Point	Questionnaire Date/time	Elapsed Time	Parameter	Assessment
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Transient Neurological Symptoms	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Was the Patient Feeling Good?	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Reported Problems	Nausea/Vomiting
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Unusual Sensations?	Y
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Symptoms	Burning, Tingling
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Location of Symptoms	Thighs anterior, Lower limbs
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Laterality of Symptoms	Bilateral
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Previous Experience of Such Symptoms?	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	zz days yy h xx min	Transient Neurological Symptoms	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	zz days yy h xx min	Was the Patient Feeling Good?	Y
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	zz days yy h xx min	Unusual Sensations?	N

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.9.4 - Transient neurological symptoms

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Spinal Injection Date/time	Time Point	Questionnaire Date/time	Elapsed Time	Parameter	Assessment
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Transient Neurological Symptoms	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Was the Patient Feeling Good?	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Reported Problems	Nausea/Vomiting
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Unusual Sensations?	Y
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Symptoms	Burning, Tingling
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Location of Symptoms	Thighs anterior, Lower limbs
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Laterality of Symptoms	Bilateral
Sjjj/nnn	ddMMMyyyy hh:mm	Day 2	ddMMMyyyy hh:mm	yy h xx min	Previous Experience of Such Symptoms?	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	zz days yy h xx min	Transient Neurological Symptoms	N
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	zz days yy h xx min	Was the Patient Feeling Good?	Y
Sjjj/nnn	ddMMMyyyy hh:mm	Day 7±1	ddMMMyyyy hh:mm	zz days yy h xx min	Unusual Sensations?	N

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.9.5 - Modified Aldrete's scoring scale

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Spinal Injection Date/time	Assessment Date/time	Elapsed Time	Parameter	Assessment
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Activity	2 - Able to move 4 extremities voluntarily or on command
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Respiration	2 - Able to breathe deeply and cough freely
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Circulation	2 - Blood pressure ± 20% of pre-anaesthetic level
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Consciousness	2 - Fully awake
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	O_2 saturation	2 - Able to maintain O_2 saturation > 92% on room air
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Dressing	2 - Dry and clean
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Pain	2 - Pain free
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Ambulation	2 - Able to stand up and walk straight
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Fasting-feeding	2 - Able to drink fluids
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Urine output	2 - Has voided
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Total Score	20
Snnn/xxx	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.9.5 - Modified Aldrete's scoring scale

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Spinal Injection Date/time	Assessment Date/time	Elapsed Time	Parameter	Assessment
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Activity	2 - Able to move 4 extremities voluntarily or on command
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Respiration	2 - Able to breathe deeply and cough freely
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Circulation	2 - Blood pressure ± 20% of pre-anaesthetic level
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Consciousness	2 - Fully awake
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	O_2 saturation	2 - Able to maintain O_2 saturation > 92% on room air
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Dressing	2 - Dry and clean
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Pain	2 - Pain free
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Ambulation	2 - Able to stand up and walk straight
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Fasting-feeding	2 - Able to drink fluids
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Urine output	2 - Has voided
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Total Score	20
Snnn/xxx	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.9.5 - Modified Aldrete's scoring scale

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Spinal Injection Date/time	Assessment Date/time	Elapsed Time	Parameter	Assessment
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Activity	2 - Able to move 4 extremities voluntarily or on command
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Respiration	2 - Able to breathe deeply and cough freely
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Circulation	2 - Blood pressure ± 20% of pre-anaesthetic level
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Consciousness	2 - Fully awake
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	O_2 saturation	2 - Able to maintain O_2 saturation > 92% on room air
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Dressing	2 - Dry and clean
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Pain	2 - Pain free
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Ambulation	2 - Able to stand up and walk straight
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Fasting-feeding	2 - Able to drink fluids
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Urine output	2 - Has voided
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Total Score	20
Snnn/xxx	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.9.5 - Modified Aldrete's scoring scale

Investigational Medicinal Product: Not Treated

Subject ID	Spinal Injection Date/time	Assessment Date/time	Elapsed Time	Parameter	Assessment
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Activity	2 - Able to move 4 extremities voluntarily or on command
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Respiration	2 - Able to breathe deeply and cough freely
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Circulation	2 - Blood pressure ± 20% of pre-anaesthetic level
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Consciousness	2 - Fully awake
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	O_2 saturation	2 - Able to maintain O_2 saturation > 92% on room air
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Dressing	2 - Dry and clean
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Pain	2 - Pain free
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Ambulation	2 - Able to stand up and walk straight
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Fasting-feeding	2 - Able to drink fluids
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Urine output	2 - Has voided
Sjjj/nnn	ddMMMyyyy hh:mm	ddMMMyyyy hh:mm	yy h xx min	Total Score	20
Snnn/xxx	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-qs-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Date of History Collection	Verbatim / Preferrec Term [1] / System Organ Class [1]	Date of Diagnosis/ Surgery	Date of Resolution (Ongoing)
Sjjj/nnn	ddMMMyyyy	Pollen allergy / Seasonal allergy / Immune system disorders	MMMyyyy	Ongoing
Sjjj/nnn	ddMMMyyyy	Appendectomy / Appendicectomy / Surgical and medical procedures	yyyy	---
Sjjj/nnn	ddMMMyyyy	Appendectomy / Appendicectomy / Surgical and medical procedures	yyyy	---
Skkk/xxx	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-mh-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Date of History Collection	Verbatim / Preferrec Term [1] / System Organ Class [1]	Date of Diagnosis/ Surgery	Date of Resolution (Ongoing)
Sjjj/nnn	ddMMMyyyy	Pollen allergy / Seasonal allergy / Immune system disorders	MMMyyyy	Ongoing
Sjjj/nnn	ddMMMyyyy	Appendectomy / Appendicectomy / Surgical and medical procedures	yyyy	---
Sjjj/nnn	ddMMMyyyy	Appendectomy / Appendicectomy / Surgical and medical procedures	yyyy	---
Skkk/xxx	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-mh-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Date of History Collection	Verbatim / Preferrec Term [1] / System Organ Class [1]	Date of Diagnosis/ Surgery	Date of Resolution (Ongoing)
Sjjj/nnn	ddMMMyyyy	Pollen allergy / Seasonal allergy / Immune system disorders	MMMyyyy	Ongoing
Sjjj/nnn	ddMMMyyyy	Appendectomy / Appendicectomy / Surgical and medical procedures	yyyy	---
Sjjj/nnn	ddMMMyyyy	Appendectomy / Appendicectomy / Surgical and medical procedures	yyyy	---
Skkk/xxx	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-mh-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Investigational Medicinal Product: Not Assigned

Subject ID	Date of History Collection	Verbatim / Preferrec Term [1] / System Organ Class [1]	Date of Diagnosis/ Surgery	Date of Resolution (Ongoing)
Sjjj/nnn	ddMMMyyyy	Pollen allergy / Seasonal allergy / Immune system disorders	MMMyyyy	Ongoing
Sjjj/nnn	ddMMMyyyy	Appendectomy / Appendicectomy / Surgical and medical procedures	yyyy	---
Sjjj/nnn	ddMMMyyyy	Appendectomy / Appendicectomy / Surgical and medical procedures	yyyy	---
Skkk/xxx	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-mh-lst.sas

Listing 16.2.10.1 - Medical and surgical history

Investigational Medicinal Product: Not Treated

Subject ID	Date of History Collection	Verbatim / Preferrec Term [1] / System Organ Class [1]	Date of Diagnosis/ Surgery	Date of Resolution (Ongoing)
Sjjj/nnn	ddMMMyyyy	Pollen allergy / Seasonal allergy / Immune system disorders	MMMyyyy	Ongoing
Sjjj/nnn	ddMMMyyyy	Appendectomy / Appendicectomy / Surgical and medical procedures	yyyy	---
Sjjj/nnn	ddMMMyyyy	Appendectomy / Appendicectomy / Surgical and medical procedures	yyyy	---
Skkk/xxx	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: N=Normal, NCS=Abnormal, Not Clinically Significant, CS=Abnormal, Clinically Significant
Program: Listings\c122-mh-lst.sas

Listing 16.2.10.2 - Physical examination

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Time Point	Date of History Collection	ASA Physical Status	Investigator's Interpretation	Clinically Significant Findings / Preferrec Term [1] / System Organ Class [1]
Sjjj/nnn	Screening	ddMMMyyyy	III	Abnormal, Not Clinically Significant	---
Skkk/ppp	Screening	ddMMMyyyy	II	Abnormal, Clinically Significant	Cardiac disorder / Cardiac disorder / Cardiac disorders
Snnn/xxx	Screening	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pe-lst.sas

Listing 16.2.10.2 - Physical examination

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Time Point	Date of History Collection	ASA Physical Status	Investigator's Interpretation	Clinically Significant Findings / Preferrec Term [1] / System Organ Class [1]
Sjjj/nnn	Screening	ddMMMyyyy	III	Abnormal, Not Clinically Significant	---
Skkk/ppp	Screening	ddMMMyyyy	II	Abnormal, Clinically Significant	Cardiac disorder / Cardiac disorder / Cardiac disorders
Snnn/xxx	Screening	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pe-lst.sas

Listing 16.2.10.2 - Physical examination

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Time Point	Date of History Collection	ASA Physical Status	Investigator's Interpretation	Clinically Significant Findings / Preferrec Term [1] / System Organ Class [1]
Sjjj/nnn	Screening	ddMMMyyyy	III	Abnormal, Not Clinically Significant	---
Skkk/ppp	Screening	ddMMMyyyy	II	Abnormal, Clinically Significant	Cardiac disorder / Cardiac disorder / Cardiac disorders
Snnn/xxx	Screening	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pe-lst.sas

Listing 16.2.10.2 - Physical examination

Investigational Medicinal Product: Not Assigned

Subject ID	Time Point	Date of History Collection	ASA Physical Status	Investigator's Interpretation	Clinically Significant Findings / Preferrec Term [1] / System Organ Class [1]
Sjjj/nnn	Screening	ddMMMyyyy	III	Abnormal, Not Clinically Significant	---
Skkk/ppp	Screening	ddMMMyyyy	II	Abnormal, Clinically Significant	Cardiac disorder / Cardiac disorder / Cardiac disorders
Snnn/xxx	Screening	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pe-lst.sas

Listing 16.2.10.2 - Physical examination

Investigational Medicinal Product: Not Treated

Subject ID	Time Point	Date of History Collection	ASA Physical Status	Investigator's Interpretation	Clinically Significant Findings / Preferrec Term [1] / System Organ Class [1]
Sjjj/nnn	Screening	ddMMMyyyy	III	Abnormal, Not Clinically Significant	---
Skkk/ppp	Screening	ddMMMyyyy	II	Abnormal, Clinically Significant	Cardiac disorder / Cardiac disorder / Cardiac disorders
Snnn/xxx	Screening	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-pe-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	CM Nr	Prior or Concomitant	Verbatim / Indication / Related to AE MH SH [1]	Standardised name [2] / Active ingredients [2] / ATC level 4 [2]	Dose	Start date/time / End date/time (Ongoing)	Frequency / Dosage form / Route
Sjjj/nnn	1	Concomitant	Paracetamol / Analgesia / AE Nr. 1	Paracetamol / Paracetamol / Anilides	500 mg	ddMMMyyyy hh:mm / ddMMMyyyy hh:mm	Once / Tablet / Oral
Sjjj/nnn	..	..	..	..	..	..	..

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: AE=Adverve Event, MH=Medical History, SH=Surgical History
Note 2: WHODDE September 1, 2015
Program: Listings\k294-cm-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	CM Nr	Prior or Concomitant	Verbatim / Indication / Related to AE MH SH [1]	Standardised name [2] / Active ingredients [2] / ATC level 4 [2]	Dose	Start date/time / End date/time (Ongoing)	Frequency / Dosage form / Route
Sjjj/nnn	1	Concomitant	Paracetamol / Analgesia / AE Nr. 1	Paracetamol / Paracetamol / Anilides	500 mg	ddMMMyyyy hh:mm / ddMMMyyyy hh:mm	Once / Tablet / Oral
Sjjj/nnn	..	..	..	..	..	..	..

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: AE=Adverve Event, MH=Medical History, SH=Surgical History
Note 2: WHODDE September 1, 2015
Program: Listings\k294-cm-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	CM Nr	Prior or Concomitant	Verbatim / Indication / Related to AE MH SH [1]	Standardised name [2] / Active ingredients [2] / ATC level 4 [2]	Dose	Start date/time / End date/time (Ongoing)	Frequency / Dosage form / Route
Sjjj/nnn	1	Concomitant	Paracetamol / Analgesia / AE Nr. 1	Paracetamol / Paracetamol / Anilides	500 mg	ddMMMyyyy hh:mm / ddMMMyyyy hh:mm	Once / Tablet / Oral
Sjjj/nnn	..	..	..	..	..	..	..

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: AE=Adverve Event, MH=Medical History, SH=Surgical History
Note 2: WHODDE September 1, 2015
Program: Listings\k294-cm-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Investigational Medicinal Product: Not Assigned

Subject ID	CM Nr	Prior or Concomitant	Verbatim / Indication / Related to AE MH SH [1]	Standardised name [2] / Active ingredients [2] / ATC level 4 [2]	Dose	Start date/time / End date/time (Ongoing)	Frequency / Dosage form / Route
Sjjj/nnn	1	Concomitant	Ringer acetate / Fluid therapy / ---	Ringer acetate / Calcium chloride/Potassium chloride / Electrolyte solutions	500 mL	ddMMMyyyy hh:mm / ddMMMyyyy hh:mm	Continuous / Injection, solution / Intravenous
Sjjj/nnn	..	..	..	..	..	..	..

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: AE=Adverve Event, MH=Medical History, SH=Surgical History
Note 2: WHODDE September 1, 2015
Program: Listings\k294-cm-lst.sas

Listing 16.2.10.3 - Prior and concomitant medications

Investigational Medicinal Product: Not Treated

Subject ID	CM Nr	Prior or Concomitant	Verbatim / Indication / Related to AE MH SH [1]	Standardised name [2] / Active ingredients [2] / ATC level 4 [2]	Dose	Start date/time / End date/time (Ongoing)	Frequency / Dosage form / Route
Sjjj/nnn	1	Concomitant	Ringer acetate / Fluid therapy / ---	Ringer acetate / Calcium chloride/Potassium chloride / Electrolyte solutions	500 mL	ddMMMyyyy hh:mm / ddMMMyyyy hh:mm	Continuous / Injection, solution / Intravenous
Sjjj/nnn	..	..	..	..	..	..	..

Note: Subjects are listed according to the dose level of the product they actually received
Note 1: AE=Adverve Event, MH=Medical History, SH=Surgical History
Note 2: WHODDE September 1, 2015
Program: Listings\k294-cm-lst.sas

Listing 16.2.10.4 - Subjects study visits

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Visit 1 Screening Day -14/1 Date (Day)	Visit 2 Day 1 Date (Day)	Final Visit Date (Day)	Early Termination Visit Date (Day)	Follow-up Day 2 Date (Day)	Follow-up Day 7±1 Date (Day)	Additional Assessment Date (Day)
Sjjj/nnn	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)
Skkk/xxx	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-sv-lst.sas

Listing 16.2.10.4 - Subjects study visits

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Visit 1 Screening Day -14/1 Date (Day)	Visit 2 Day 1 Date (Day)	Final Visit Date (Day)	Early Termination Visit Date (Day)	Follow-up Day 2 Date (Day)	Follow-up Day 7±1 Date (Day)	Additional Assessment Date (Day)
Sjjj/nnn	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)
Skkk/xxx	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-sv-lst.sas

Listing 16.2.10.4 - Subjects study visits

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Visit 1 Screening Day -14/1 Date (Day)	Visit 2 Day 1 Date (Day)	Final Visit Date (Day)	Early Termination Visit Date (Day)	Follow-up Day 2 Date (Day)	Follow-up Day 7±1 Date (Day)	Additional Assessment Date (Day)
Sjjj/nnn	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)	ddMMMyyyy (j)
Skkk/xxx	...	...	...	...	...	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-sv-lst.sas

Listing 16.2.10.4 - Subjects study visits

Investigational Medicinal Product: Not Assigned

Subject ID	Visit 1 Screening Day -14/1 Date (Day)	Visit 2 Day 1 Date (Day)	Final Visit Date (Day)	Early Termination Visit Date (Day)	Follow-up Day 2 Date (Day)	Follow-up Day 7±1 Date (Day)	Additional Assessment Date (Day)
Sjjj/nnn	ddMMMyyyy (j)	---	---	---	---	---	---
Skkk/xxx	...	---	---	---	---	---	---

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-sv-lst.sas

Listing 16.2.10.4 - Subjects study visits

Investigational Medicinal Product: Not Treated

Subject ID	Visit 1 Screening Day -14/1 Date (Day)	Visit 2 Day 1 Date (Day)	Final Visit Date (Day)	Early Termination Visit Date (Day)	Follow-up Day 2 Date (Day)	Follow-up Day 7±1 Date (Day)	Additional Assessment Date (Day)
Sjjj/nnn	ddMMMyyyy (j)	ddMMMyyyy (j)	---	---	---	---	---
Skkk/xxx	...	...	---	---	---	---	---

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-sv-lst.sas

Listing 16.2.10.5 - Pregnancy test

Investigational Medicinal Product: Chloroprocaine 1% - 30 mg

Subject ID	Time Point	Urine Collection Date/time	Pregnancy Test Result
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Negative
Skkk/ppp	Screening	ddMMMyyyy hh:mm	Negative
Snnn/xxx	Screening	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-xt-lst.sas

Listing 16.2.10.5 - Pregnancy test

Investigational Medicinal Product: Chloroprocaine 1% - 40 mg

Subject ID	Time Point	Urine Collection Date/time	Pregnancy Test Result
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Negative
Skkk/ppp	Screening	ddMMMyyyy hh:mm	Negative
Snnn/xxx	Screening	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-xt-lst.sas

Listing 16.2.10.5 - Pregnancy test

Investigational Medicinal Product: Chloroprocaine 1% - 50 mg

Subject ID	Time Point	Urine Collection Date/time	Pregnancy Test Result
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Negative
Skkk/ppp	Screening	ddMMMyyyy hh:mm	Negative
Snnn/xxx	Screening	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-xt-lst.sas

Listing 16.2.10.5 - Pregnancy test

Investigational Medicinal Product: Not Assigned

Subject ID	Time Point	Urine Collection Date/time	Pregnancy Test Result
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Negative
Skkk/ppp	Screening	ddMMMyyyy hh:mm	Negative
Snnn/xxx	Screening	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-xt-lst.sas

Listing 16.2.10.5 - Pregnancy test

Investigational Medicinal Product: Not Treated

Subject ID	Time Point	Urine Collection Date/time	Pregnancy Test Result
Sjjj/nnn	Screening	ddMMMyyyy hh:mm	Negative
Skkk/ppp	Screening	ddMMMyyyy hh:mm	Negative
Snnn/xxx	Screening	...	...

Note: Subjects are listed according to the dose level of the product they actually received
Program: Listings\c122-xt-lst.sas

Figure 16.2.5.j - Subject [Sxxx]/[nnn] - Individual plasma concentration curves of Chloroprocaine and CABA

Individual plasma concentration curves of Chloroprocaine and CABA (linear scale and logarithmic/linear scale)