STATISTICAL ANALYSIS PLAN

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multiple-Site Clinical Study to Evaluate the Efficacy and Safety of Desoximetasone Topical Spray, 0.15% (Taro Pharmaceuticals, U.S.A., Inc.) in Patients with Mild to Moderate Plaque Psoriasis

Protocol Number: DSXS 1505
Novum Study Number: 71542603

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Final Version 1.0

NOVUM PHARMACEUTICAL RESEARCH SERVICES
STATISTICAL ANALYSIS PLAN

Desoximetasone Spray, 0.15% **Protocol / Study No. DSXS 1505 / 71542603**

SAP Final Version Approvals

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multiple-Site Clinical Study to Evaluate the Efficacy and Safety of Desoximetasone Topical Spray, 0.15% (Taro Pharmaceuticals, U.S.A., Inc.) in Patients with Mild to Moderate Plaque Psoriasis

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Desoximetasone Spray, 0.15% **Protocol / Study No. DSXS 1505 / 71542603**

Revision History

VERSION	DATE	DESCRIPTION OF REVISIONS	REVISED BY
Draft 1.0	February 18, 2016	New Document	Jianhua Liu
Final 1.0	March 4, 2016	SAP Finalization	Jianhua Liu

List of Abbreviations and Definition of Terms

ADaM	Analysis Data Model
AE	Adverse Event
ANCOVA	Analysis of Covariance
BP	Blood Pressure
BSA	Body Surface Area
C	Celsius
CRF	Case Report Form
CDISC	Clinical Data Interchange Standards Consortium
CRO	Contract Research Organization
F	Fahrenheit
FDA	Food and Drug Administration
HR	Heart Rate
Hg	Mercury
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IGA	Investigator's Global Assessment
IND	Investigational New Drug
LOCF	Last Observation Carried Forward
MedDRA	Medical Dictionary for Regulatory Activities
ITT	Intent-to-Treat
LOCF	Last Observation Carried Forward
OGD	The Office of Generic Drugs
PASI	Psoriasis Area Severity Index
PP	Per-Protocol
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SDTM	Study Data Tabulation Model
TLSS	Total Lesion Severity Score
USA	United States of America

TABLE OF CONTENTS

1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the final Clinical Study Protocol DSXS 1505 (Novum Study No. 71542603) Rev. 4 dated 02/24/2016. The SAP provides details on the planned statistical methodology for the analysis of the study data. The SAP also outlines the statistical programming specifications for the tables, listings and figures.

This SAP describes the study endpoints, derived variables, anticipated data transformations and manipulations, and other details of the analyses not provided in the study protocol. This SAP therefore outlines in detail all other aspects pertaining to the planned analyses and presentations for this study.

The following documents were reviewed in preparation of this SAP:

- Final Clinical Study Protocol DSXS 1505 (Novum Study No. 71542603) Rev. 4 dated 02/24/2016
- Case Report Form Booklet Version 1.0 for Novum Study No. 71542603 dated September 3, 2015

The reader of this SAP is encouraged to also read the clinical protocol for details on the conduct of this study, and the operational aspects of clinical assessments and timing for completing a patient in this study.

2. OBJECTIVES

To evaluate the therapeutic efficacy and safety of desoximetasone topical spray, 0.15% (Taro Pharmaceuticals, U.S.A., Inc.) compared to a Placebo (vehicle) spray (Taro Pharmaceuticals, U.S.A., Inc.) in patients with mild to moderate plaque psoriasis.

3. OVERALL STUDY DESIGN

This double-blind, randomized, placebo-controlled, parallel group, multi-site study is designed to evaluate the therapeutic efficacy and safety of desoximetasone topical spray, 0.15% (Taro Pharmaceuticals, U.S.A., Inc.).

Up to 120 patients will be enrolled to randomize up to 60 patients in the Test group and 60 in the Placebo group. Before any study-specific procedures are performed all patients will read and sign the IRB-approved informed consent form. In addition, patients considered as minors by the state law in which the clinical site is located (in most States under 18 years of age), must have a signed parental/guardian Informed Consent Form (ICF), indicating approval to participate, as well as a signed assent to participate form.

To qualify for inclusion in the study, patients must be at least 12 years of age with a confirmed diagnosis of mild to moderate plaque psoriasis and must fulfill the following primary inclusion criteria:

- An affected BSA of 5 - 10% (Appendix A)
- A IGA score of 2 (mild) or 3 (moderate) (Appendix B)
- Target Lesion area of at least 5 cm^2
- Plaque Elevation Score $\geq$ 2 for the Target Lesion (based on TLSS score, Appendix B)

At Visit 1, patients who meet all inclusion/exclusion criteria will be randomized in a 1:1 ratio (Test: Placebo) for 28 days of treatment:

- **Test:** Desoximetasone topical spray, 0.15% (Taro Pharmaceuticals, U.S.A., Inc.)
- **Placebo:** Vehicle spray (Taro Pharmaceuticals, U.S.A., Inc.)

Randomized study medication will be self-administered by the patient for 28 days. Patients will be instructed to spray the study medication directly to all affected areas and gently and completely rub in the study drug twice a day for 28 days. Study medication will be applied in the morning and evening approximately 12 hours apart. Patients will return to the clinic at scheduled Visits 2, 3 and 4. Each patient will be provided with a dosing diary in which they will be required to record dosing dates and times. These diaries should be brought to each visit so that the study staff may check compliance. At the end of the study, the dosing diaries will be retained in the patient's file as source documentation.

During the study patients will visit the research center for a total of 4 scheduled visits:

- **Visit 1:** Randomization (Day 1),
- **Visit 2:** Interim Visit (Day 7 $\pm$ 2),
- **Visit 3:** Interim Visit (Day 14 $\pm$ 2),
- **Visit 4:** End of Treatment (Day 28 $\pm$ 2).

Patients will be contacted at Day 42 $\pm$ 4 (Visit 5) for a Telephone Follow-up to report any Adverse Events that have occurred since the end of treatment,

Evaluation of therapeutic efficacy will be primarily based on dermatological evaluation of psoriasis. The evaluation will include scoring of the extent and severity of plaque psoriasis. Refer to Appendices A, B and C for body surface area (BSA) estimation, Investigator's Global Assessment Scale (IGA), Total Lesion Severity Score (TLSS) and Psorasis Area Score Index

(PASI), respectively. Selected sites will be instructed to take photographs of a target lesion at each visit.

Figure 1 Study Schematic

PROCEDURE	VISIT 1 Randomization Day 1	VISIT 2 Interim Visit Day 7 ± 2 days	VISIT 3 Interim Visit Day 14 ± 2 days	VISIT 4 End of Treatment Day 28 ± 2 days	VISIT 5 Telephone Follow-Up Visit Day 42 ± 4 days
Informed Consent	X				
Medical History & Demographics	X				
Height and Weight	X				
Vital Signs	X	X	X	X	
Dermatological Assessment	X	X	X	X	
% BSA Assessment	X	X	X	X	
IGA Score	X	X	X	X	
Total Lesion Severity Score	X	X	X	X	
PASI Score	X	X	X	X	
Application Site Reactions	X	X	X	X	
Target Lesion Photograph**	X	X	X	X	
Pregnancy Test*	X			X	
Concomitant Medication	X	X	X	X	
Collect/Dispense Study Medication	X		X	X	
Provide/Review patient Dosing Diary	X	X	X	X	
Adverse Events		X	X	X	X
Evaluation of Patient Compliance to the Protocol		X	X	X	

* Pregnancy Test will be conducted for women of child-bearing potential
** Selected sites will be designated to take photographs of a defined target lesion at each Clinic Visit

4. RANDOMIZATION AND BLINDING

The study drug will be randomized, packaged and blinded by an independent packaging company. Randomization will be pre-planned according to a computer-generated randomization schedule. The randomization will be generated in blocks, each containing 4 patients' worth of medication (2 x Test product and 2 x Placebo). Each patient kit will contain 2 x 100 ml bottles of study medication.

The randomization number will be a unique 4 digit number.

A perforated or two-part label will be attached to the box of drug supplies for each patient. Both pieces of the label should include the following information: protocol number, randomization number, space for patient's initials, statement that the drug is for Investigational Use Only, space for dispensing date, storage information and the Sponsor's name. One part of the label shall remain attached to the box. The other part will be removed before dispensing and attached to the patient's source documents.

At the end of the study, after all the clinical data have been entered and the study database has been locked, a copy of the randomization will be sent to the statistician.

The Investigator, staff at the study site, study monitors, and data analysis/management personnel will be blinded to the patient assignment.

5. SAMPLE SIZE

The primary analyses of interest are the proportion of patients in the Test and Vehicle treatment groups who are considered to be a Clinical Success and Treatment Success on Day 28.

In-house data from two Phase III studies that evaluated the safety and efficacy of desoximetasone spray 0.25% (twice daily for 28 days) in patients with moderate to severe plaque psoriasis were used for sample size determination. These studies were conducted in support of Taro's NDA #204141, Topicort® (desoximetasone) Topical Spray, 0.25%. In those studies the Clinical Success rates were 31% and 53% for the active product (42% average) and 5% and 18% for the vehicle treatment (12% average), and the Treatment Success rates were 39% and 53% for the active product (46% average) and 7% and 17% for the vehicle treatment (12% average).

Based on the average results from these two studies on the 0.25% spray, the proportion of subjects in the Test group considered a Clinical Success and Treatment Success is expected be 40% or higher and the proportion of subjects in the Vehicle group considered a Clinical Success and Treatment Success is expected to be 12% or less for desoximetasone spray 0.15% in patients with mild to moderate plaque psoriasis. With these assumptions, 50 evaluable subjects in the ITT in each treatment group will demonstrate superiority of the Test to the Vehicle group with 89% power

at the 5% level of significance ($p < 0.05$, using two-sided *Z*-test), assuming 100% correlation between Clinical and Treatment Success rates.

To allow for patients who may drop out from the study or are otherwise non-evaluable, up to 120 patients may be enrolled (60 in the Test group and 60 in the Vehicle group).

6. STUDY ENDPOINTS

Primary Efficacy Endpoints

1. The proportion of patients in each treatment group who are considered a Clinical Success at Day 28 ± 2 (i.e., at least a 2-grade improvement from the patient's baseline IGA score)
2. The proportion of patients in each treatment group who are considered a Treatment Success for the Target Lesion at Day 28 ± 2 (i.e., a TLSS value of 0 or 1 at Day 28 ± 2 for each of the three signs and symptoms (i.e., erythema, scaling and plaque elevation) depending on the patient's baseline TLSS)

Definitions:

1. Treatment Success: To be considered a Treatment Success the patient's TLSS value at Day 28 ± 2 must be 0 if their baseline TLSS value is 2 and must be 0 or 1 if their baseline TLSS value is > 2 for each of the individual signs and symptoms
2. Treatment Failure: A patient will be considered a Treatment Failure if:
    a. the patient's TLSS value is > 0 if their baseline TLSS value is 2 or >1 if their baseline IGA score is > 2 for any of the individual signs and symptoms
    b. the patient was considered to have an insufficient therapeutic response
3. Clinical Success: To be considered a Clinical Success the patient must have at least a 2-grade improvement from their baseline IGA score. That is, an IGA score of 0 at Day 28 ± 2 if their baseline IGA score is 2 or an IGA score of 0 or 1 at Day 28 ± 2 if their baseline IGA score is 3
4. Clinical Failure: A patient will be considered a Clinical Failure if:
    a. the patient's IGA score is > 0 if the baseline IGA score is 2 or > 1 if the baseline IGA score is 3
    b. the patient was considered to have an insufficient therapeutic response

Secondary Efficacy Endpoint

The change from baseline in %BSA affected at Day 28 ± 2

7. STUDY POPULATIONS

Intent-to-Treat (ITT) Population

The ITT population will include:

- All randomized subjects.

Patients discontinued early for any reason will be included in the ITT with their Last Observation Carried Forward (LOCF).

Per-Protocol (PP) Population

The PP population is a sub-population of the ITT population and will include:

- Patients who met all inclusion and exclusion criteria and were randomized according to the randomized treatment assignment.
- Patients who applied at least one dose AND had at least one post-baseline evaluation.
- Patients who were compliant with the dosage regimens following randomization.
- Patients who had no major protocol deviations.

Safety Population

- All patients who were randomized and received at least one dose of the study product.

8. STATISTICAL ANALYSIS METHODS

If not otherwise specified, statistical significance is defined as $p<0.05$ and is two-tailed. Data will be summarized with respect to demographic and baseline characteristics and safety variables.

For categorical variables, the number and percent of each category within a parameter will be calculated for non-missing data. For continuous variables, statistics will include n, mean, standard deviation, median, minimum and maximum values.

All statistical analyses will be conducted using SAS®, Version 9.4 or higher. Datasets will be prepared using headings from Clinical Data Interchange Consortium (CDISC) Study Data Tabulation Model (SDTM) implementation for human clinical trials and ADaM (Analysis Dataset Model).

8.1 Baseline Characteristics

8.1.1 Patient Disposition

The patient disposition information will be summarized by treatment. The number of patients randomized, treated with study medication will be tabulated by treatment. In addition, completion status and primary reason for withdrawal will be summarized by treatment.

8.1.2 Demographic and Other Baseline Characteristics

Baseline comparability of all treatment groups will be evaluated separately in the ITT, PP and Safety populations.

The following baseline demographics (determined from their initial study visit) will be evaluated:

- Age (years)
- Gender (male/female)
- Ethnicity (Hispanic/non Hispanic)
- Race (White, Black/African American, Native Hawaiian or Other Pacific Islander, Asian, American Indian or Alaska Native, Other)
- Baseline total BSA
- Baseline % BSA affected with psoriasis
- IGA score
- TLSS Score
- PASI Score
- Target Lesion size (area)

Summary tables by treatment will be presented. Continuous variables will be summarized using descriptive statistics (n, mean, standard deviation, median, minimum, maximum). Categorical variables will be summarized using frequencies and percentage.

Baseline comparability of the treatments will be presented using Chi-square test for the categorical variables, and Analysis of Variance for the continuous variables.

All data will be listed by treatment and patient.

8.1.3 Medical History

At Visit 1 patients will be questioned about personal medical history including psoriasis history

and all medication use within the previous 12 weeks.

Medical history data will be listed by treatment and patient.

8.1.4 Concomitant Medications

At each clinic visit, patients will be questioned about current and concomitant medication use. Patients will also be questioned about ongoing or new concomitant medication use during the treatment period at Visits 2, 3 and 4.

All prior and concomitant medications taken since screening until the end of the study will be listed by treatment and patient.

8.1.5 Pregnancy Test

All females of childbearing potential will have a urine pregnancy test performed at Visit 1 and Visit 4.

Pregnancy test results will be listed by treatment and patient.

8.2 Efficacy Analyses

8.2.1 Primary Efficacy Analysis

The primary endpoints are: 1) the proportion of patients in each treatment group who are considered a Clinical Success at Day 28 ± 2 (i.e., at least a 2-grade improvement from the patient's baseline IGA score). 2) the proportion of patients in each treatment group who are considered a Treatment Success for the Target Lesion at Day 28 ± 2 (i.e., a TLSS value of 0 or 1 at Day 28 ± 2 for each of the three signs and symptoms (i.e., erythema, scaling and plaque elevation) depending on the patient's baseline TLSS).

The Test treatment will be compared with Placebo for each primary endpoint at the 5% significance level ($p < 0.05$; using two-tailed Z-test) in the ITT population using last observation carried forward (LOCF). Superiority of Test over Placebo will be demonstrated if both dichotomous endpoints show statistical significance at the 5% significance level by the Z-tests.

For sensitivity testing, the primary analysis will also be performed using the PP population.

8.2.2 Secondary Efficacy Analysis

The secondary endpoint is the change from baseline in %BSA affected at Day 28 ± 2.

The Test treatment will be compared with Placebo for the secondary endpoint at the 5% significance level in the ITT population using LOCF. Analysis of Covariance (ANCOVA) with

treatment and site as fixed effects and baseline %BSA as a covariate in the model will be used for the evaluation of the secondary endpoint.

The LSMeans for each treatment, the LSMeans of the treatment difference together with the corresponding 95%-confidence interval and the p-value will be presented.

Descriptive statistical analysis (number of patients, mean, standard deviation, median, minimum and maximum) will be generated to compare the efficacy results in each treatment group at each visit.

8.2.3 Treatment-by-Site Interaction and Pooling of Clinical Sites

As this is a multiple-site study, the interaction of treatment-by-site may be evaluated for superiority testing by the Cochran-Mantel-Haenszel test (stratified by site) for the primary efficacy endpoints and by ANCOVA for the secondary endpoint at the 5% significance level ($p < 0.05$, 2-sided) in the ITT population. A site(s) with a low enrollment rate(s) may be pooled with its geographically closest site, so as to avoid bias in the estimation of a treatment-by-site interaction effect. The pooling will be done for low enrolling sites that account for less than 4-7% of the total number of patients in the ITT population at the site with the highest enrolling rate. If no treatment-by-site interaction is identified with the primary endpoints then no adjustment will be made to any efficacy analysis and treatment-by site interaction will not be included as a term in the statistical models for evaluating superiority.

8.3 Safety Analysis

Safety analysis will be conducted on safety population.

8.3.1 Adverse Events

All the adverse events (AEs) reported throughout the study will be coded and classified according to the MedDRA (Medical Dictionary for Regulatory Activities) coding dictionary (Version 17.0 or higher). Each adverse event is to be evaluated for date of start and end, seriousness, severity, causal relationship with the study drugs, action taken and outcome.

All AEs will be listed by treatment and patient.

A summary table of the number and percent of patients with AEs by system organ class, preferred term, and treatment will be presented. Each patient will be counted only once within each preferred term.

A frequency summary table of the number of AEs by system organ class, preferred term, severity, and treatment will be presented. Severity will be classified as "Mild", "Moderate", or "Severe".

Similarly, a frequency summary table of the number of AEs by system organ class, preferred term, and relationship to a study drug, and treatment will be presented. Relationship to a study drug will be classified as "Not Related" or "Related" where "Related includes "Possible", "Probable", or "Definite".

Should sufficient data exist, adverse event frequencies will be compared between treatments using Fisher's exact test.

8.3.2 Vital Signs

The patient's vital signs will be recorded (heart rate, blood pressure, temperature and respiration rate) at Visit 1, 2, 3 and 4.

Descriptive summaries (number of observations, mean, standard deviation, minimum, median and maximum) will be provided by treatment and visit.

All data will be listed by treatment and patient.

8.3.3 Application Site Reactions

At each visit the Investigator will examine the treatment area and complete the signs and symptoms of irritation assessment based on the scale provided in Appendix E.

A frequency summary table comparing the application site reactions for each treatment group will be presented by visit.

All data will be listed by treatment and patient.

8.4 Multiple Comparisons

No multiple comparison adjustment will be made in this study.

8.5 Methods for Handling Missing Data

For demographic and baseline characteristics, each variable will be analyzed using all available data. Patients with missing data will be excluded only from analyses for which data are not available.

For primary and secondary efficacy analysis, patients discontinued early for any reason will be included in the ITT with their Last Observation Carried Forward (LOCF).

8.6 Interim Analyses

There is no interim analysis planned in this study.

9. TABLE, LISTING AND FIGURE SHELLS

The following shells are provided in order to provide a framework for the display of data from this study. These shells may not be reflective of every aspect of this study but are intended to show the general layout of the Tables, Listings and Figures that will be included in the final clinical study report. Tables, Listings and Figures are numbered following the ICH structure. Table headers, variables names and footnotes will be modified as needed following data analyses. All descriptive and inferential statistical analyses will be performed using SAS® statistical software Version 9.4 or higher, unless otherwise noted.

TABLE, LISTING AND FIGURE SHELLS

T16.1.9.1 Summary of Discontinued Patients

Patients	Test: Desoximetasone Topical spray, 0.15%	Placebo: Vehicle spray	Total
Screened			xxx
Randomized	xxx	xxx	xxx
Completed Study	xxx	xxx	xxx
Terminated Early	xxx	xxx	xxx
Early Termination Reason	xxx	xxx	xxx
Adverse Event	xxx	xxx	xxx
Insufficient therapeutic response/treatment failure	xxx	xxx	xxx
Lost to follow-up	xxx	xxx	xxx
etc.			
Other	xxx	xxx	xxx

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T16.1.9.2 Summary of Protocol Deviations

	Test: Desoximetasone Topical spray, 0.15%	Placebo: Vehicle spray	Total
Total Patients with Protocol Deviations	xxx	xxx	xxx
Total Deviations	xxx	xxx	xxx
Lost to Follow-up	xxx	xxx	xxx
Missed Visit	xxx	xxx	xxx
Missed more than 3 consecutive days of dosing	xxx	xxx	xxx
Non-compliance with dosing requirements	xxx	xxx	xxx
Outside Visit Window	xxx	xxx	xxx
Restricted Medication Use	xxx	xxx	xxx
Randomized in Error	xxx	xxx	xxx
Other	xxx	xxx	xxx

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T16.1.9.3.1 Summary of Patients Excluded from Efficacy Analysis (Population Determination)

	Test: Desoximetasone Topical spray, 0.15%	Placebo: Vehicle spray	Total
Randomized / ITT Population	xxx	xxx	xxx
Safety Population	xxx	xxx	xxx
PP Population	xxx	xxx	xxx
Excluded from PP population	xxx	xxx	xxx
Inclusion/Exclusion criteria not met	xxx	xxx	xxx
Non-compliant with dosing requirement	xxx	xxx	xxx
Major protocol deviations	xxx	xxx	xxx
etc.	xxx	xxx	xxx
	xxx	xxx	xxx

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T16.1.9.3.2 Summary of Patients Included in Analysis Population by Study Center

Site No.	Name	Total Randomized	PPP			ITT			Safety		
			Test	Placebo	Total	Test	Placebo	Total	Test	Placebo	Total
xx	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xx	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

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T16.1.9.4.1 Summary of Demographic Data

		Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx	Total N=xx	P-value
Age (years)	n	xx	xx	xx	x.xxxx
	Mean ± SD	xx.x ± x.x	xx.x ± x.x	xx.x ± x.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx-xx	xx-xx	xx-xx	
Age Groups	< 18	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	x.xxxx
	18 – 40	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	41 – 64	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	65 – 75	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	> 75	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Race	American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	x.xxxx
	Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Black/African American	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Native Hawaiian or other Pacific Islander	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	White	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Other	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Ethnicity	Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	x.xxxx
	Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Gender	Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	x.xxxx
	Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	

N= number of patients in the treatment; n= number of patient with data available; % is based on N

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T16.1.9.4.2 Summary of Baseline Dermatological Assessment

		Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx	Total N=xx	P-value
Baseline Total BSA	n	xx	xx	xx	x.xxxx
	Mean ± SD	xx.x ± x.x	xx.x ± x.x	xx.x ± x.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx-xx	xx-xx	xx-xx	
% BSA Affected with Psoriasis	n	xx	xx	xx	x.xxxx
	Mean ± SD	xx.x ± x.x	xx.x ± x.x	xx.x ± x.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx-xx	xx-xx	xx-xx	
Baseline IGA Score	Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	x.xxxx
	Minimal	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	

N= number of patients in the treatment; n= number of patient with data available; % is based on N

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T16.1.9.4.2 Summary of Baseline Dermatological Assessment

		Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx	Total N=xx	P-value
Baseline TLSS	Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	x.xxxx
	Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Very Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Baseline Scaling Score	Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	x.xxxx
	Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Very Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Baseline Erythema Score	Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	x.xxxx
	Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Very Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	

N= number of patients in the treatment; n= number of patient with data available; % is based on N

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T16.1.9.4.2 Summary of Baseline Dermatological Assessment

		Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx	Total N=xx	P-value
Baseline Plaque Elevation	Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	x.xxxx
	Almost Clear	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	Very Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
Baseline PASI Score	n	xx	xx	xx	x.xxxx
	Mean ± SD	xx.x ± x.x	xx.x ± x.x	xx.x ± x.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx-xx	xx-xx	xx-xx	
Target Lesion Size (area, cm^2)	n	xx	xx	xx	x.xxxx
	Mean ± SD	xx.x ± x.x	xx.x ± x.x	xx.x ± x.x	
	Median	xx.x	xx.x	xx.x	
	Range	xx-xx	xx-xx	xx-xx	
Baseline PASI Score	n	xx	xx	xx	x.xxxx

N= number of patients in the treatment; n= number of patient with data available; % is based on N

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Similar tables will be created for T16.1.9.5.1, T16.1.9.5.2, T16.1.9.6.1 and T16.1.9.6.2

T16.1.9.5.1 Summary of Demographic Data (Intent-to-Treat Population)

T16.1.9.5.2 Summary of Baseline Dermatological Assessment (Intent-to-Treat Population)

T16.1.9.6.1 Summary of Demographic Data (Per-Protocol Population)

T16.1.9.6.2 Summary of Baseline Dermatological Assessment (Per-Protocol Population)

T16.1.9.7.1 Summary of Frequency of Investigator Global Assessment (IGA) (Intent-to-Treat Population)

Visit	Score	Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx
1	0 (Clear)	xx (xx.x%)	xx (xx.x%)
	1 (Minimal)	xx (xx.x%)	xx (xx.x%)
	2 (Mild)	xx (xx.x%)	xx (xx.x%)
	3 (Moderate)	xx (xx.x%)	xx (xx.x%)
	4 (Severe)	xx (xx.x%)	xx (xx.x%)
2	0 (Clear)	xx (xx.x%)	xx (xx.x%)
	1 (Minimal)	xx (xx.x%)	xx (xx.x%)
	2 (Mild)	xx (xx.x%)	xx (xx.x%)
	3 (Moderate)	xx (xx.x%)	xx (xx.x%)
	4 (Severe)	xx (xx.x%)	xx (xx.x%)
3			
4			

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T16.1.9.7.2 Summary of Frequency of Investigator Global Assessment (IGA) (Per-Protocol Population)

Visit	Score	Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx
1	0 (Clear)	xx (xx.x%)	xx (xx.x%)
	1 (Minimal)	xx (xx.x%)	xx (xx.x%)
	2 (Mild)	xx (xx.x%)	xx (xx.x%)
	3 (Moderate)	xx (xx.x%)	xx (xx.x%)
	4 (Severe)	xx (xx.x%)	xx (xx.x%)
2	0 (Clear)	xx (xx.x%)	xx (xx.x%)
	1 (Minimal)	xx (xx.x%)	xx (xx.x%)
	2 (Mild)	xx (xx.x%)	xx (xx.x%)
	3 (Moderate)	xx (xx.x%)	xx (xx.x%)
	4 (Severe)	xx (xx.x%)	xx (xx.x%)
3			
4			

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T16.1.9.8.1 Summary of Superiority Analysis Results of Co-Primary Efficacy Endpoint (Proportion of Patients in each Treatment that Have Clinical Success based on IGA at Day 28±2) (Intent-to-Treat Population)

Treatment Group	Number of Patients (N)	Number of Patients with Clinical Success (n)	Proportion of Patients with Clinical Success (%)	Treatment vs. Placebo	
				Difference	P-value
Placebo	xxx	xxx	xx.x%		
Test	xxx	xxx	xx.x%	xx.x%	x.xxxx

Superiority of Test over Placebo was tested at the 5% significance level ($p < 0.05$; using two-sided Z-test) in the ITT population using last observation carried forward (LOCF).

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T16.1.9.8.2 Sensitivity Testing: Summary of Superiority Analysis Results of Co-Primary Efficacy Endpoint (Proportion of Patients in each Treatment that Have Clinical Success based on IGA at Day 28±2) (Per-Protocol Population)

T16.1.9.9.1 Summary of Frequency of Total Lesion Severity Score (TLSS)
(Intent-to-Treat Population)

Signs and Symptoms	Visit	Score	Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx
TLSS	1	0 (Clear)	xx (xx.x%)	xx (xx.x%)
		1 (Almost Clear)	xx (xx.x%)	xx (xx.x%)
		2 (Mild)	xx (xx.x%)	xx (xx.x%)
		3 (Moderate)	xx (xx.x%)	xx (xx.x%)
		4 (Severe)	xx (xx.x%)	xx (xx.x%)
		5 (Very Severe)	xx (xx.x%)	xx (xx.x%)
	2	0 (Clear)	xx (xx.x%)	xx (xx.x%)
		1 (Minimal)	xx (xx.x%)	xx (xx.x%)
		2 (Mild)	xx (xx.x%)	xx (xx.x%)
		3 (Moderate)	xx (xx.x%)	xx (xx.x%)
		4 (Severe)	xx (xx.x%)	xx (xx.x%)
		5 (Very Severe)	xx (xx.x%)	xx (xx.x%)
	3			
	4			
Scaling				
Erythema				
Plaque Elevation				

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T16.1.9.9.2 Summary of Frequency of Total Lesion Severity Score (TLSS)
(Per-Protocol Population)

T16.1.9.10.1 Summary of Superiority Analysis Results of Co-Primary Efficacy Endpoint (Proportion of Patients in each Treatment that Have Treatment Success based on TLSS at Day 28±2) (Intent-to-Treat Population)

Treatment Group	Number of Patients (N)	Number of Patients with Treatment Success (n)	Proportion of Patients with Treatment Success (%)	Treatment vs. Placebo	
				Difference	P-value
Placebo	xxx	xxx	xx.x%		
Test	xxx	xxx	xx.x%	xx.x%	x.xxxx

Superiority of Test over Placebo was tested at the 5% significance level ($p < 0.05$; using two-sided Z-test) in the ITT population using last observation carried forward (LOCF).

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T16.1.9.10.2 Sensitivity Testing: Summary of Superiority Analysis Results of Co-Primary Efficacy Endpoint (Proportion of Patients in each Treatment that Have Treatment Success based on TLSS at Day 28±2) (Per-Protocol Population)

T16.1.9.11 Summary of Percent BSA Affected by Visit

(Intent-to-Treat Population)

Visit	Statistic	Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx
1 (Baseline)	n	xx	xx
	Mean ± SD	xxx.x ± xx.x	xxx.x ± xx.x
	Median	xxx.x	xxx.x
	Range	xxx - xxx	xxx – xxx
2			
3			
4			
Change from Baseline to Day 28 ± 2			

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T16.1.9.12 Summary of ANCOVA Analysis Results of Secondary Efficacy Endpoint (Change from Baseline in %BSA Affected at Day 28 ± 2) (Intent-to-Treat Population)

				Treatment vs. Placebo			
Treatment Group	Number of Patients (N)	LSMean	Std Err LSMean	LSMean Difference	Std Err Difference	95% CI	P-value
Placebo	xxx	xxx.xx	xxx.xx				
Test	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Analysis of Covariance (ANCOVA) with treatment and site as fixed effects and baseline %BSA as a covariate in the model was used for superiority testing at the 5% significance level in the ITT population using LOCF.

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T16.1.9.13 Overall Summary of Adverse Events

Description	Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx	Total N=xx
Patients Randomized	xxx	xxx	xxx
Patients with at least one AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Discontinued study drug due to above AEs	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
AEs reported	xxx	xxx	xxx
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Serious AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Related includes "Possible", "Probable", or "Definite" related.

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T16.1.9.14 Summary of Frequency of All Adverse Events by Body System (Safety Population)

		Test: Desoximetasone Topical spray, 0.15% (N = xxx)		Placebo: Vehicle spray (N = xxx)		
Body System	**MedDRA Term**	**Events**	**Patients**	**Events**	**Patients**	**Fisher's p-value**
Patients with at least one AE	Total	xx	xx (xx.x%)	xx	xx (xx.x%)	x.xxxx
Ear and labyrinth disorders	Ear pain	xx	xx (xx.x%)	xx	xx (xx.x%)	x.xxxx
	etc.					
etc.						

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T16.1.9.15 Summary of Frequency of All Adverse Events by Relationship (Safety Population)

		Test: Desoximetasone Topical spray, 0.15% # of Events (N = xxx)		Placebo: Vehicle spray # of Events (N = xxx)	
Body System	**MedDRA Term**	**Related**	**Not Related**	**Related**	**Not Related**
Total AEs	Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ear and labyrinth disorders	Ear pain	xx	xx	xx	xx
	Hypoacusis	xx	xx	xx	xx

N = Total number of events in each treatment group; Percentage is based on total number of events.
Related includes "Possible", "Probable", or "Definite" related.

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T16.1.9.16 Summary of Frequency of All Adverse Events by Severity (Safety Population)

		Test: Desoximetasone Topical spray, 0.15% # of Events (N = xxx)			Placebo: Vehicle spray # of Events (N = xxx)		
Body System	**MedDRA Term**	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**
Total AEs	Total	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ear and labyrinth disorders	Ear pain	xx	xx	xx	xx	xx	xx
	Hypoacusis	xx	xx	xx	xx	xx	xx

N = Total number of events in each treatment group; Percentage is based on total number of events.

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T16.1.9.17 Summary of Frequency of Serious Adverse Events
(Safety Population)

Body System	MedDRA Term	Test: Desoximetasone Topical spray, 0.15% # Events	Placebo: Vehicle spray # Events
Injury, poisoning and procedural complications	Alcohol poisoning	xx	xx

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T16.1.9.18 Summary of Adverse Events by Treatment
(Safety Population)
Test: Desoximetasone Topical spray, 0.15%

	Severity			Relationship to Study Drug	
Body System MedDRA Term	Mild n (%)	Moderate n (%)	Severe n (%)	Related n (%)	Not Related n (%)
Total AEs (N=xxx)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ear and labyrinth disorders	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ear pain	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Hypoacusis	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

N = Total AEs in Test Group; n (%) = Number of AEs (Percent of Total AEs in Test Group)
Related includes "Possible", "Probable", or "Definite" related.

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Programming Note: Similar tables will be created for Placebo groups.

T16.1.9.19 Summary of Vital Signs

Vital Signs	Visit	Statistic	Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx
Systolic Blood Pressure (mmHg)	1	n	xx	xx
		Mean ± SD	xxx.x ± xx.x	xxx.x ± xx.x
		Median	xxx.x	xxx.x
		Range	xxx - xxx	xxx – xxx
	2			
	3			
	4			
Diastolic Blood Pressure (mmHg)				
Heart Rate (bpm)				
Respiration Rate (rpm)				
Temperature (F)				

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T16.1.9.20 Summary of Frequency of Application Site Reaction (Safety Population)

Signs and Symptoms	Visit	Statistic	Test: Desoximetasone Topical spray, 0.15% N=xx	Placebo: Vehicle spray N=xx
Burning	1	Absent	xxx (xx.x%)	xxx (xx.x%)
		Mild	xxx (xx.x%)	xxx (xx.x%)
		Moderate	xxx (xx.x%)	xxx (xx.x%)
		Severe	xxx (xx.x%)	xxx (xx.x%)
	2			
	3			
	4			
Dryness				
Edema				
Erosion				
Itching				
Pain				

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L16.2.1 Listing of Discontinued Patients

Treatment	Patient Randomization Number	Discontinuation Reason	Population
Test	xx-xxxx	Withdrawal by Subject	Per-Protocol
	xx-xxxx	Lost to Follow-up	Safety
Placebo			

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L16.2.2 Listing of Protocol Deviations

Treatment Group	Patient Randomization Number	Event Description	Population
Test	xx-xxxx	Outside Visit Window (Visit 3)	Safety
Placebo			

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L16.2.3 Patients Excluded from the Per-Protocol Population

Treatment Group	Patient Randomization Number	Exclusion Reason
Test	xx-xxxx	Major protocol deviation
Placebo		

L16.2.4.1 Listing of Demographic Data

Treatment Group	Patient Randomization Number	Age	Gender	Ethnicity	Race
Test	xx-xxxx	30	Female	Not Hispanic or Latino	Black or African American
Placebo					

L16.2.4.2 Listing of Medical History

Treatment Group	Patient Randomization Number	System	Diagnosis or Surgical Procedure	Start Date	End Date	Ongoing
Test	xx-xxxx	Gynecologic	Menopause	yyyy-mm-dd	yyyy-mm-dd	
Placebo						

L16.2.4.3 Listing of Concomitant Medication

Treatment Group	Patient Randomization Number	Treatment Area	Medication	Dosage	Frequency	Route	Start/End Date	Indication
Test	xx-xxxx	No	Lisinopril	20 MG	QD	PO	yyyy-mm-dd / yyyy-mm-dd	Hypertension
Placebo								

L16.2.5.1 Listing of Visit Date Information

Treatment Group	Patient Randomization Number	Informed Consent Signed	Visit 1	Visit 2	Visit 3	Visit 4 / Early Termination	Visit 5 Follow-up
Test	xxxx	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd
Placebo							

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L16.2.5.2 Listing of Drug Administration

Treatment Group	Patient Randomization Number	Date of First Dose	Date of Last Dose	Total Intended	Total Doses Applied	Compliance (%)
Test	xxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx	xx.x
Placebo						

Note to programmer:
Compliance = [Actual number of applications] / [Planned number of applications] * 100%, where:

Planned number of applications is determined as follows:
for patients who completed the study successfully: 56 applications (28 days of twice daily dosing);
for patients who discontinued early: the minimum between 56 and [(Date of Discontinuation – Date of First Application +1)*2].

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L16.2.5.3 Listing of Study Medication Weight

Treatment Group	Patient Randomization Number	Bottle	Date Dispensed	Weight Dispensed (g)	Date Collected	Weight Collected (g)
Test	xxxx	Bottle 1	yyyy-mm-dd	xx	yyyy-mm-dd	xx
		Bottle 2	yyyy-mm-dd	xx	yyyy-mm-dd	xx
Placebo						

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L16.2.6.1 Listing of Investigator Global Assessment (IGA)

Treatment Group	Patient Randomization Number	IGA*				Clinical Success
		Visit 1	Visit 2	Visit 3	Visit 4 / Early Termination	
Test	xx-xxxx	3	3	2	0	Success
	xx-xxxx	3	3	2	2	Failure
Placebo						

*IGA: 0 = Clear; 1 = Minimal; 2 = Mild; 3 = Moderate; 4 = Severe;

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L16.2.6.2 Listing of Total Lesion Severity Score (TLSS)

Treatment Group	Patient Randomization Number	Visit	Scaling*	Erythema*	Plaque Elevation*	TLSS**	Treatment Success
Test	xxxx	1	0	1	3	4	
		2	0	1	3	4	
		3	0	1	3	4	
		4	0	1	1	2	Success
Placebo							

*Scaling and Erythema: 0 = Clear; 1 = Almost Clear; 2 = Mild; 3 = Moderate; 4 = Severe; 5 = Very Severe
** TLSS = Scaling + Erythema + Plaque elevation

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L16.2.6.3 Listing of Psoriasis Area Severity Index (PASI), Target Lesion size and BSA Affected

Treatment Group	Patient Randomization Number	Visit	PASI	% BSA Affected with Plaque Psoriasis	Target Lesion Size (cm^2)	Total Baseline BSA (m^2)
Test	xxxx	1	xxx	xxx%	xxx.x	x.xxx
		2	xxx	xxx%		
		3	xxx	xxx%		
		4	xxx	xxx%		
Placebo						

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L16.2.6.4 Listing of Investigator Evaluator Initials

Treatment Group	Patient Randomization Number	Visit	IGA	PASI	TLSS	Application Site Reactions
Test	xxxx	1	ABC	XYZ	D-G	D-G
		2				
		3				
		4				
Placebo						

L16.2.7.1 Listing of Adverse Events by Treatment

Treatment Group	Patient Randomization Number	Body System / MedDRA Term / AE Term	Treatment Area	Start /End Date	Severity	Relationship to Study Drug	Outcome	Action Taken	Other Action Taken	SAE?
Test	xx-xxxx	Nervous system disorders / Headache / Headache	No	yyyy-mm-dd / yyyy-mm-dd	Mild	Possible	Recovered	Dose Not Changed	None	No
Placebo										

L16.2.7.2 Listing of Application Site Reaction

Treatment Group	Patient Randomization Number	Visit	Signs and Symptoms*					
			Burning	Erosion	Edema	Pain	Itching	Dryness
Test	xxxx	1	0	0	0	1	0	0
		2	0	1	0	0	0	0
		3	0	0	0	1	0	0
		4	0	0	0	1	0	2
Reference Placebo								

*Signs and symptoms: 0 = Absent; 1 = Mild; 2 = Moderate; 3 = Severe

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L16.2.8.1 Listing of Pregnancy Test Results

Treatment Group	Patient Randomization Number	Visit	Result
Test	xx-xxxx	1	Negative
		4	Negative
Placebo			

L16.2.8.2 Listing of Vital Signs

Treatment Group	Patient Randomization Number	Visit	Systolic BP (mmHg)	Diastolic BP (mmHg)	Heart Rate (bpm)	Respiration Rate (rpm)	Temperature (F)	Height (cm)	Weight (kg)
Test	xx-xxxx	1	120	70	84	18	98.6	xxx	xxx.x
		2	140	80	74	18	97.0		
		3							
		4							
Placebo									

10. APPENDICES

Appendix A: Total Body Surface Area Calculation

To calculate the Total BSA the following procedure (Mosteller Formula)[21] should be followed.

Total Body Surface Area (BSA) in meters squared

m^2 = ((height (cm) x weight (kg)) /3600)^{½}

Patient's height and weight should preferably be measured in cm and kg however if needed:
To convert inches (in) to centimeters (cm) the following conversion should be used
1 inch = 2.54 cm

To convert pounds (lbs) to kilograms (kg) the following conversion should be used.
1 lb = 0.45 kg

The patient's height and weight should be reported to the nearest cm and nearest 0.5 kg. The BSA should be reported to the nearest second decimal place.

For example a patient who is 68 inches tall and weighs 180 lbs will have a reported BSA of:

68 in x 2.54 = 173 cm
180 lb x 0.45 = 81.0 kg

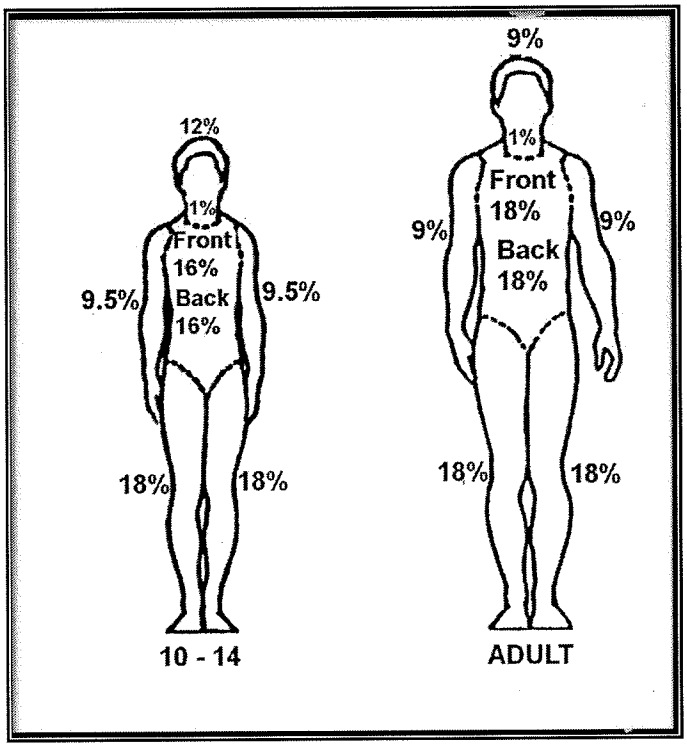
BSA = SQRT ((173 x 81.0)/3600)
= 1.97 m^2

%BSA Affected

To calculate the %Body Surface Area Affected the "Rule of Nine" will be used.

Body Surface Area affected will be calculated using the standard medical procedure of the "Rule of Nines". The patient's palm surface of the hand represents approximately one percent of his/her body surface area. [5] Calculate to the nearest whole percentage.

Part	10-14 year child body % of total	Adult body % of total
Arm	9.5%	9%
Head	12%	9%
Neck	1%	1%
Leg	18%	18%
Anterior trunk	16%	18%
Posterior trunk	16%	18%



To be eligible for inclusion in the study a patient must have a % BSA affected of 5-10%

Appendix B: Total Lesion Severity Score (TLSS)

Score	Grade	Erythema	Scaling	Plaque Elevation
0	Clear	No evidence of erythema	No evidence of scaling	No evidence of plaques above normal skin level
1	Almost Clear	Pink discoloration, minimal erythema	Occassional fine scales hardly noticeable	Slight, just discernable elevation above normal skin level
2	Mild	Light red coloration	Slight but definite roughness, fine scale present, no cracking	Discernable elevation above normal skin level upon examination, but not pronounced
3	Moderate	Moderate redness, but not dark	Moderate roughness, somewhat coarse scaling	Definite plaque formation with rounded/sloped edges to plaque
4	Severe	Dark red coloration	Marked roughness, coarse/thick scaling, cracking may be evident	Marked elevation with hard, distinct edges to plaque
5	Very Severe	Very dark red coloration with induration present	Very thick scales covering extensive area, severe cracking/fissures may be evident	Very marked elevation, very hard and sharp edges to plaque

To be considered for inclusion in the study, the Target Lesion must have a minimum plaque elevation score of ≥ 2.

Appendix C: Investigator's Global Assessment (IGA)

To be eligible for inclusion in the study the IGA must be 2 - 3 at baseline.

Score	Category	Description
0	Clear	Plaque: elevation: no evidence of plaque elevation above normal skin level. Scaling: no evidence of scaling Erythema: no redness
1	Minimal	Plaque elevation: very slight elevation above normal skin level, easier felt than seen Scaling : limited amount of very fine scales partially covers some of the plaques Erythema: very few of the plaques are light red
2	Mild	Plaque elevation: slight but definite elevation above the normal skin level, typically with edges that are indistinct or sloped on some of the plaques. Scaling: mainly fine scales, some plaques are partially covered. Erythema: some plaques are light red
3	Moderate	Plaque elevation: moderate elevation with rounded or sloped edges on most of the plaques Scaling: somewhat coarser scales; most plaques are partially covered. Erythema: most plaques are red
4	Severe	Plaque elevation: marked to very marked elevation, with hard to very hard sharp edges on virtually all or all of the plaques. Scaling: coarse, thick scales; virtually all or all plaques are covered; rough surface. Erythema : virtually all or all plaques are bright to dusky red.

Appendix D: Psoriasis Area Severity Index (PASI)

The PASI is a composite score based on the severity of four different signs of atopic dermatitis in four different areas of the body multiplied by the percent of that specific body area affected multiplied by a weighting factor.

Erythema, Induration, Scaling will be evaluated using the severity scale below:
0 = Clear
1 = Mild
2 = Moderate
3 = Severe
4 = Very Severe

PASI Score
The PASI score is calculated as follows:
Head/neck (E + I + S) x Area x 0.1
Upper Limbs (E + I + S) x Area x 0.2
Trunk (E + I + S) x Area x 0.3
Lower Limbs (E + I + S) x Area x 0.4
PASI SCORE = SUM OF ABOVE 4 REGIONS

E: Erythema,
I: Induration
S: Scaling

Severity is based on the Investigator's assessment of individual signs and symptoms
0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe using the definitions above

The % of each body region affected is scored as the variable Area above in the PASI formula. For the 4 body regions (head/neck, upper limbs, trunk and lower limbs) if the:

Area = 0 if % affected is 0%
Area = 1 if % affected is 1 to 9%
Area = 2 if % affected is 10 to 29%
Area = 3 if % affected is 30 to 49%
Area = 4 if % affected is 50 to 69%
Area = 5 if % affected is 70 to 89%
Area = 6 if % affected is 90 to 100%

PASI Score can be presented to the nearest whole number (no decimals and all numbers should be rounded, 0.5 should be rounded up to the nearest whole number). The minimum score would be 0 and the Maximum Score would be 72.

Appendix E: Application Site Reactions

The following application site reactions will be evaluated at each visit based on the scale provided below:

Burning
Erosion
Edema
Pain
Itching
Dryness

Absent	0	
Mild	1	(slight, barely perceptible)
Moderate	2	(distinct presence)
Severe	3	(marked, intense)