STATISTICAL ANALYSIS PLAN

Name	Statistical Analysis Plan (SAP) on Protocol LDP0114
Version	Final Version, 2.0

Study drug	Levopront® (levodropropizine)
Study code	LDP0114
Title of Study	Multicenter open-label randomized clinical trial of the efficacy and safety of Levopront® syrup 30 mg/5 ml in comparison with Libexin® 100 mg tablets in patients suffering from dry nonproductive cough caused by acute upper respiratory infection.
Sponsor	Dompé farmaceutici s.p.a.
CRO	IPHARMA LLC
Data Processing	KeyStat Ltd.

Version Control

Version	Version Date	Change reason
Draft Version, 0.1	14 September 2016	Initial version
Draft Version, 0.2	28 April 2017	Comments to the primary efficacy variable
Final Version, 1.0	01 June 2017	Document finalization
Draft Version, 2.0	02 April 2018	Changes due to Protocol Amendment
Final Version, 2.0	05 April 2018	Document finalization

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1. LIST OF ABBREVIATIONS

Abbreviation	Explanation
ADR	Adverse Drug Reaction
AE	Adverse Event
ALT	Alanine Aminotransferase
AP	Arterial Pressure
APTT	Activated Partial Thromboplastin Time
AST	Aspartate Aminotransferase
BLQ	Below the Limit of Quantification
BMI	Body Mass Index
CI	Confidence Interval
CLcr	Creatinine Clearance
CRF	Case Report Form
CRO	Contract Research Organization
CS	Clinically Significant
ECG	Electrocardiogram
ESR	Erythrocyte Sedimentation Rate
FEV_1	Forced Expiratory Volume for a second
GCP	Good Clinical Practice
GGT	Gamma-glutamyltransferase
HBV, HCV	Hepatitis B and C
IC	Informed Consent
ICH	International Conference on Harmonization
ICH GCP	Guidelines for Good Clinical Practice of the International Conference on Harmonization
IEC	Independent Ethics Committee
ITT	Intent-to-treat
LME	Linear Mixed Effect Model
Mean	Mean value
N	Number of observations
PP	Per Protocol
PTT	Prothrombin Time
p-value	p-value for H_0 of test performed
SADR	Serious Adverse Drug Reaction
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SD	Standard Deviation
SE	Standard Error
TESS	Treatment Emergency Sign and Symptom
VAS	Visual Analogue Scale
WHO	World Health Organization

2. INTRODUCTION

This document contains further details to the statistical analyses described in the protocol LDP0114 and is the primary source of all statistical analyses for the study.

2.1 STUDY DESIGN

The present study is a multicenter open-label randomized comparative Phase 3 clinical trial in parallel groups. The study will be conducted at 8 Russian sites. The total expected number of enrolled patients is 184 (92 per each group). Taking into account the possibility of 20% screen-failure rate, up to 230 patients will be screened.

The study will consist of 3 periods: screening and randomization, study therapy, follow-up.

Patients meeting all inclusion/exclusion criteria will be randomized into two groups (at a 1:1 ratio):

- Levopront® syrup 30 mg/5 ml — 10 ml t.i.d. for 7 days
- Libexin® 100 mg tablets — 1 tablet t.i.d. for 7 days

The study drugs will be taken 3 times a day (with the interval of not less than 6 hours, between meals) during 7 days. The first study drug administration will be performed at the clinical site on the day of randomization; the last study drug administration will be performed in the evening before Day 8.

Figure 2.1 Study diagram

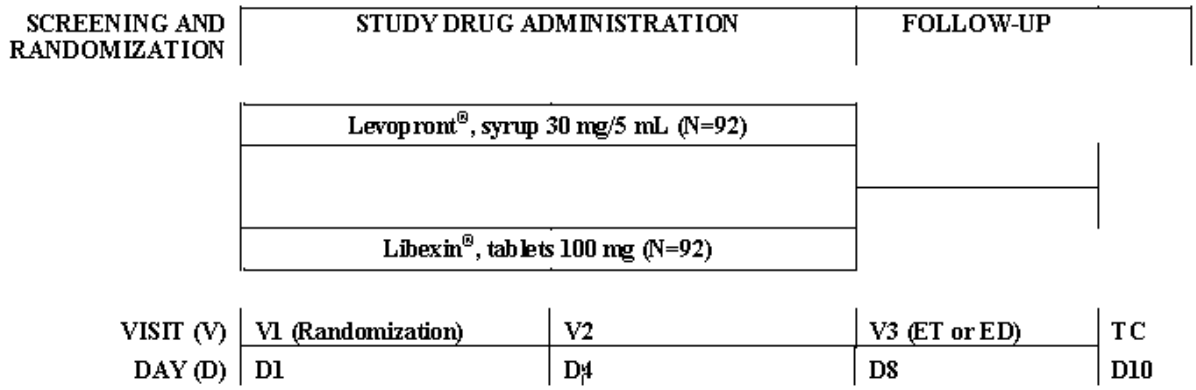

Table 2.1 Study procedure Schedule

	Screening and randomization	Study treatment		Follow-up
Visit (V)	**V1**	**V2**	**V3 ET or ED**	**TC**
Day (D)	**D1**	**D4**	**D8**	**D10**
Visit window		**± 1 day**	**± 1 day**	**± 1 day**
Informed consent	☒			
Patient's registration	☒			
Demography data	☒			
Medical history	☒			
Physical examination	☒	☒	☒	
Vital signs	☒	☒	☒	
Body height and weight[5]	☒			
Cough severity and frequency assessment with the "Six-point daytime and nighttime cough assessment scale"	☒	☒	☒	
Cough intensity assessment with the visual-analogue scale.	☒	☒	☒	
Laboratory testing:				
- hematology	☒		☒	
- biochemistry	☒		☒	
- urinalysis	☒		☒	
- pregnancy test[1]	☒		☒	
ECG	☒			
Spirometry[2]	☒		☒	
Chest X-ray or fluorography[3]	☒			
Inclusion/exclusion criteria	☒			
Randomization[4]	☒			
Study drug and Patient's dairy distribution to patient[4]	☒	☒		
Return and accountability of the study drug. Patient's dairy review		☒	☒	
Concomitant medications assessment	☒	☒	☒	
AE assessment	☒	☒	☒	☒

Abbreviations: ET — end of treatment, ED — early discontinuation, ECG — electrocardiography, AE — adverse events, TC – telephone contact

Footnotes:

[1] Pregnancy test will be performed at the clinical site using the test-strip (only for the women of childbearing potential including the women in menopause of less than two years) before chest x-ray of fluorography.

[2] At visit Day 1 pre- and post-bronchodilator spirometry will be performed. At visit Day 8 only pre-bronchodilator spirometry will be performed.

[3] Results of the chest x-ray or fluorography performed before signing the Informed Consent Formas a part of routine patient's examination for main disease (ARVI) can be used for the protocol purposes (if written conclusion report is available).

[4] Patient's randomization and distribution of the study drug to the patient (along with the Patient's dairy) on Day 1 will be performed only after assessment of all inclusion/exclusion criteria. The first dose of the study drug will be taken at the clinical site.

[5] The growth measure should be performed only during screening visit. For calculated values of lung function growth measured only at screening and weight measured during screening and Visit 3 (Day 8) should be used.

2.2 SAMPLE SIZE[1]

The sample size is calculated for the primary efficacy endpoint - the proportion of

[1] Citation from the protocol

patients with response to therapy (daily cough symptoms permission to visit Day 8) and non-inferiority hypothesis.

According to available data in the literature (Schroeder K., Fahey T. Over-the-counter medications for acute cough in children and adults in ambulatory settings) in clinical studies antitussives difference between the active treatment group and the placebo group was about 44%. In the placebo-controlled study (Smith SM, Schroeder K., Fahey T. Over-the-counter (OTC) medications for acute cough in children and adults in community settings) the difference between the active treatment groups and the placebo group was 25% and 35%. According to the meta-analysis of clinical trials of levodropropizine in two placebo-controlled studies the difference between the efficacy of the study drug and placebo was 45% in the pediatric population of patients (study Fiocchi) and 39% in the adult population of patients (study Allegra, where efficacy of levodropropizine was about 80%[1,2]).

According to ICH guideline, the selected non-inferiority margin (non-inferiority margin) should not exceed the minimum difference between the performance indicators of the active drug and placebo[3]. Based on the above data, non-inferiority margin $\delta = 20\%$ was chosen for the study.

The sample size estimation in the protocol amendment is based on the results of the study interim analysis that showed approximately 70% efficacy in both groups vs. 80% efficacy that had been projected initially. Thus, the interim analysis at α = 0.05 (one-sided) showed lack of power for the hypothesis testing (< 80%).

The sample size was calculated using the formula for non-inferiority for comparison of two independent proportions:

$$n = \left(Z_{\frac{\alpha}{2}} + Z_{\beta}\right)^2 \times [p_1 \times (100\% - p_1) + p_2 \times (100\% - p_2)]/(p_1 - p_2 - \delta)^2$$

where n – sample size for each group, p_1 - success rate in the control group, p_2 – success rate in the treatment group, δ – non-inferiority margin, $Z_{\frac{\alpha}{2}}$ is 1.645 for one-sided $\alpha = 0.05$ and Z_{β} is 0.84 for 80% power.

In order to achieve power 80%, with corrected α = 0.025 (one-sided), expected efficacy rate of 70% in both groups, non-inferiority margin δ = 20%, and ED rate not exceeding 10%, 184 patients should be enrolled in the study at 1:1 ration (92 patients per treatment group).

Assuming the screen-failure rate of about 20%, up to 230 patients will be screened in the study.

2.3 STUDY OBJECTIVES

To assess the efficacy of Levopront® in comparison with Libexin® based on daytime cough resolution rate by Day 8.

The daytime cough symptoms resolution corresponds to 0 or 1 points on the "Six-point daytime and nighttime cough assessment scale".

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[1] Allegra L, Bossi R. Clinical trials with the new antitussive levodropropizine in adult bronchitic patients. Arzneimittelforschung. 1988 Aug;38(8):1163-6

[2] Zanasi et al. Levodropropizine for treating cough in adult and children: a meta-analysis of published studies Multidisciplinary Respiratory Medicine (2015) 10:19

[3] EMA CHMP Guideline on the choice of the non-inferiority margin EMEA/CPMP/EWP/2158/99, 2005

3. INTERIM ANALYSIS, FINAL ANALYSIS AND UNBLINDING

No interim analysis is planned.

There is open-label study. No unblinding required.

4. ENDPOINTS AND COVARIATES

4.1 EFFICACY ENDPOINTS

Primary efficacy endpoint

- To assess the efficacy of Levopront® in comparison with Libexin® based on daytime cough resolution rate by Day 8.

Secondary efficacy endpoints

- To assess the efficacy of Levopront® in comparison with Libexin® based on nighttime cough resolution rate by Day 8
- Daytime and nighttime cough symptoms resolution according to “Six-point daytime and nighttime cough assessment scale” by Day 4
- Change in severity and frequency of daytime and nighttime cough according to “Six-point daytime and nighttime cough assessment scale” on Day 4 and Day 8 from baseline on Day 1
- Cough intensity change according to the visual-analogue scale on Day 4 and Day 8 from baseline on Day 1
- Change of FEV1 on Day 8 from baseline values on Day 1

4.2 SAFETY ENDPOINTS

Rate of Adverse events (AE) and Serious Adverse Events (SAE) of the various severity according to subjective complaints, laboratory test results, physical examination, vital signs and spirometry.

5. ANALYSIS SETS

5.1 PER PROTOCOL POPULATION

Per-protocol population includes all randomized patients completing treatment with the study drug, having primary efficacy analysis assessment done and considered to be compliant. Patients without serious deviations from protocol during the study will be considered compliant. The key protocol deviations will be determined before the date of database lock. PP population is the primary population for the primary endpoint (Non-inferiority) analysis

5.2 INTENT-TO-TREAT POPULATION

The population of patients is based on the initial treatment assignment and not on the treatment eventually received (ITT).

5.3 SAFETY ANALYSIS SET

All patients who received at least one dose of the study drug will be included into the safety population.

5.4 PROTOCOL DEVIATIONS

A full list of protocol deviations will be compiled and reviewed to identify major and

minor deviations prior to database lock.

6. HANDLING OF MISSING VALUES

6.1 EFFICACY PARAMETERS

Replacement of missing data is not planned for efficacy parameters.

6.2 SAFETY PARAMETERS

6.2.1 Missing onset dates in AE

AE with missing onset date will be counted as TESS (Treatment Emergency Sign and Symptom).

In case of AE date is incomplete following rules will be used:

Day	Month	Year	Condition
Missing	Missing	In place	In case of month and year of onset > date of start study time (IC date) - TESS
Missing	Missing	In place	In case of year of onset ≥ year of start study time (IC date) - TESS
Missing	Missing	Missing	TESS
Missing	In place	Missing	TESS
Missing	Missing	In place	Year of onset ≥ year of start study time (IC date) - TESS

7. STATISTICAL METHODOLOGY AND STATISTICAL ANALYSES

7.1 STATISTICAL METHODS

Statistical analysis will be done using statistical software R (www.r-project.org).

For the statistical analysis is planned to use descriptive statistics, confidence intervals for difference in proportion (See section 8 [1]), mixed-effect model, two sample t-test, one-sample t-test, Wilcoxon test, Mann-Whitney test, Fisher exact test, Shapiro-Wilk test and permutation tests (See section 8 [2]).

7.2 STATISTICAL ANALYSES

7.2.1 Disposition of Subjects

Disposition of all subjects (enrolled, randomized, discontinued) in analyzed population will be presented.

7.2.2 Demographic and baseline characteristics

This data will be presented for ITT population by treatments group at baseline (Day 1).

Continuous data will be presented with number of non-missing values, mean, standard deviation, median, minimal and maximal values.

Nominal data will be presented with absolute and relative (percent) frequencies.

Between groups continuous data will be compared using unpaired Student's *t*-test (for normally distributed data) or Mann-Whitney test (for free distribution data). Between groups binominal data will be compared using Fisher exact test, for categorical data Mann-Whitney test will be used.

7.2.3 Primary Efficacy Analysis

According to the Guideline EMA/EWP-482 (Superiority-non-inferirority and switching), in non-inferiority study primary analysis must be performed on Per-Protocol population (see chapter IV.1.4 Choice of analysis set of the guideline).

The main efficacy analysis population is defined as Per-Protocol (PP).

Study statistical testing hypothesis is expressed as:

H0: Lower bound of the 97.5% one-sided CI (p1-p2) ≤ -20% => Non-inferiority rejected

H1: Lower bound of the 97.5% one-sided CI (p1-p2) > -20% => Non-inferiority accepted

The primary objective is to demonstrate the "non-inferiority" of Levopront® comparing to Libexin® with regards to the primary endpoint. For this purpose, the one-sided 97.5% Confidence Interval (CI) will be calculated for the two proportions difference — the rate of patients who responded to treatment (**cough absents**, when score is 0 or 1 at “six-point cough scale” vs. **cough presents,** when score is ≥ 2 at “six-point cough score”) by Day 8 in the study treatment group and in the control group with a non-inferiority margin of δ = 20%. The null hypothesis (H0) that in the study treatment group the rate of treatment responders is less than in the control group, will be declined if the lower bound of the 97.5% one-sided CI for the two proportions difference is located to the right of the **-0.20**, with the final conclusion of non-inferiority of Levopront® versus Libexin®.

The proportion difference will be calculated using **Newcombes Hybrid Score** method (1998). See 8 [1].

7.2.4 Secondary Efficacy Analyses

Secondary efficacy analysis will be performed on the ITT population.

7.2.4.1 Nighttime cough resolution rate by Day 8

Nighttime cough symptoms will be classified as **Absent** (<2 at six-point cough scale) or **Present** (≥2 at six-point cough scale). For such derivation treatment groups will be compared using the Fisher exact test.

7.2.4.2 Daytime and nighttime cough symptoms resolution by Day 4

Daytime and Nighttime cough symptoms will be classified as **Absent** (<2 at sit-point cough scale) or **Present** (≥2 at six-point cough scale). Resolution Daytime (<2 at scale) and Nighttime (<2 at scale) symptoms at Day 4 will be described by treatment groups. Treatment groups will be compared using the Fisher exact test.

7.2.4.3 Change in severity and frequency of daytime and nighttime cough on Day 4 and Day 8 from baseline on Day 1

Scores from the six-point cough scale will be described by visits and treatment groups together with changes from baseline (Day 1). Within group change will be tested using paired t-test (normal data) or Wilcoxon sign test (violation of normality), between groups test – two sample t-test (normal data) or Mann-Whitney test (violation of normality). Test for normality – Shapiro-Wilk.

Treatment groups will be also compared at baseline (Day 1). In case of significant difference (statistically) in scores\values at baseline a mixed-effect model will be

discussed.

Parameter dynamics also will be presented with graphics (see Figure 9.1).

7.2.4.4 Cough intensity change according to the visual-analogue scale on Day 4 and Day 8 from baseline on Day 1

Analysis is similar to 7.2.4.3.

7.2.4.5 Change of FEV1 on Day 8 from baseline values on Day 1

Analysis is similar to 7.2.4.3.

7.3 SAFETY ANALYSIS

Analysis will be performed for the safety population.

7.3.1 Adverse Events

Adverse Events will be summarized by treatment groups. Relation of AE to the therapy will be defined by AE onset date and period start date for the patient. All AEs will be coded with MEDDRA dictionary. AEs will be summarized by SOC (System Organ Class) and PT (Preferred Terms).

Adverse Events (if any) started before the first dose of the study drug(s) will be presented in the separate table.

AE frequencies will be compared between treatment groups. For such comparisons MedDRA Preferred Terms (PT) will be used. Treatment groups will be compared by set of frequencies of PT terms using permutation tests. One p-value will be provided (H_0: treatment groups are equal in set of AE frequencies).

7.3.2 Laboratory Data

Laboratory data will be summarized by treatment group as clinical relevance (normal/abnormal, without clinical relevance/ abnormal, with clinical relevance) and as continuous data (absolute values).

All laboratory data and changes from baseline will be described as continuous variables at each visit.

Treatment groups will be compared for the set of parameters (hematology set, biochemistry set, urinalysis set and microscopic urine examination set). Only clinically significant deviations (CS) will be taken into account. Permutation test will be used see 8 [2].

7.3.3 Compliance

Patient’s compliance will be described by treatment groups.

7.3.4 Vital Signs Data

Vital signs data such as blood pressure, heart rate and body temperature will be summarized as continuous data by treatment group.

All vital signs data and changes from baseline will be described at each visit.

7.3.5 Physical Examination Data

Physical examination data will be summarized as normal/abnormal data.

Physical examination data will be compared between treatment groups as each time

point using permutation tests.

7.3.6 Concomitant Treatments

Concomitant therapy and immunosuppressive therapy during the study time will be summarized by treatment groups. Drugs will be presented by ATC groups as nominal data (absolute and relative frequencies).

7.3.7 Listings

Additionally, combined listings from the database will be presented for:

- Laboratory data
- Adverse events and serious adverse events data.

Laboratory data listings will be presented with patient number, age of patient, study period, group of treatment and laboratory data with units and flag of clinically significant abnormalities. Separately the same format listing will be presented for laboratory data but for patients who had abnormal values.

7.4 CHANGES IN THE PLANNED ANALYSES

Any changes in the planned statistical methods will be documented and justified in the Clinical Study Report.

8. REFERENCES

1. **Newcombes Hybrid Score method: Schuirmann, D. J. (1999), "Confidence Interval Methods for Bioequivalence** Testing with Binomial Endpoints," in *Proceedings of the Biopharmaceutical Section*, 227–232, Alexandria, VA: American Statistical Association.

2. **Permutation Tests methodology:**

   - Helmut Strasser & Christian Weber (1999). On the asymptotic theory of permutation statistics. **Mathematical Methods of Statistics** *8*, 220-250.
   - Torsten Hothorn, Kurt Hornik, Mark A. van de Wiel & Achim Zeileis (2006). A Lego System for Conditional Inference. **The American Statistician**, *60*(3), 257-263.
   - Torsten Hothorn, Kurt Hornik, Mark A. van de Wiel & Achim Zeileis (2008). Implementing a class of permutation tests: The coin package, **Journal of Statistical Software**, *28*(8), 1-23. http://www.jstatsoft.org/v28/i08

9. TABLE EXAMPLES[1]

9.1 DEMOGRAPHICS AND BASELINE

Table 9.1 Disposition

	Levopront® (T) n (%)	Libexin® (C) n (%)
Enrolled subject	xx	xx
Randomized subjects	xx (xx.x%)	xx (xx.x%)
ITT Analysis Set	xx (xx.x%)	xx (xx.x%)
Safety Analysis Set	xx (xx.x%)	xx (xx.x%)
Completed Study per protocol	xx (xx.x%)	xx (xx.x%)
Discontinued prematurely	xx (xx.x%)	xx (xx.x%)
Adverse Event	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)
Infection of lower respiratory tract	xx (xx.x%)	xx (xx.x%)
Lost to follow-up		
Consent withdrawn	xx (xx.x%)	xx (xx.x%)
Investigator decision	xx (xx.x%)	xx (xx.x%)
Protocol violation, including non-compliance	xx (xx.x%)	xx (xx.x%)
Protocol entry criteria not met	xx (xx.x%)	xx (xx.x%)
Study is stopped by Sponsor decision	xx (xx.x%)	xx (xx.x%)
Study is stopped by regulatory authorities / ethics committee	xx (xx.x%)	xx (xx.x%)
Other	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)

Table 9.2 Demographic and other baseline characteristics. ITT analysis set. Screening (baseline). N = xx

Parameter	Levopront® (T) n (%)	Libexin® (C) n (%)	p-value
Age (years)			
N	xx	xx	0.xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	
Gender			
Male	xx (xx.x%)	xx (xx.x%)	0.xxx
Female	xx (xx.x%)	xx (xx.x%)	
No data[2]	xx (xx.x%)	xx (xx.x%)	
Race			
Caucasian	xx (xx.x%)	xx (xx.x%)	
Other	xx (xx.x%)	xx (xx.x%)	
No data[3]	xx (xx.x%)	xx (xx.x%)	
Height (cm)			
N	xx	xx	---
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	
Weight (kg)			
N	xx	xx	---
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min – Max	xx.x – xx.x	xx.x – xx.x	
BMI (kg/m^2)			
N	xx	xx	0.xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	
Duration of the acute upper respiratory infection (days)[1]			

[1] Tables in the report may differ from this templates but meaning and information presented should be kept
[2] if any
[3] if any

Parameter	Levopront® (T) n (%)	Libexin® (C) n (%)	p-value
N	xx	xx	0.xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	
Duration of dry non-productive cough (days)[2]			
N	xx	xx	0.xxx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	
Smoking history			
Never smoked			
Currently smokes			
Duration			
N	xx	xx	---
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	
Smoked in the past			
Duration			
N	xx	xx	---
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	
Not known			

Table 9.3 Medical history. ITT analysis set. Screening (baseline). N = xx

MedDRA System Organ Class term *MedDRA Preferred term*	Levopront® (T) n (%)		Libexin® (C) n (%)	
	x (%)	*Y*	*x (%)*	*Y*
BODY SYSTEM CODE	xx (xx.x)	xx	xx (xx.x)	xx
Term 1	xx (xx.x)	xx	xx (xx.x)	xx
Term 2	xx (xx.x)	xx	xx (xx.x)	xx
…				

Table 9.4 Ongoing diseases/diagnosis/abnormalities. ITT analysis set. Screening (baseline). N = xx

MedDRA System Organ Class term *MedDRA Preferred term*	Levopront® (T) n (%)		Libexin® (C) n (%)	
	x (%)	*Y*	*x (%)*	*Y*
BODY SYSTEM CODE	xx (xx.x)	xx	xx (xx.x)	xx
Term 1	xx (xx.x)	xx	xx (xx.x)	xx
Term 2	xx (xx.x)	xx	xx (xx.x)	xx
…				

Table 9.5 Previous medication. ITT analysis set. Screening (baseline). N = xx

ATC code Drug	Levopront® (T) n (%)	Libexin® (C) n (%)
Group		
Total	xx (xx.x%)	xx (xx.x%)
DRUG (ATC)	xx (xx.x%)	xx (xx.x%)
…		

[1] Relative to the informed consent date
[2] Relative to the informed consent date

Table 9.6 Physical examination. ITT analysis set. Screening. N = xx

Category	Levopront® (T) n (%) N = XX	Libexin® (C) n (%) N = XX	p-value
Screening (baseline). Day 1			0.xxx
General appearance			
Normal	xx (xx.x%)	xx (xx.x%)	
Abnormal	xx (xx.x%)	xx (xx.x%)	
Not done	xx (xx.x%)	xx (xx.x%)	
Eyes, ears, nose, throat			
Normal	xx (xx.x%)	xx (xx.x%)	
Abnormal	xx (xx.x%)	xx (xx.x%)	
Not done	xx (xx.x%)	xx (xx.x%)	
Neck (including thyroid)			
Normal	xx (xx.x%)	xx (xx.x%)	
Abnormal	xx (xx.x%)	xx (xx.x%)	
Not done	xx (xx.x%)	xx (xx.x%)	
..			

Table 9.7 Vital signs. ITT analysis set. Screening. N = xx

	Levopront® (T) n (%) N = XX	Libexin® (C) n (%) N = XX	p-value
Screening (baseline)			
Body temperature (°C)			0.xxx
N	xx	xx	
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	
Pulse (beats/min)			0.xxx
N	xx	xx	
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min – Max	xx.x – xx.x	xx.x – xx.x	
Respiratory rate (/min)			0.xxx
N	xx	xx	
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	
Systolic blood pressure (Hg mm)			0.xxx
N	xx	xx	
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	
Diastolic blood pressure (Hg mm)			0.xxx
N	xx	xx	
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	
Median	xx.x	xx.x	
Min - Max	xx.x – xx.x	xx.x – xx.x	

9.2 EFFICACY

Table 9.8 Primary efficacy. Daytime cough resolution. PP analysis set. N = xx

	Levopront® (Test) n (%) N = XX	Libexin® (Control) n (%) N = XX
Daytime cough resolution		
Ongoing (≥2)	xx (xx.x%)	xx (xx.x%)
Resolved (<2)	xx (xx.x%)	xx (xx.x%)
Test – Control (resolved)	xx (xx.x%) 97.5% CI [xx.x%; --]	

Table 9.9 Primary efficacy. Daytime cough resolution.
ITT analysis set. N = xx

	Levopront® (Test) n (%) N = XX	Libexin® (Control) n (%) N = XX
Daytime cough resolution		
Ongoing (≥2)	xx (xx.x%)	xx (xx.x%)
Resolved (<2)	xx (xx.x%)	xx (xx.x%)
Test – Control (resolved)	xx (xx.x%) 97.5% CI [xx.x%; --]	

Table 9.10 Secondary efficacy. Nighttime cough resolution.
ITT population set. N = xx

	Levopront® (Test) n (%) N = XX	Libexin® (Control) n (%) N = XX
Nighttime cough resolution		
Ongoing (≥2)	xx (xx.x%)	xx (xx.x%)
Resolved (<2)	xx (xx.x%)	xx (xx.x%)
p-value (Fisher)	0.xxx	

Table 9.11 Secondary efficacy. Daytime and Nighttime cough resolution.
ITT population set. N = xx

	Levopront® (Test) n (%) N = XX	Libexin® (Control) n (%) N = XX
Daytime & Nighttime cough resolution		
Ongoing (≥2)	xx (xx.x%)	xx (xx.x%)
Resolved (<2)	xx (xx.x%)	xx (xx.x%)
p-value (Fisher)	0.xxx	

Table 9.12 Change in severity and frequency of daytime and nighttime cough on Day 4 and Day 8 from baseline on Day 1. ITT population. N = xx

	Day 1 (baseline)	Day 4	Change at Day 4	Day 8	Change at Day 8
Levopront®					
Daytime cough					
N	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
p-change			0.xxx		0.xxx
Libexin®					
Daytime cough					
N	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
p-change			0.xxx		0.xxx
p-between	0.xxx		0.xxx		0.xxx
Levopront®					
Nighttime cough					
N	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
p-change			0.xxx		0.xxx
Libexin®					

	Day 1 (baseline)	Day 4	Change at Day 4	Day 8	Change at Day 8
Nighttime cough					
N	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
p-change			0.xxx		0.xxx
p-between	0.xxx		0.xxx		0.xxx

Figure 9.1 Graphics example

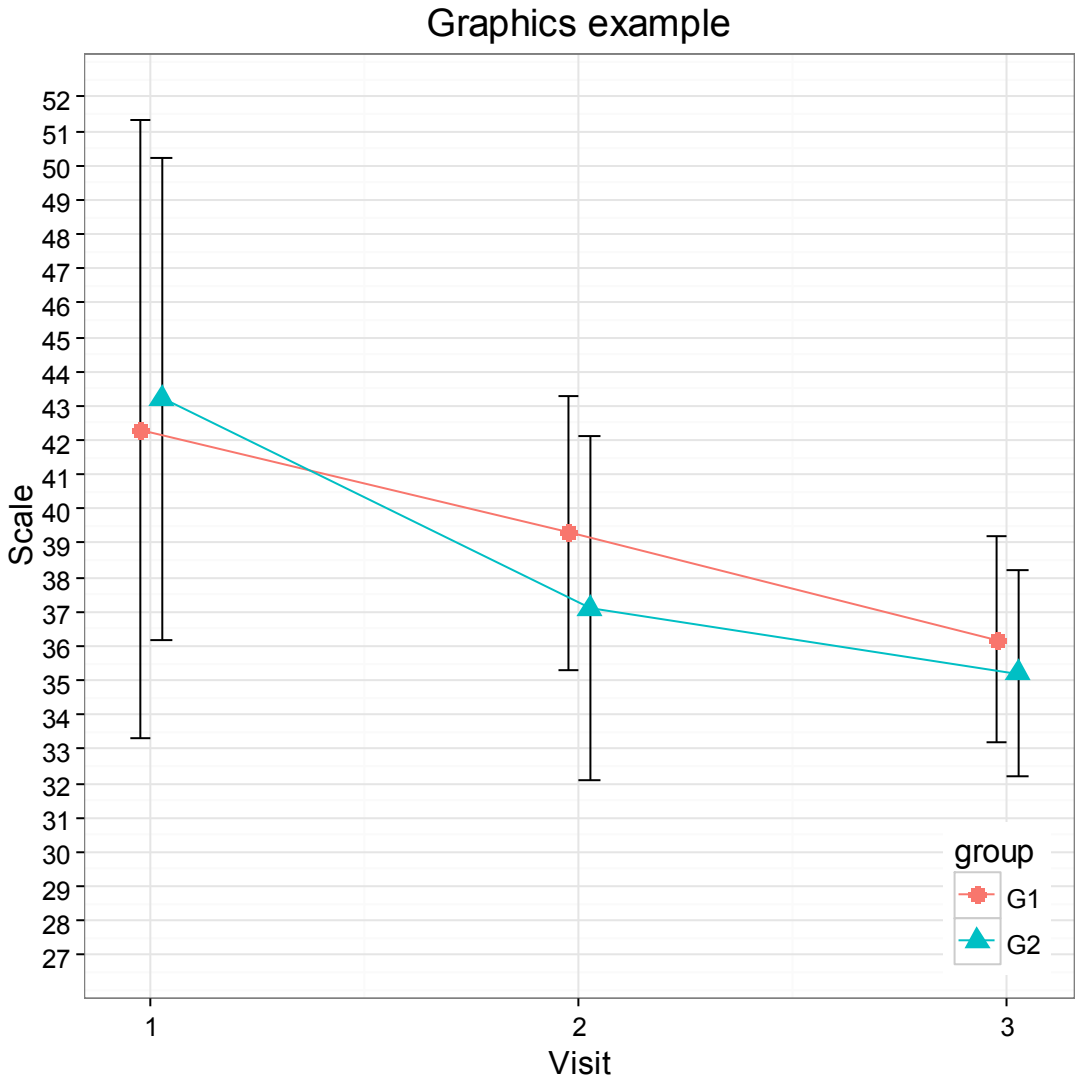

Table 9.13 Cough intensity change according to the visual-analogue scale on Day 4 and Day 8 from baseline on Day 1. ITT population. N = xx

	Day 1 (baseline)	Day 4	Change at Day 4	Day 8	Change at Day 8
Levopront®					
Cough intensity. VAS					
N	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
p-change			0.xxx		0.xxx
Libexin®					

	Day 1 (baseline)	Day 4	Change at Day 4	Day 8	Change at Day 8
Cough intensity. VAS					
N	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
p-change			0.xxx		0.xxx
p-between	0.xxx		0.xxx		0.xxx

Table 9.14 Change of FEV1 on Day 8 from baseline values on Day 1. ITT population. N = xx

	Day 1 (baseline)	Day 8	Change at Day 8
Levopront®			
FEV_1 (liters)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
p-change			0.xxx
Libexin®			
FEV_1 (litres)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
p-change			0.xxx
p-between	0.xxx		0.xxx
Levopront®			
FEV_1 (%)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
p-change			0.xxx
Libexin®			
FEV_1 (%)			
N	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
p-change			0.xxx
p-between	0.xxx		0.xxx

9.3 SAFETY

Table 9.15 Physical examination. Safety population. N = xx

Category	Levopront® (T) n (%) N = XX	Libexin® (C) n (%) N = XX	p-value
Screening (baseline). Day 1			0.xxx
General appearance			
Normal	xx (xx.x%)	xx (xx.x%)	
Abnormal	xx (xx.x%)	xx (xx.x%)	
Not done	xx (xx.x%)	xx (xx.x%)	
Eyes, ears, nose, throat			
Normal	xx (xx.x%)	xx (xx.x%)	
Abnormal	xx (xx.x%)	xx (xx.x%)	
Not done	xx (xx.x%)	xx (xx.x%)	
Neck (including thyroid)			
Normal	xx (xx.x%)	xx (xx.x%)	
Abnormal	xx (xx.x%)	xx (xx.x%)	
Not done	xx (xx.x%)	xx (xx.x%)	

Category	Levopront® (T) n (%) N = XX	Libexin® (C) n (%) N = XX	p-value
..			
Day 4			0.xxx
…			
Day 8/ET or ED			0.xxx
…			

Table 9.16 Vital signs. Safety population. N = xx

	Levopront® (T) N = XX	Libexin® (C) N = XX
Day 1 (baseline)		
Body temperature (°C)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x
Heart rate (beats/min)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x
Respiratory rate (/min)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x
Systolic blood pressure (Hg mm)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x
Diastolic blood pressure (Hg mm)		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x
Day 4		
…		
Day 4. Change from baseline		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min - Max	xx.x – xx.x	xx.x – xx.x
p-change	0.xxx	0.xxx
Day 8/ET or ED		
…		
Day 8/ET or ED. Change from baseline		
…		

Table 9.17 Urine pregnancy test (females only). Safety population. N = xx

	Levopront® (T) n (%) N = XX	Libexin® (C) n (%) N = XX
Screening (Day 1)		
Positive	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)
No data	xx (xx.x%)	xx (xx.x%)
Day 8/ED		
Positive	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)
No data	xx (xx.x%)	xx (xx.x%)

Table 9.18 Concomitant medication. Safety population. During the study. N = xx

ATC code Drug	Levopront® (T) n (%) N = XX	Libexin® (C) n (%) N = XX
Group		
Total	xx (xx.x%)	xx (xx.x%)
DRUG (ATC)	xx (xx.x%)	xx (xx.x%)
…		

Table 9.19 Laboratory parameters. Hematology. Deviation from normal values. Safety population. N = xx

Parameter	Day 1		Day 8\ET	
	Levopront®	Libexin®	Levopront®	Libexin®
Hemoglobin				
No data	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CNS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hematocrit				
No data	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CNS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				

Parameters to be presented: Hemoglobin, Hematocrit, RBC, WBC, Neutrophils (abs), Lymphocytes (abs), Monocytes (abs), Eosinophils (abs), Basophils (abs), Platelets, ESR, Neutrophils (%), Lymphocytes (%), Monocytes (%), Eosinophils (%), Basophils (%).

Table 9.20 Laboratory parameters. Hematology. CS deviations only. Safety population. N = xx

Parameter	Day 1		Day 8\ET	
	Levopront®	Libexin®	Levopront®	Libexin®
Hemoglobin				
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hematocrit				
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
p-value[1]		0.xxx		0.xxx

Table 9.21 Laboratory parameters. Biochemistry. Deviation from normal values. Safety population. N = xx

Parameter	Day 1		Day 8\ET	
	Levopront®	Libexin®	Levopront®	Libexin®
Total protein				
No data	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[1] For the set of parameters at visit

Parameter	Day 1		Day 8\ET	
	Levopront®	Libexin®	Levopront®	Libexin®
CNS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Albumin				
No data	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CNS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				

Parameters to be presented: Total protein, Albumin, Total cholesterol, Total bilirubin, Conjugated bilirubin, ALT, AST, Serum creatinine, Glomerular filtration rate.

Table 9.22 Laboratory parameters. Biochemistry. CS deviations only. Safety population. N = xx

Parameter	Day 1		Day 8\ET	
	Levopront®	Libexin®	Levopront®	Libexin®
Total protein				
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Albumin				
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
p-value		0.xxx		0.xxx

Table 9.23 Laboratory parameters. Urinalysis. Deviation from normal values. Safety population. N = xx

Parameter	Day 1		Day 8\ET	
	Levopront®	Libexin®	Levopront®	Libexin®
Color				
No data	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CNS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Clarity				
No data	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CNS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				

Parameters to be presented: Color, Clarity, Specific gravity, pH, Protein, Glucose, Bilirubin, Urobilinogen, Ketone bodies, Nitrites, Hemoglobin.

Table 9.24 Laboratory parameters. Urinalysis. CS deviations only. Safety population. N = xx

Parameter	Day 1		Day 8\ET	
	Levopront®	Libexin®	Levopront®	Libexin®
Color				
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Clarity				
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
p-value		0.xxx		0.xxx

Table 9.25 Laboratory parameters. Microscopic urine examination. Deviation from normal values. Safety population. N = xx

Parameter	Day 1		Day 8\ET	
	Levopront®	Libexin®	Levopront®	Libexin®
Epithelium				
No data	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CNS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Erythrocytes				
No data	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CNS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Normal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				

Parameters to be presented: Epithelium, Erythrocytes, Leukocytes, Casts, Bacteria, Salts.

Table 9.26 Laboratory parameters. Microscopic urine examination. CS deviations only. Safety population. N = xx

Parameter	Day 1		Day 8\ET	
	Levopront®	Libexin®	Levopront®	Libexin®
Epithelium				
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Erythrocytes				
CS deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
…				
p-value		0.xxx		0.xxx

Table 9.27 Laboratory parameters. Hematology. Absolute values. Safety population. N = xx

	Day 1 (baseline)		Day 8/ET or ED		Change at Day 8	
	Levopront®	Libexin®	Levopront®	Libexin®	Levopront®	Libexin®
Hemoglobin						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
Hematocrit						
N	xx	xx	xx	xx	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x	xx.x	xx.x	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x	xx.x – xx.x
…						

Parameters to be presented: Hemoglobin, Hematocrit, RBC, WBC, Neutrophils (abs), Lymphocytes (abs), Monocytes (abs), Eosinophils (abs), Basophils (abs), Platelets, ESR, Neutrophils (%), Lymphocytes (%), Monocytes (%), Eosinophils (%), Basophils (%).

Table 9.28 Laboratory parameters. Biochemistry. Absolute values. Safety population. N = xx

Similar

Parameters to be presented: Total protein, Albumin, Total cholesterol, Total bilirubin, Conjugated bilirubin, ALT, AST, Serum creatinine, Glomerular filtration rate.

Table 9.29 Laboratory parameters. Urinalysis. Absolute values. Safety population. N = xx

Similar

Parameters to be presented: Color, Clarity, Specific gravity, pH, Protein, Glucose, Bilirubin, Urobilinogen, Ketone bodies, Nitrites, Hemoglobin.

Table 9.30 Laboratory parameters. Microscopic urine examination. Absolute values. Safety population. N = xx

Similar

Parameters to be presented: Epithelium, Erythrocytes, Leukocytes, Casts, Bacteria, Salts.

Table 9.31 Compliance. Safety population. N = XX

	Levopront® N = XX	Libexin® N = XX
Compliance		
N	xx	xx
Mean (SD)	xx.x (xx.x)	xx.x (xx.x)
Median	xx.x	xx.x
Min – Max	xx.x – xx.x	xx.x – xx.x

Table 9.32 Adverse Events (including SAE) started before the first dose of the study drug(s). Safety population. N = xx

MEDDRA System Organ Class term MEDDRA Preferred term	Levopront® (T) n (%)		Libexin® (C) n (%)	
	x (%)	*Y*	*x (%)*	*Y*
SOC term	xx (xx.x)	xx	xx (xx.x)	xx
Preferred term 1	xx (xx.x)	xx	xx (xx.x)	xx
Preferred term 2	xx (xx.x)	xx	xx (xx.x)	xx
…				

X = Number of subjects having at least one AE from the group.
% = Percent of patients having at least one AE from the group
Y = Total number of events

Table 9.33 Adverse events. Summary table. Safety population. N = XX

Parameter	Levopront® N = XX	Libexin® N = XX	p-value Fisher test
Patients with AE/SAE	xx (xx.x%)	xx (xx.x%)	0.xxx
Patients with SAE	xx (xx.x%)	xx (xx.x%)	0.xxx
Patients with death outcome AE/SAE	xx (xx.x%)	xx (xx.x%)	0.xxx
Patients with mild and moderate AE/SAE	xx (xx.x%)	xx (xx.x%)	0.xxx
Patients with severe AE/SAE	xx (xx.x%)	xx (xx.x%)	0.xxx
Patients with related (possible probable or highly probable) AE/SAE	xx (xx.x%)	xx (xx.x%)	0.xxx
Patients with AE/SAE leaded to discontinuation	xx (xx.x%)	xx (xx.x%)	0.xxx

Table 9.34 Adverse Events (including SAE). Safety population. N = xx

MEDDRA System Organ Class term MEDDRA Preferred term	Levopront® (T) n (%)		Libexin® (C) n (%)	
	x (%)	*Y*	*x (%)*	*Y*
SOC term	xx (xx.x)	xx	xx (xx.x)	xx
Preferred term 1	xx (xx.x)	xx	xx (xx.x)	xx
Preferred term 2	xx (xx.x)	xx	xx (xx.x)	xx
…				

X = Number of subjects having at least one AE from the group.
% = Percent of patients having at least one AE from the group
Y = Total number of events

p-value = 0.xxx

Table 9.35 Adverse Events (including SAE) and severity.
Safety population. N = xx

MEDDRA System Organ Class term MEDDRA Preferred term	Severity	Levopront® (T) n (%)		Libexin® (C) n (%)	
		x (%)	*Y*	*x (%)*	*Y*
SOC term		xx (xx.x)	xx	xx (xx.x)	xx
Preferred term 1	Mild	xx (xx.x)	xx	xx (xx.x)	xx
Preferred term 2	Moderate	xx (xx.x)	xx	xx (xx.x)	xx
…					

X = Number of subjects having at least one AE from the group.
% = Percent of patients having at least one AE from the group
Y = Total number of events

Table 9.36 Adverse Events (including SAE) and relation to study drug(s).
Safety Set. N = xx

Similar

Table 9.37 Serious Adverse Events (only). Safety population. N = xx

MEDDRA System Organ Class term MEDDRA Preferred term	Levopront® (T) n (%)		Libexin® (C) n (%)	
	x (%)	*Y*	*x (%)*	*Y*
SOC term	xx (xx.x)	xx	xx (xx.x)	xx
Preferred term 1	xx (xx.x)	xx	xx (xx.x)	xx
Preferred term 2	xx (xx.x)	xx	xx (xx.x)	xx
…				

X = Number of subjects having at least one AE from the group.
% = Percent of patients having at least one AE from the group
Y = Total number of events

Table 9.38 Serious Adverse Events (only) and severity.
Safety population. N = xx

MEDDRA System Organ Class term MEDDRA Preferred term	Severity	Levopront® (T) n (%)		Libexin® (C) n (%)	
		x (%)	*Y*	*x (%)*	*Y*
SOC term		xx (xx.x)	xx	xx (xx.x)	xx
Preferred term 1	Mild	xx (xx.x)	xx	xx (xx.x)	xx
Preferred term 2	Moderate	xx (xx.x)	xx	xx (xx.x)	xx
…					

X = Number of subjects having at least one AE from the group.
% = Percent of patients having at least one AE from the group
Y = Total number of events

Table 9.39 Serious Adverse Events (only) and relation to study drug(s).
Safety Set. N = xx

Similar