STATISTICAL ANALYSIS PLAN IMPLEMENTATION DOCUMENT (SAPID)

Santalis Pharmaceuticals

Protocol: SAN007-02

A Double-Blind, Randomized, Placebo-Controlled, Safety, Tolerability, and Efficacy Trial of a Novel Botanical Drug Product, Containing East Indian Sandalwood Oil (EISO) For the Treatment of Atopic Dermatitis

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Document status: FINAL
Version dates: 11OCT2018

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LIST OF ABBREVIATIONS

AE	Adverse Event
BSA	Body Surface Area
cm	Centimeter
EASI	Eczema Area and Severity Index
eCRF	Electronic Case Report Form
EISO	East Indian Sandalwood Oil
FAS	Full Analysis Set
g	Gram
IGA	Investigator's Global Assessment
ITT	Intent-to-Treat
kg	Kilogram
MedDRA	Medical Dictionary for Regulatory Activities
N	population size (N for sample size, n for available data)
PP	Per Protocol
PT	Preferred Term
SAPID	Statistical Analysis Plan Implementation Document
SAS	Statistical Analysis System
SD	Standard Deviation
SOC	System Organ Class
TEAE	Treatment Emergent Adverse Event

Note: The first occurrence of some abbreviations is not spelled out in the document (e.g. units of measure).

1.0 STUDY INTRODUCTION

This statistical analysis plan is based on the protocol "A Double-Blind, Randomized, Placebo-Controlled, Safety, Tolerability, and Efficacy Trial of a Novel Botanical Drug Product, Containing East Indian Sandalwood Oil (EISO) For the Treatment of Atopic Dermatitis", Amendment No. 6, dated 18 September 2017.

1.1 Study Objectives

1.1.1 Primary Objectives

The primary objective of this study is to evaluate the safety of SAN007 when administered to subjects with mild to moderate atopic dermatitis. Safety will be assessed by evaluating the number and percentage of subjects reporting at least one adverse event (AE) tabulated with respect to severity, duration, and relationship to the study drug.

1.1.2 Additional Objectives

Additional objectives are to evaluate tolerability and preliminary efficacy. Tolerability will be assessed based on the number of subjects reporting discomfort during or immediately following application of study drug in the treatment areas. Discomfort will also be recorded as an AE. Preliminary efficacy will be assessed based on the following summaries:

- Percentage of subjects who have a ≥25% reduction in the Eczema Area and Severity Index (EASI) at any point during the trial.
- Number of subjects with an Investigator's Global Assessment (IGA) score of "clear" or "almost clear" at any time during the 28 days of treatment.
- Percentage of subjects who have a ≥50% reduction in the EASI at any point during the trial.
- Percentage of subjects achieving at least a 1-grade improvement in IGA score.
- Percentage of subjects who have at least a 20% reduction in BSA affected by atopic dermatitis.

2.0 STUDY DESIGN

2.1 Overview of Study Design

This trial will be a double blind, multi-center, randomized, placebo controlled study to evaluate the safety, tolerability, and preliminary efficacy of SAN007 when administered topically for up to 28 days to adults at least 18 years of age with atopic dermatitis. Subjects will enter the Screening Period once the informed consent and photographic consent process has been completed. Subjects with a total body surface area (BSA) of ≥2% and ≤ 15% atopic dermatitis involvement in the treatable areas, and who meet all of the inclusion, and none of the exclusion criteria, will be enrolled.

The original protocol design is based on randomization of enrolled subjects to either 5% SAN007 cream or placebo cream in a 2:1 ratio. Amendment 6 of the study protocol added the randomization of 10% SAN007 cream or placebo cream in a 2:1 ratio. This new randomization is implemented at new sites and sites continuing enrollment once the 5%/Placebo randomization had been completed at the site. This will result in some sites with only the 5%/Placebo groups, some sites with only the

10%/Placebo groups, and some sites with both 5%/Placebo and 10%/Placebo groups. Once subject eligibility is confirmed and the screening procedures completed, all enrolled subjects will start the Treatment Period of the study. All enrolled subjects will receive either 10% SAN007 cream, 5% SAN007 cream or placebo cream as described above with the first dose applied at Visit 1 Baseline. Subjects will be instructed on how to apply the study medication twice daily, ≥ 8 hours between applications, for 28 days. Subjects will return to the clinic for study-related assessments on Study Days 7, 14, and 28 for study-related assessments. On Study Days 21 and 35, subjects will receive a follow-up phone call.

Table 2.1: Visit Schedule

Screening	Baseline[1]	←——— Treatment ———→				Follow-up
Day -7 to 0	Day 1	Day 7 (±2 days)	Day 14 (±2 days)	Day 21 (±2 days)	Day 28 (±2 days)	Day 35 (±2 days)
	Visit 1	Visit 2	Visit 3	Visit 4 Call	Visit 5	Call

[1] Screening and Baseline may occur on the same day.

2.2 Sample Size

There is no formal assessment of sample size. The sample size of 100 subjects was chosen to ensure at least 90 subjects complete the study. The sample size is not expected to yield statistically significant results.

3.0 ANALYSIS POPULATIONS

3.1 Safety Analysis Set

The Safety Analysis Set is defined as all enrolled and randomized subjects who applied at least one treatment of the study drug.

3.2 Full Analysis Set

The Full Analysis Set (FAS) is defined as all randomized subjects who applied at least one administration of the study drug and who had at least one post-baseline efficacy assessment.

3.3 Per Protocol Analysis Set

The Per Protocol Analysis Set (PP) is defined as all randomized subjects who applied at least one administration of the study drug and who had at least one post-baseline efficacy assessment and who do not have any major protocol violations, including:

- Violations of inclusion/exclusion criteria;
- Use of prohibited concomitant medications'
- Noncompliance (i.e., less than 60% compliant with study treatment), as determined by the average product usage for the duration of participation;
- Failure to provide a clinical observation at Day 28;
- A scheduled visit occurring more than 5 days outside of the +/- 2-day visit window.

Although non-compliance is defined in the protocol as <90% compliance with study treatment, subsequent consideration of subject medication use evaluated prior to study data unmasking lead to a reduction in the threshold to <60% compliance.

3.4 Other Analysis Sets

An Intent-to-Treat Analysis Set (ITT) is defined as all subjects enrolled and randomized into the study. However, there is no analysis specific to the ITT population and it will not be used in the generation of any tables or listings.

The Enrolled Population is defined as all subjects who signed the informed consent. The Enrolled Population is referred to in the generation of listings and tabulation of subject disposition.

3.5 Treatment Assignment

For all analysis sets described above, subjects will be analyzed as treated. Mis-randomizations that resulted in subjects receiving an incorrect treatment will not be reassigned. These subjects will be noted in the clinical study report.

4.0 STATISTICAL METHODS OF ANALYSIS

4.1 Statistical Considerations

Data listings and summary tables will be provided. Listings will include all data captured on the electronic case report form (eCRF) unless specified otherwise. Calculated (derived) variables will be listed as appropriate. Summary tables will be provided for select variables as described in Section 5 through Section 8. Analyses by visit will be performed on nominal visits regardless of actual visit day. Early termination visits will be assigned to a visit if they fall into a visit window, otherwise, their data will still be included in the carry forward algorithm. Unscheduled visit data will be included in the carry forward algorithm.

4.1.1 Quantitative Assessments

Quantitative assessments (continuous data) will be summarized by reporting the number of subjects (n), mean, standard deviation (SD), median, minimum value, and maximum value.

4.1.2 Qualitative Assessments

Qualitative assessments (categorical data) will be summarized by reporting the frequency (count and percent) of subjects falling within the category. Unless specified otherwise for a particular assessment, the denominator for calculating a percentage will be the total number of subjects in the analysis population for the subgroup being analyzed; for example, within study arm, the number of subjects within the study arm in the analysis population will be the denominator. For overall summaries, the total number of subjects in the analysis population will be used as the denominator.

4.2 Methods for Handling Missing Data

Missing efficacy data will be imputed using the last observation carried forward unless specified otherwise; unscheduled visit data will be included in the carry forward procedure. No imputations will be made for missing safety data.

5.0 EVALUATION OF SUBJECT DISPOSITION AND EXPOSURE

5.1 Subject Disposition

All analyses in this section will be performed using the Enrolled Population. Subject disposition in terms of all randomized, completed or discontinued status, and reason for discontinuation will be summarized for each study arm and over all study arms by count and percent. Analysis populations (FAS, PP, and Safety) will be summarized for each study arm and over all study arms by count and percent. All percentages will be based on the Enrolled Population. Details of subject disposition and discontinuation status will be provided in a by-subject listing.

5.2 Study Product and Visit Compliance

All analyses in this section will be performed using the Safety Population. Study visit attendance will be summarized by study arm for each study visit. The count and percent of subjects who attended each visit will be calculated.

Study product compliance parameters will be summarized using descriptive statistics for each study arm. These parameters include the following:

- Number of applications missed (quantitative assessment)
- Total weight of product used (quantitative assessment)
- Average weight per application of product (quantitative assessment)
- The number and percentage of subjects who received fewer than 60% of prescribed applications (and considered non-compliant with the treatment) at each visit, and over all study visits.

For the assessment of compliance to product use the number of missed applications will be summarized instead of the number of received applications (specified in the protocol). The number of missed applications is collected at each visit whereas the number of applications received would be calculated by number of days on study times two minus the missed applications.

Compliance will also be based on information collected in the Treatment Medication Dispensation page. For any period, compliance (%) will be calculated as 100 x (weight of tube that was dispensed – weight of tube returned)/(number of days in this period x 2 x DOSE). DOSE will be calculated as initial weight of tube – weight of tube after first on site application (Day 1) since this is the dose application demonstrated to the subject. This value may be greater than 100%. However, if the value is less than 60%, the subject will be considered non-compliant for that study treatment interval.

Using these same calculations, compliance over all study visits will be calculated using available data from the medication dispensation log. Weight of drug used from a tube will be the difference of the last medication weight reported and the weight of the tube at dispensation. If multiple tubes are used, cumulative product weight will be calculated.

6.0 EVALUATION OF BASELINE CHARACTERISTICS

Analyses in this section will be performed using the Safety Analysis Set by study arm and overall study arms.

6.1 Demographics

Demographic data will be summarized for the quantitative (or numerical) assessments (age, height (cm), and weight (kg)) and the qualitative (or categorical) assessments (gender, race, and ethnicity). If multiple races are reported for a single subject or if races are listed besides the ones being summarized the count will be ascribed to the 'other' category. Percentages will be based on the number of non-missing responses. Results will be presented in by-subject listings.

6.2 Baseline Disease Characteristics

Disease characteristics at baseline will be summarized for quantitative assessments, percent of body surface area being treated and EASI, and the qualitative assessments, target treatment area and IGA score.

6.3 Medical History/Signs and Symptoms

Medical conditions reported in the pertinent medical history will be mapped to preferred term (PT) and system organ class (SOC) using the Medical Dictionary for Regulatory Activities (MedDRA 19.0). Results will be provided in a by-subject listing.

7.0 EVALUATION OF SAFETY PARAMETERS

All safety analyses will be performed using the Safety Analysis Set.

The safety parameters collected and monitored during this study include adverse events, treatment tolerability, and concomitant medications.

7.1 Adverse Events

An adverse event (AE) means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. An AE (also referred to as an adverse experience) can be any unfavorable and unintended sign (e.g., an abnormal laboratory finding), symptom, or disease temporally associated with the use of the drug, without judgment about causality. An adverse event can arise from any use of the drug (e.g., off-label use, use in combination with another drug) and from any route of administration, formulation, or dose, including an overdose. Non-serious AEs will be captured through the last treatment application, Day 28/exit, and serious AEs will be captured up through 28 days following the discontinuation of therapy.

All AEs reported will be considered to be treatment-emergent. Verbatim adverse events will be mapped to PT and SOC using MedDRA 19.0.

Tabular summaries of treatment-emergent adverse events (TEAEs) in terms of number of subjects will be presented by each study arm for the following:

- PT presented in order of descending incidence in the SAN007 group then alphabetically
- SOC and PT presented in order of descending incidence in SOC, then PT, in the SAN007 group, then alphabetically by SOC and PT
    - repeat presentation for subset of study-drug related events

- SOC, PT, and maximum severity grade (mild, moderate, severe) presented alphabetically by SOC and PT

Adverse events will be counted as treatment related if they are evaluated as possibly, probably, or definitely related to study treatment. Missing relationship will be treated as related. Subjects will be counted once within each level of summarization within each study arm for the calculation of incidence.

A summary of count and percent of subjects with at least one event in the following categories will be tabulated: any TEAE, any mild TEAE, any moderate TEAE, any severe TEAE, any treatment-related TEAE, any serious TEAE, any TEAE that led to discontinuation of study drug, and any deaths. Note that any AE is only considered for its maximum severity. However a subject can have more than one AE and each may have a different maximum severity. Thus severity levels are not mutually exclusive.

A comprehensive listing of all AEs will be provided by subject, which will include the duration of each event. Duration will be calculated as the stop date of the event minus the start date, unless the event is determined ongoing at exit.

7.2 Treatment Tolerability

Treatment tolerability will be summarized at each visit by the number of subjects who experienced discomfort during or immediately following the study drug application. Tolerability will be summarized over all study visits by the number of subjects who reported discomfort at any visit during the study. In these analyses, all percentages will be based on the number of responses. Results will be provided in a by-subject listing.

7.3 Prior and Concomitant Medication/Therapy

All prior and concomitant medications will be coded with WHODrug (MAR2016) and results will be presented in a by-subject listing with prior or ongoing-at-baseline medication/therapy identified.

8.0 EVALUATION OF EFFICACY PARAMETERS

Analyses in this section will be based on the FAS and the PP analysis set. The primary set for efficacy analyses will be the FAS; supportive analyses will be based on the PP. All analyses will be performed by study arm with missing data imputed using the last observation carried forward.

Throughout this section the term ‘follow-up visit’ will refer to any post-baseline visit, whether an office visit or a telephone contact. Only safety data and status of atopic dermatitis were to be collected at the Day 35 follow-up visit.

8.1 Investigator’s Global Assessment

The IGA is a categorical assessment of the treated area made according to the following scale:

Grade	Score	Description
Clear	0	No inflammatory signs of AD
Almost Clear	1	Just perceptible erythema and just perceptible population/infiltration
Mild	2	Mild erythema and mild population/infiltration
Moderate	3	Moderate erythema and moderate population/infiltration
Severe	4	Severe erythema and severe population/infiltration

The incidence of clear/almost clear grading (score of 0 or 1) will be summarized by follow-up visit. A summary over all follow-up visits will also be provided and is defined as the number and percentage of subjects achieving clear/almost clear at any time point during the 28 days of therapy.

Improvement in scores will also be calculated as change from baseline score (follow-up value – baseline value) by follow-up visit and over all follow-up visits; over all follow-up visits will be based on the best change from baseline (lowest value) at any time point during the 28 days of therapy. Improvement in score from baseline score will be assigned to the category of no improvement if either no change or a worsening score (positive change) occurs, or the category(ies) ≥1 grade improvement, ≥2 grade improvement. Count and percent of subjects will be provided.

The frequency distribution of scores by each visit will be provided, and the results will be presented in a by-subject listing.

8.2 **Eczema Area Severity Index**

The EASI is a continuous measure of eczema severity with scores that can range from 0 to 72 with higher scores indicating more severe conditions. For this study the population is required to have EASI scores between 2 and 50, inclusive, at baseline. Scores will be summarized by visit with n, mean, SD, median, minimum, and maximum. Change from baseline will be calculated at each follow-up visit (follow-up value – baseline value) and summarized by follow-up visit. Change values that are negative represent an improvement. Percent change from baseline ((follow-up value – baseline value)/baseline value) x 100 will also be summarized by follow-up visit.

Percent change from baseline will be assigned to one or more of the following categories:

Group	Percent Reduction Category	Percent change from baseline values
1	< 25% Reduction	> -25.0
2	≥ 25% Reduction	≤ -25.0
3	≥ 50% Reduction	≤ -50.0
4	≥ 75% Reduction	≤ -75.0

These groups are not mutually exclusive; results that fall into group 4 will also be counted in groups 2 and 3, likewise results that fall into group 3 but not group 4 will also be counted in group 2. The frequency distribution of subjects within each of these groups will be summarized by visit. A summary over all study visits will include the number and percent of subjects achieving their best (lowest value/greatest reduction) percent change at any time point during the 28 days of therapy.

The results will be presented in a by-subject listing.

8.3 **Body Surface Area**

Body surface area is a continuous measure of the percent of atopic dermatitis involvement in the permitted treatment areas. For this study the population inclusion criteria specified a body surface area between 2.0% and 15.0% inclusive. Values will be summarized by visit with n, mean, SD, median, minimum, and maximum. Change from baseline will be calculated (follow-up value – baseline value) and summarized by follow-up visit. Here, change values that are negative represent an improvement. Percent change from baseline ((study visit value – baseline value)/baseline value) x 100 will also be summarized by follow-up visit. Finally a table will be generated showing percent of subjects achieving at least a 20% reduction in BSA affected by Atopic Dermatitis.

The results will be presented in a by-subject listing.

8.4 **Post Study Status**

Data will be presented in a by-subject listing.

9.0 CONVENTIONS FOR CALCULATIONS AND TABULATIONS

Table 9.0 Conventions for Calculations and Tabulations

CONVENTION	DESCRIPTION
Age calculation	Age is calculated as an integer in years as the difference between the subject's date of informed consent and the date of birth. Specifically, if a subject's birthday has been reached by the informed consent date then age will be the difference in years, otherwise age will be the difference in years minus 1.
Baseline	Baseline is defined as assessments completed on Visit 1 (Day 1) prior to the administration of the study drug unless otherwise

CONVENTION	DESCRIPTION
	specified.
Study Day	Date of visit or evaluation – baseline date + 1
Percentage calculation	Percentages are calculated as 100*numerator/denominator. Rounding is not necessary because rounding is handled by the display format. Denominator is the total number of subjects in a column group unless otherwise specified.
AE counting: treatment emergence	An AE will be considered treatment emergent if it begins on or after the time of the first study treatment application. If the start date is the same as the date of first application (Day 1), the times are not present, or there is no indication that the AE began before dosing, the event will be considered treatment emergent.
AE counting: general summary	In summary displays, AEs are counted only once per subject within a category (e.g., over all and preferred term).
AE counting: summary by assessment	When AEs are summarized within levels of another AE assessment (e.g., causality or severity), AEs are counted once per subject at the worst level of the assessment (e.g., least complementary relationship or greatest severity). A missing or unknown value for the assessment will be considered worst.
Change from Baseline	current visit value – baseline visit value
Percent Change from Baseline	((current visit value —baseline visit value) / baseline visit value) x 100

10.0 **SPECIFICATIONS FOR ANALYSIS DISPLAYS**

All headers, titles, footnotes, and footers specified in the table and listing shells will be displayed in the produced output. Notes to the programmer will not be included in the produced output. Any minor deviation will not necessitate a revision to the Statistical Analysis Plan Implementation Document (SAPID) nor will it be considered a deviation from planned analyses. Only major differences in the analysis methods or data handling will necessitate such documentation. The shells of tables and listings are provided in Appendix A.

10.1 **Format**

All analysis displays will be created by using statistical and summarization procedures in SAS®, Version 9.4 or later, using a line size of 132 and a page size of 50. All margins of all tables and listing will be a minimum of 0.8 inch.

All displays are intended to be printed in landscape layout unless otherwise specified.

At the top of each table/listing, a number followed by the title will be presented. After the title line, a sub-title or population information may be presented. Horizontal lines will appear before and after the column heading of the table/listing. Footnotes will be under the main body of the table or listing display.

The sponsor name, protocol number, status of the output (i.e., draft or final), SAS program name, and the date and time of creation will be on the output. The page number will appear on the upper right corner of each output (Page X of Y).

10.1.1 **Conventions for Tables**

Tables will be delivered to the sponsor in Microsoft Word, Times New Roman, 10 point font. If necessary for formatting, an alternate font type or size may be used. The conventions for the analysis displays are shown in Table 10.1.1.

Table 10.1.1 Conventions for Tables

CONVENTION	DESCRIPTION
Decimals for summary statistics	General Rule: Relative to the number of decimals in the original data, 1 more decimal for the mean, median, and percentiles, 2 more decimals for standard deviation (SD) will be displayed, and the same number for minimum, maximum, and/or range. The maximum number of decimals will be 4. Some lab parameters or other data may require judicious deviation from this rule. Wherever possible, data will be decimal aligned.
Decimals and format for percentages	Unless otherwise specified, frequency tabulations will be presented by number and percentage, with the percentage in parentheses following the number. Percentages will be displayed to 1 decimal. A count of zero will exclude any percentage display. The '%' will not follow the percentage value if 'n(%)' is displayed in the column header.

10.1.2 **Conventions for Listings**

Listings will include all data recorded on the eCRFs. Listings may include derived variables that are reflected in analyses, where specified in Section 5 through Section 8 (e.g., change from baseline values, study day).

Listings will be delivered to the sponsor in Microsoft Word, Courier New, 8 point font. If necessary for formatting, an alternate font type or size may be used. The conventions for the listings are shown in Table 10.1.2, and apply for each listing where relevant.

Table 10.1.2 Conventions for Listings

CONVENTION	DESCRIPTION

CONVENTION	DESCRIPTION
Population	All enrolled subjects will be included unless otherwise specified.
Subject ID	Subject ID will be displayed as site number – subject number (XX-XXX).
Dates	Date information in the listing will use the *date9.* format (i.e., 01JAN2011) where possible. Otherwise, date formats will be displayed as recorded on the eCRF.
Unknown	'U' will represent 'Unknown' in date variables and categorical variables unless otherwise specified on the eCRF.
Missing Values	Missing values will be listed as represented in the clinical database (e.g., blanks, 'NR' for not reported).
Variable Units	In the listings, a unit associated with a variable will be presented within parentheses in the column label.
Visit Description	A visit column will be provided with the Visit ID (or label) and an adjacent column with the corresponding date of evaluation, if available.
Sort order	All listings will be sorted by 10% SAN007 first, followed by 5% SAN007, then Placebo, subject ID, followed by the collection date, or visit date if the collection date is unavailable, or AE start state followed by AE stop date for Adverse Events.

10.2 **Summary Tables to be Provided**

Table 10.2 Summary Tables

Table Number	**Title**	**Analysis Population**
14.1.1	Subject Disposition and Exit Status	Enrolled
14.1.2	Demographics and Baseline Characteristics	Safety
14.1.3	Baseline Disease Characteristics	Safety
14.2.1.1.1	Study Visit Compliance	Full Analysis Set
14.2.1.1.2	Study Visit Compliance	Per Protocol
14.2.1.2.1	Study Product Compliance	Full Analysis Set
14.2.1.2.2	Study Product Compliance	Per Protocol
14.2.2.1.1	Investigator's Global Assessment (IGA) – Incidence of Clear/Almost Clear During the Study	Full Analysis Set
14.2.2.1.2	Investigator's Global Assessment (IGA) – Incidence of Clear/Almost Clear During the Study	Per Protocol

Table Number	Title	Analysis Population
14.2.2.2.1	Investigator's Global Assessment (IGA) – Improvement by Visit	Full Analysis Set
14.2.2.2.2	Investigator's Global Assessment (IGA) – Improvement by Visit	Per Protocol
14.2.2.3.1	Investigator's Global Assessment (IGA) – Scores by Visit	Full Analysis Set
14.2.2.3.2	Investigator's Global Assessment (IGA) – Scores by Visit	Per Protocol
14.2.3.1.1	Eczema Area and Severity Index (EASI) – Categories of Percent Reduction	Full Analysis Set
14.2.3.1.2	Eczema Area and Severity Index (EASI) – Categories of Percent Reduction	Per Protocol
14.2.3.2.1	Eczema Area and Severity Index (EASI) – Scores by Visit	Full Analysis Set
14.2.3.2.2	Eczema Area and Severity Index (EASI) – Scores by Visit	Per Protocol
14.2.3.3.1	Eczema Area and Severity Index (EASI) – Change from Baseline by Visit	Full Analysis Set
14.2.3.3.2	Eczema Area and Severity Index (EASI) – Change from Baseline by Visit	Per Protocol
14.2.3.4.1	Eczema Area and Severity Index (EASI) – Percent Change from Baseline by Visit	Full Analysis Set
14.2.3.4.2	Eczema Area and Severity Index (EASI) – Percent Change from Baseline by Visit	Per Protocol
14.2.4.1.1	Body Surface Area (BSA) Affected by Atopic Dermatitis – Percentage Involvement by Visit	Full Analysis Set
14.2.4.1.2	Body Surface Area (BSA) Affected by Atopic Dermatitis – Percentage Involvement by Visit	Per Protocol
14.2.4.2.1	Body Surface Area (BSA) Affected by Atopic Dermatitis – Change from Baseline in Percentage Involvement by Visit	Full Analysis Set
14.2.4.2.2	Body Surface Area (BSA) Affected by Atopic Dermatitis – Change from Baseline in Percentage Involvement by Visit	Per Protocol
14.2.4.3.1	Body Surface Area (BSA) Affected by Atopic Dermatitis – Percent Change from Baseline in Percentage Involvement by Visit	Full Analysis Set
14.2.4.3.2	Body Surface Area (BSA) Affected by Atopic Dermatitis – Percent Change from Baseline in Percentage Involvement by Visit	Per Protocol
14.2.4.4.1	Body Surface Area (BSA) – Subjects Achieving at Least a 20% Reduction in BSA Affected by Atopic Dermatitis During the Study	Full Analysis Set
14.2.4.4.2	Body Surface Area (BSA) – Subjects Achieving at Least a 20% Reduction in BSA Affected by Atopic Dermatitis During the Study	Per Protocol
14.3.1.1	Summary of Treatment-Emergent Adverse Events	Safety
14.3.1.2	Incidence of Treatment-Emergent Adverse Events by Preferred Term	Safety
14.3.1.3	Incidence of Treatment-Emergent Adverse Events by Preferred	Safety

Table Number	Title	Analysis Population
	Term within System Organ Class	
14.3.1.4	Incidence of Treatment-Emergent Adverse Events Related to Treatment by Preferred Term within System Organ Class	Safety
14.3.1.5	Incidence of Treatment-Emergent Adverse Events by Maximum Severity and Preferred Term within System Organ Class	Safety
14.3.2.1	Tolerability by Visit	Safety

10.3 Listings to be Provided

Listings are numbered considering the ICH guidance, and are based on the Enrolled Population unless noted otherwise in Table 10.3.

Table 10.3 Listings

Listing Number	Title	Analysis Population
16.2.1.1	Study Completion/Termination	Enrolled
16.2.1.2	Evaluability	Enrolled
16.2.2	Demographics and Eligibility	Enrolled
16.2.2a	Inclusion/Exclusion Criteria	Enrolled
16.2.3	Alcohol, Cigarette, and Illegal Drug/Substance Use	Enrolled
16.2.4	Pertinent Medical History	Enrolled
16.2.5	Pregnancy Test	Enrolled
16.2.6.1	Treatment Medication Dispensation	Enrolled
16.2.6.2	Treatment Application, Compliance, and Tolerability Assessment	Enrolled
16.2.6.3	Target Treatment Area and Body Surface Area	Enrolled
16.2.6.4	Investigator Global Assessment	Enrolled
16.2.6.5	Eczema	Enrolled
16.2.6.6	Photography of Treatment Areas	Enrolled
16.2.7	Adverse Events	Enrolled
16.2.8	Prior and Concomitant Medication or Therapy	Enrolled
16.2.9	Complete Physical Exam	Enrolled
16.2.10	Telephone Contact	Enrolled
16.2.11	Visit Dates and Subject Status	Enrolled

11.0 APPENDIX A. SHELL TABLES AND LISTINGS