STATISTICAL ANALYSIS PLAN

Santalis Pharmaceuticals

Protocol: SAN021-03

A DOUBLE BLIND, MULTI-CENTER, RANDOMIZED, PLACEBO CONTROLLED SAFETY, TOLERABILITY AND EFFICACY TRIAL OF A NEW BOTANICAL DRUG PRODUCT CONTAINING EAST INDIAN SANDALWOOD OIL (EISO) AT ONE DOSE LEVEL FOR THE TREATMENT OF MILD-TO-MODERATE PLAQUE PSORIASIS IN ADULT SUBJECTS

Author: Julie Mordaunt

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LIST OF ABBREVIATIONS

AE	Adverse Event
cm	centimeter
eCRF	Electronic Case Report Form
EISO	East Indian Sandalwood Oil
FAS	Full Analysis Set
g	gram
ITT	Intent-to-Treat
kg	kilogram
MedDRA	Medical Dictionary for Regulatory Activities
N	population size (N for sample size, n for available data)
PASI	Psoriasis Area and Severity Index
PGA	Physician's Global Assessment
PP	Per Protocol
PT	Preferred Term
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, Multi-Center, Randomized, Placebo Controlled Safety, Tolerability, and Efficacy Trial of a New Botanical Drug Product Containing East Indian Sandalwood Oil (EISO) at One Dose Level for the Treatment of Mild-to-Moderate Plaque Psoriasis in Adult Subjects", dated 08 August 2017.

1.1 Study Objectives

1.1.1 Primary Objectives

The primary objective of this study is to evaluate the safety of SAN021 compared to placebo when administered topically for up to 42 days to adults who have a clinical diagnosis of mild-to-moderate plaque psoriasis. 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 Psoriasis Area and Severity Index (PASI) score at any point during the 42 days of treatment.
- Percentage of subjects who have a ≥50% reduction in the PASI score at any point during the 42 days of treatment.
- Percentage of subjects with a PGA score of "clear" or "almost clear" at any time during the 42 days of treatment.
- Percentage of subjects achieving at least a 1-grade improvement in Physician's Global Assessment (PGA) score.
- Percentage of subjects achieving a 2-grade improvement in PGA score.

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 efficacy of SAN021 when administered topically for up to 42 days to adults between the ages of 18 to 65 years inclusive who have a clinical diagnosis of mild-to-moderate plaque psoriasis. Subjects will enter the Screening Period once the informed consent and photographic consent process has been completed. Subjects with mild-to-moderate plaque psoriasis, as defined by a PASI score between 2 and 12, that, in the opinion of the investigator, is appropriate for topical treatment, covers a minimum of 1.0% and a maximum of 10.0% body surface area in the permitted treatment areas, and who meet all of the inclusion and none of the exclusion criteria will be enrolled.

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% SAN021

or placebo serum (randomized in a 2:1 ratio) with the first dose applied at the Day 1 Study Visit. Subjects will be instructed on how to apply the study medication twice daily for 42 days. Subjects will return to the clinic for study-related assessments on Study Days 7, 14, 28 and a final visit on Day 42. On Study Day 49, subjects will receive a follow-up phone call and be queried for condition status since going off study.

Table 2.1: Visit Schedule

Screening	**Baseline[1]**	**←——— Treatment ———→**				**Follow-up Call[2]**
Day -7 to 0	**Day 1**	**Day 7 (±2 days)**	**Day 14 (±2 days)**	**Day 28 (±2 days)**	**Day 42 (±2 days)**	**Day 49 (±2 days)**
	Visit 1	**Visit 2**	**Visit 3**	**Visit 5**	**Visit 6**	

[1] Screening and Baseline may occur on the same day provided the informed consent and photography consent process has been completed and the consents have been signed.
[2] Follow-up may be extended if adverse events require time to assess.

2.2 Sample Size

There is no formal assessment of sample size. The sample size of 72 subjects was chosen to ensure at least 60 subjects complete the study. The sample size is not expected to yield statistically significant results, and there are no inferential statistical analyses.

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 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 42.
- A scheduled visit occurring more than 5 days outside of the +/- 2-day visit window.

Although non-compliance is defined in the protocol as <80% 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 described in the protocol as all subjects enrolled who apply at least one treatment of the study drug or placebo. 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 equivalent to the ITT and is referred to in the generation of listings and tabulation of patient disposition.

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. The exception will be the case where a subject discontinued prior to Day 42 yet data were mistakenly logged in the Day 42 eCRFs, as Day 42 represents end of treatment. Here data will be analyzed on the appropriate study visit day according to the visit window in which the actual study day falls; this will allow for correct implementation of the last observation carried forward method.

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.

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 follow-up visit. The count and percent of subjects who attended their 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 follow-up visits.

Compliance will be based on the baseline body surface area (bsa) of the treated area times 0.25 (W=bsa x 0.25). The number of applications per study day is two, and will be assumed to be one on each visit day, except baseline, which will be assigned two applications. The number of applications (X) for an interval will then be:

- from baseline to a follow-up visit: X = (current visit date – baseline date) x 2 + 1
- from a follow-up visit to a subsequent follow-up visit:
  X = (current visit date – previous visit date) x 2;

and therefore, the expected weight of drug applied (EW) will be calculated as:

EW=X (W)

The actual amount of drug applied in an interval (AW) will be the difference between the bottle weights at the relevant visits:

AW= weight of bottle at current visit – weight of bottle at previous visit

The actual compliance will be calculated as the percentage (C) of what was used versus what was expected to be used:

C= (AW/EW) x 100

This value may be greater than 100%. However, if the value is less than 60%, then the subject will be considered non-compliant for that study treatment interval.

Using these same calculations, compliance over all follow-up visits will be calculated using available data from the medication dispensation log. Weight of drug used from a bottle will be the difference of the last medication weight reported and the weight of the bottle at dispensation. If multiple bottles 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 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 PASI, and the qualitative assessments, target treatment area and PGA score.

6.3 Medical History/Signs and Symptoms

Medical conditions reported in the 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 AE is any reaction, side effect, or other untoward event, regardless of relationship to study drug, that starts any time after the beginning of dosing. Non-serious AEs will be captured through the last treatment application, Day 42/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 SAN021 group then alphabetically
- SOC and PT presented in order of descending incidence in SOC, then PT, in the SAN021 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. 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.

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 even 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 (Yes, Discomfort). Tolerability will be summarized over all follow-up 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.

8.1 Physician's Global Assessment

The PGA is a categorical assessment of psoriasis severity made according to the following scale:

Grade	Score	Description
Clear	0	No signs of psoriasis (post-inflammatory hyperpigmentation may be present)
Almost Clear	1	Intermediate between mild and clear
Mild	2	Slight scaling plaque elevation, scaling, and/or erythema
Moderate	3	Moderate plaque elevation, scaling, and/or erythema
Severe	4	Very marked plaque elevation, scaling, and/or erythema

The incidence of clear/almost clear grading (score of 0 or 1) will be summarized by 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 42 days of therapy.

Improvement in scores will also be calculated as change from baseline score (follow-up – baseline) 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 42 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 into one or both of the categories >=1 grade improvement, and =2 grade improvement (i.e., subjects with a 2 grade improvement will also be counted in the >= 1 grade improvement). Count and percent of subjects in each category 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 **Psoriasis Area and Severity Index**

The PASI is a continuous measure of psoriasis 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 PASI scores between 2 and 12, inclusive, at baseline. Scores 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. 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 follow-up visits will include the number and percent of subjects achieving their best (lowest value/greatest reduction) percent change at any time point during the 42 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 psoriasis extent. For this study the population inclusion criteria specified a body surface area between 1.0% and 10.0% 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 ((follow-up value – baseline value)/baseline value) x 100 will also be summarized by follow-up visit.

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 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

CONVENTION	DESCRIPTION
	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 (SAP) 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 will be provided in a separate document from this SAP.

10.1 Format

All analysis displays (with the exception of figures) 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/figure, 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
Population	All enrolled subjects will be included unless otherwise specified.
Subject number	Subject numbers 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.

CONVENTION	DESCRIPTION
Sort order	All listings will be sorted by SAN021 first, followed by Placebo, the subject number portion of the subject ID (site # - subject #), 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**

Tables that will be generated for both the FAS and PP analysis sets will be identified by the last decimal value of the table number '.1' and '.2' respectively, and appear as *'.X'* in the table shells.

Table 10.2 Summary Tables

Table Number	Title	Analysis Population
14.1.1	Subject Disposition and Exit Status	Enrolled Population
14.1.2	Demographics and Baseline Characteristics	Safety Population
14.1.3	Baseline Disease Characteristics	Safety Population
14.2.1.1	Study Visit Compliance	Safety Population
14.2.1.2	Study Product Compliance	Safety Population
14.2.2.1.*X*	Physician's Global Assessment – Incidence of Clear/Almost Clear During the Study	Full Analysis Set, Per Protocol
14.2.2.2.*X*	Physician's Global Assessment - Improvement by Visit	Full Analysis Set, Per Protocol
14.2.2.3.*X*	Physician's Global Assessment - Scores by Visit	Full Analysis Set, Per Protocol
14.2.3.1.*X*	Psoriasis Area and Severity Index – Categories of Percent Reduction	Full Analysis Set, Per Protocol
14.2.3.2.*X*	Psoriasis Area and Severity Index – Score by Visit	Full Analysis Set, Per Protocol
14.2.3.3.*X*	Psoriasis Area and Severity Index –Change from Baseline	Full Analysis Set, Per Protocol
14.2.3.4.*X*	Psoriasis Area and Severity Index –Percent Change from Baseline	Full Analysis Set, Per Protocol
14.2.4.1.*X*	Body Surface Area – Score by Visit	Full Analysis Set, Per Protocol
14.2.4.2.*X*	Body Surface Area – Change from Baseline	Full Analysis Set, Per Protocol
14.2.4.3.*X*	Body Surface Area – Percent Change from Baseline	Full Analysis Set /Per Protocol
14.3.1.1	Summary of Treatment-Emergent Adverse Events	Safety Population

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

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 Population
16.2.1.2	Evaluability	Enrolled Population
16.2.2.1	Demographics and Eligibility	Enrolled Population
16.2.2.2	Inclusion/Exclusion Criteria	Enrolled Population
16.2.3	Alcohol, Cigarette, and Illegal Drug/Substance Use	Enrolled Population
16.2.4	Medical History	Enrolled Population
16.2.5	Pregnancy Test	Enrolled Population
16.2.6.1	Treatment Medication Dispensation	Enrolled Population
16.2.6.2	Treatment Application, Compliance, and Tolerability Assessment	Enrolled Population
16.2.6.3	Target Treatment Area and Body Surface Area	Enrolled Population
16.2.6.4	Physician's Global Assessment and Psoriasis Area and Severity Index	Enrolled Population
16.2.6.5	Photography of Treatment Areas	Enrolled Population
16.2.7	Adverse Events	Enrolled Population
16.2.8	Prior and Concomitant Medication or Therapy	Enrolled Population
16.2.9	Physical Exam	Enrolled Population
16.2.10	Telephone Contact	Enrolled Population
16.2.11	Visit Dates and Subject Status	Enrolled Population