STATISTICAL ANALYSIS PLAN

A Randomized, Double-Blind, Vehicle-Controlled, Parallel-Design, Multiple-Site, Phase III Clinical Study to Evaluate the Efficacy and Safety of Desoximetasone 0.25% Shampoo in Patients with Mild to Severe Scalp Psoriasis

Protocol Number: DSXS 1536
Novum Study Number: 71515013

Sponsor:
Taro Pharmaceuticals U.S.A., Inc.
3 Skyline Drive,
Hawthorne, NY 10532
USA

Contract Research Organization:
Novum Pharmaceutical Research Services
225 W. Station Square Drive, Suite 200
Pittsburgh, PA 15219

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Final Version 1.0

NOVUM PHARMACEUTICAL RESEARCH SERVICES
STATISTICAL ANALYSIS PLAN

Desoximetasone 0.25% Shampoo **Protocol / Study No. DSXS 1536 / 71515013**

SAP FINAL VERSION APPROVALS

A Randomized, Double-Blind, Vehicle-Controlled, Parallel-Design, Multiple-Site, Phase III Clinical Study to Evaluate the Efficacy and Safety of Desoximetasone 0.25% Shampoo in Patients with Mild to Severe Scalp Psoriasis

Written By: Signature: _____ Jianhua Liu, MSc Senior Biostatistician Novum Pharmaceutical Research Services	Date: 10/13/2016
Reviewed By: Signature: _____ Pina D'Angelo, MSc Senior Director, Scientific Affairs (Biostatistics) Novum Pharmaceutical Research Services	Date: Oct 13, 2016
Approved By: Signature: _____ Natalie Yantovskiy Senior Director, Clinical Research Taro Pharmaceuticals U.S.A., Inc.	Date: 12 October 2016

Desoximetasone 0.25% Shampoo **Protocol / Study No. DSXS 1536 / 71515013**

Revision History

VERSION	DATE	DESCRIPTION OF REVISIONS	REVISED BY
Draft 1.0	October 03, 2016	New Document	Jianhua Liu
Final 1.0	October 11, 2016	Incorporate client comments and finalize SAP	Jianhua Liu

List of Abbreviations and Definition of Terms

ADaM	Analysis Data Model
AE	Adverse Event
BP	Blood Pressure
C	Celsius
CRF	Case Report Form
CDISC	Clinical Data Interchange Standards Consortium
CRO	Contract Research Organization
F	Fahrenheit
FDA	Food and Drug Administration
HEENT	Head, Eyes, Ears, Nose, Throat
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
OGD	The Office of Generic Drugs
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SDTM	Study Data Tabulation Model
USA	United States of America

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1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the final Clinical Study Protocol DSXS 1536 (Novum Study No. 71515013) Rev. 2 dated 05/31/2016. 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 1536 (Novum Study No. 71515013) Rev. 2 dated 05/31/2016
- Case Report Form Booklet Version 1.0 for Novum Study No. 71515013 dated 03/03/2016

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

The objective of this study is to evaluate the therapeutic efficacy and safety of desoximetasone 0.25% shampoo (Taro Pharmaceuticals, U.S.A., Inc.) compared to a Vehicle shampoo (Taro Pharmaceuticals, U.S.A., Inc.) in patients with mild to severe scalp psoriasis.

3. OVERALL STUDY DESIGN

This randomized, double-blind, vehicle-controlled, parallel-group multiple-site study is designed to evaluate the therapeutic efficacy and safety of the investigational product, desoximetasone 0.25% shampoo (Taro Pharmaceuticals, U.S.A.), for the treatment of mild to severe scalp psoriasis.

Up to 370 eligible patients with scalp psoriasis that satisfy all eligibility criteria will be enrolled into the study at Visit 1. Patients must be at least 18 years of age, in overall good health. They should have a current diagnosis of mild to severe scalp psoriasis with IGA score of at least 2.

Patients who meet all inclusion/exclusion criteria will be randomized in a 1:1 ratio (Test: Vehicle) at Visit 1. At least 185 qualified patients will receive Test product and 185 patients will receive Vehicle product. The product will be left in place on the scalp for 15 minutes.

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

The study products are:

- **Test**: Desoximetasone 0.25% Shampoo (Taro)
- **Vehicle**: Test Vehicle Shampoo (Taro)

Patients in each randomized treatment group will apply product once daily, according to provided instructions, for a total of 28 days starting on Day 1.

During the study patients will visit the clinical center for a total of 3 scheduled visits:

- **Visit 1 (Day -1 to 1)**: Randomization
- **Visit 2 (Day 14 ± 2):** Interim Visit
- **Visit 3 (Day 29 ± 2):** End of Study or Early Termination

The primary efficacy endpoint is the proportion of patients in each treatment group who are considered a Clinical Success, as defined by an IGA score of 0 (clear) or 1 (almost clear) with at least a 2-grade improvement from baseline IGA at Day 29 ± 2. That is, at Day 29 ± 2, patients with an IGA score of 3 or 4 at baseline must achieve a score of 0 or 1, patients with an IGA score of 2 at baseline must achieve a score of 0 to be considered a Clinical Success. The 5-point IGA score represents an overall severity of scalp psoriasis based on plaque elevation, scaling and erythema. Severity represented by a score of 0-4 is categorized as 'clear', 'minimal', 'mild', 'moderate' or 'severe'. Refer to Appendix A for IGA scoring.

The safety profile of each treatment group will be evaluated by comparing adverse events, dermal and ocular discomfort and vital signs obtained through the study duration.

Figure 1 Study Schematic

	Visit 1	Visit 2	Visit 3
Day	**-1 to 1**	**14 ± 2**	**29 ± 2**
Procedures	Baseline/Randomization†	Interim Visit	End of Study
Informed Consent	X		
Medical History and Baseline Demographics	X		
Inclusion/Exclusion	X		
Physical Examination	X		X
HEENT Examination	X	X	X
Vital Signs	X	X	X
Pregnancy Test*	X	X	X
Percent Scalp Affected	X	X	X
Investigator's Global Assessment	X	X	X
Skin Assessment	X	X	X
Ocular Discomfort Assessment		X	X
Concomitant Medications	X	X	X
Weigh and Dispense Study Product	X	X	
Collect and Weigh Study Product		X	X
Review/Provide Patient Diary	X	X	X
Adverse Events		X	X

* Pregnancy test will be conducted for females of childbearing potential.

† Patients should administer study product once daily for 28 days starting on Day 1 through Day 28. The product will be left in place on the scalp for 15 minutes.

4. RANDOMIZATION AND BLINDING

At Visit 1 eligible patients will be randomized to the study and assigned a randomization number. Patient numbers will consist of a 2-digit site number and 4-digit randomization number. The 4-digit randomization numbers will be assigned in ascending order beginning with the lowest number at each study site.

The study product will be packaged and blinded by an independent clinical packaging company. The randomization will be generated in blocks of 4 to accommodate the 1:1 randomization scheme (2 Test:2 Vehicle).

Each eligible patient will receive 2 x 120 ml bottles of study product (Test or Vehicle). Patients will be randomized to a treatment group in a blinded fashion by assigning randomization numbers in ascending sequential order starting with the lowest available randomization number at each site. All patients randomized will be identified by initials, date of birth, and a unique six-digit patient number. A perforated two-part label will be attached to each of the small sized boxes of study product supplies. Both pieces of the label will include the following information: Protocol number, randomization number, dosing instructions, space for patient's initials, statement that the study product is for investigational use only, space for dispensing date and the Sponsor's name. One part of the label shall remain attached to the box. The other part will be removed prior to dispensing and attached to the patient source documents. In addition all patients will be provided with written instructions on how to use the study product. Prior to dispensing, study product will be weighed.

At the end of the study, after all the clinical data has 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 statistical analysis of interest is a comparison of clinical success, as defined by an IGA score of 0 (clear) or 1 (almost clear) with at least 2 grades reduction from baseline at Day 29 ± 2, of the Test treatment, desoximetasone 0.25% shampoo, to the clinical success of the respective Vehicle shampoo in the ITT population. Based on results from Taro's Phase II study 71342608, the clinical success of the Test formulation is expected to be approximately 27% for an application duration of 15 minutes. The clinical success of the Vehicle formulation is expected to be approximately 10% for the same application duration. Based on a two-sided, Yates' continuity-corrected Z-test and a pooled response rate for the standard error of the difference in proportions, 166 patients in the active group and 166 patients in the placebo group of the ITT population will provide at least 97% power to demonstrate superiority at the 5% significance level ($p < 0.05$) for the active treatment over placebo. To allow for about 10% of patients who may drop out from the study or are otherwise non-evaluable, up to 370 patients may be enrolled (185 in the active group and 185 in the placebo group).

6. STUDY ENDPOINTS

The primary efficacy endpoint is the proportion of patients in each treatment group who are considered a Clinical Success at Day 29 ± 2, as defined by an IGA score of 0 (clear) or 1 (almost clear) with at least a 2 grades reduction from baseline at Day 29 ± 2. That is, at Day 29 ± 2, patients with an IGA score of 3 or 4 at baseline must achieve a score of 0 or 1 and patients with an IGA score of 2 at baseline must achieve a score of 0 to be considered a Clinical Success.

7. STUDY POPULATIONS

Intent-to-Treat (ITT) Population

The ITT population will include:

- All randomized subjects.

Safety Population

- All patients who were randomized and applied 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 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)
- % Scalp affected
- Number of months and/or years patient has suffered from symptoms caused by scalp psoriasis

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 acute and chronic medical history and medical history relevant to their scalp psoriasis, as well as all medication use within the past 24 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 and 3.

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

8.2 Efficacy Analyses

8.2.1 Primary Analysis

Superiority of the Test shampoo over the Vehicle shampoo at Day 29 ± 2 will be tested using a two-sided Cochran-Mantel-Haenszel (CMH) test, stratified by clinical site, at the 5% significance level. The primary analysis will be performed using Last Observation Carried Forward (LOCF) approach.

Patients discontinued because of lack of treatment effect will be included in the primary analysis as treatment failures.

8.2.2 Sensitivity Analyses

The following two sensitivity analyses will also be performed on the primary efficacy endpoint:

1. Primary analysis will be performed also including patients without an assessment at Day 29 ± 2. Patients with missing data at Day 29 ± 2 will be considered clinical failures.
2. Primary analysis will be performed also including patients without an assessment at Day 29 ± 2. Patients from the Vehicle group with missing data at Day 29 ± 2 will be treated as clinical successes and patients from the Test group with missing data at Day 29 ± 2 will be treated as clinical failures.

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 18.1 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. Other summaries may be added based on the obtained data.

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 (pulse rate, blood pressure, temperature and respiration rate) at Visit 1, 2 and 3.

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 Skin Safety Assessments

As a part of safety evaluation at each clinic visit, the Investigator/designated clinician will conduct an careful assessment of the scalp and adjacent skin (e.g., ears, forehead and neck) for local tolerability and a score will be documented (refer to Appendix B).

A summary table of the number and percent of patients with different dermal response score will be presented by visit and treatment group.

All data will be listed by patient and visit.

8.3.4 Ocular Discomfort Assessment

Ocular discomfort will be assessed by subjects and reported to clinic staff during scheduled visits (refer to Appendix C). If the shampoo comes into contact with the patient's eyes, the patient will be asked to report the contact at each visit.

Ocular safety evaluations will be assessed at the discretion of the Investigator based on the findings of the HEENT exam performed at each visit along with the ocular discomfort reported by the patient. Medical records associated with the ocular safety evaluation should be obtained for the study chart.

Ocular discomfort assessment will be listed by patient and visit.

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.

The primary analysis will be performed using Last Observation Carried Forward (LOCF) approach.

Patients discontinued because of lack of treatment effect will be included in the primary analysis as treatment failures.

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 Patient Disposition

Patients	Test Desoximetasone 0.25% Shampoo	Vehicle Test Vehicle Shampoo	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
Lack of Efficacy	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 0.25% Shampoo	Vehicle Test Vehicle Shampoo	Total
Total Patients with Protocol Deviations	xxx	xxx	xxx
Total Deviations	xxx	xxx	xxx
Dosed more than twice on any particular day	xxx	xxx	xxx
Failure to meet randomization criteria	xxx	xxx	xxx
Lost to Follow-up	xxx	xxx	xxx
Missed Visit	xxx	xxx	xxx
Missed 4 or more consecutive doses	xxx	xxx	xxx
Non-compliance with study drug	xxx	xxx	xxx
Outside Visit Window	xxx	xxx	xxx
Restricted Medication Use	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 0.25% Shampoo	Vehicle Test Vehicle Shampoo	Total
Randomized / ITT Population	xxx	xxx	xxx
Safety Population	xxx	xxx	xxx
Excluded from Safety population	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	ITT			Safety		
			Test Desoximetasone 0.25% Shampoo	Vehicle Test Vehicle Shampoo	Total	Test Desoximetasone 0.25% Shampoo	Vehicle Test Vehicle Shampoo	Total
xx	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xx	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

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T16.1.9.4 Summary of Demographic Data
(Safety Population)

		Test Desoximetasone 0.25% Shampoo N=xx	Vehicle Test Vehicle Shampoo 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	
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 Summary of Demographic Data (continued) (Safety Population)

		Test Desoximetasone 0.25% Shampoo N=xx	Vehicle Test Vehicle Shampoo N=xx	Total N=xx	P-value
Percent Scalp Affected	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	
Number of months and/or years patient has suffered from symptoms caused by scalp psoriasis	≤3 months	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	x.xxxx
	>3 months and ≤6 months	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	>6 months and ≤1 year	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	>1 year and ≤3 years	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	>3 years and ≤5 years	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	
	>5 years	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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Similar tables will be created for T16.1.9.5

T16.1.9.5 Summary of Demographic Data (Intent-to-Treat Population)

T16.1.9.6 Summary of Frequency of Investigator Global Assessment (IGA) (Intent-to-Treat Population)

Visit	Score	Test Desoximetasone 0.25% Shampoo N=xx	Vehicle Test Vehicle Shampoo N=xx
Visit 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%)
Visit 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%)
Visit 3/Early termination	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%)

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T16.1.9.7 Summary of Analysis Results of Proportion of Patients in each Treatment that Have Clinical Success at Visit 3 (Day 29±2) (Intent-to-Treat Population)

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

Superiority of Test over Placebo was tested using a two-sided Cochran-Mantel-Haenszel (CMH) test, stratified by clinical site, at the 5% significance level using last observation carried forward (LOCF).

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T16.1.9.8 Sensitivity Testing 1: Summary of Analysis Results of Proportion of Patients in each Treatment that Have Clinical Success at Visit 3 (Day 29±2) (Intent-to-Treat Population)

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

Superiority of Test over Placebo was tested using a two-sided Cochran-Mantel-Haenszel (CMH) test, stratified by clinical site, at the 5% significance level.
Patients with missing data at Day 29 ± 2 will be considered clinical failures.

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T16.1.9.9 Sensitivity Testing 2: Summary of Analysis Results of Proportion of Patients in each Treatment that Have Clinical Success at Visit 3 (Day 29±2) (Intent-to-Treat Population)

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

Superiority of Test over Placebo was tested using a two-sided Cochran-Mantel-Haenszel (CMH) test, stratified by clinical site, at the 5% significance level.
Patients from the Vehicle group with missing data at Day 29 ± 2 will be treated as clinical successes and patients from the Test group with missing data at Day 29 ± 2 will be treated as clinical failures.

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T16.1.9.10 Summary of Percent Scalp Affected with Scalp Psoriasis by Visit (Intent-to-Treat Population)

Visit	Statistic	Test Desoximetasone 0.25% Shampoo N=xx	Vehicle Test Vehicle Shampoo N=xx
Visit 1	n	xx	xx
	Mean ± SD	xxx.x ± xx.x	xxx.x ± xx.x
	Median	xxx.x	xxx.x
	Range	xxx - xxx	xxx – xxx
Visit 2	n	xx	xx
	Mean ± SD	xxx.x ± xx.x	xxx.x ± xx.x
	Median	xxx.x	xxx.x
	Range	xxx - xxx	xxx – xxx
Visit 3/Early termination	n	xx	xx
	Mean ± SD	xxx.x ± xx.x	xxx.x ± xx.x
	Median	xxx.x	xxx.x
	Range	xxx - xxx	xxx – xxx

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T16.1.9.11 Overall Summary of Adverse Events

Description	Test Desoximetasone 0.25% Shampoo N=xx	Vehicle Test Vehicle Shampoo 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 = "Possible", "Probable", or "Definite" related.

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T16.1.9.12 Summary of Frequency of All Adverse Events by Body System (Safety Population)

		Test Desoximetasone 0.25% Shampoo N=xx		Vehicle Test Vehicle Shampoo N=xx		
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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Repeat table T16.1.9.12 for frequency ≥ 2% in any treatment group

T16.1.9.13 Summary of Frequency of All Adverse Events by Body System with Frequency ≥ 2% in Any Treatment Group (Safety Population)

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

		Test Desoximetasone 0.25% Shampoo # of Events (N = xxx)		Vehicle Test Vehicle Shampoo # 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.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%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

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

		Test Desoximetasone 0.25% Shampoo # of Events (N = xxx)			Vehicle Test Vehicle Shampoo # 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.x%)	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%)	xx (xx.x%)

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

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T16.1.9.16 Summary of Frequency of Serious Adverse Events
(Safety Population)

Body System	MedDRA Term	Test Desoximetasone 0.25% Shampoo # Events	Vehicle Test Vehicle Shampoo # Events
Injury, poisoning and procedural complications	Alcohol poisoning	xx	xx

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T16.1.9.17 Summary of Vital Signs
(Safety Population)

Vital Signs	Visit	Statistic	Test Desoximetasone 0.25% Shampoo N=xx	Vehicle Test Vehicle Shampoo N=xx
Systolic Blood Pressure (mmHg)	Visit 1	n	xx	xx
		Mean ± SD	xxx.x ± xx.x	xxx.x ± xx.x
		Median	xxx.x	xxx.x
		Range	xxx - xxx	xxx – xxx
	Visit 2			
	Visit 3/Early termination			
Diastolic Blood Pressure (mmHg)				
Pulse rate (bpm)				
Respiration Rate (rpm)				
Temperature (F)				

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T16.1.9.18 Summary of Skin Irritation Assessment
(Safety Population)

Visit	Response Score	Test Desoximetasone 0.25% Shampoo N=xx	Vehicle Test Vehicle Shampoo N=xx
Visit 1	0 (N)	xxx (xx.x%)	xxx (xx.x%)
	1 (N)	xxx (xx.x%)	xxx (xx.x%)
	1 (A)	xxx (xx.x%)	xxx (xx.x%)
	etc	xxx (xx.x%)	xxx (xx.x%)
Visit 2			
Visit 3/Early termination			

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L16.2.1 Listing of Discontinued Patients

Treatment	Patient Randomization Number	Discontinuation Reason	Population
Desoximetasone 0.25% Shampoo	xx-xxxx	Withdrawal by Patient	Safety
	xx-xxxx	Lost to Follow-up	Safety
Test Vehicle Shampoo			

L16.2.2 Listing of Protocol Deviations

Treatment Group	Patient Randomization Number	Event Description	Population
Desoximetasone 0.25% Shampoo	xx-xxxx	Outside Visit Window (Visit 3)	Safety
Test Vehicle Shampoo			

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L16.2.3 Patients Excluded from the Analysis Population

Treatment Group	Patient Randomization Number	Included in Safety Population?	Reason. If Not Included in Safety Population	Included in ITT Population?	Reason. If Not Included in ITT Population
Desoximetasone 0.25% Shampoo	xx-xxxx	Yes	xxxxxxxxxxx	No	xxxxxxxxxxx
Test Vehicle Shampoo					

L16.2.4.1 Listing of Demographic Data

Treatment Group	Patient Randomization Number	Age	Gender	Ethnicity	Race
Desoximetasone 0.25% Shampoo	xx-xxxx	30	Female	Not Hispanic or Latino	Black or African American

Test Vehicle Shampoo

L16.2.4.2 Listing of Medical History

Treatment Group	Patient Randomization Number	System	Diagnosis or Surgical Procedure	Start Date	End Date	Ongoing
Desoximetasone 0.25% Shampoo	xx-xxxx	Gynecologic	Menopause	yyyy-mm-dd	yyyy-mm-dd	

Test Vehicle Shampoo

L16.2.4.3 Listing of Concomitant Medication

Test: Desoximetasone 0.25% Shampoo

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

Table will continue for vehicle group.

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L16.2.5.1 Listing of Drug Administration

Treatment Group	Patient Randomization Number	Date of First Dose	Date of Last Dose	Total Doses Applied	Compliance (%)
Desoximetasone 0.25% Shampoo	xxxx	yyyy-mm-dd	yyyy-mm-dd	xx	xx.x
Test Vehicle Shampoo					

Programming notes:

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: 28 applications (28 days of once daily dosing);
for patients who discontinued early: the minimum between 28 and (Date of Discontinuation – Date of First Application +1).

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L16.2.5.2 Listing of Study Medication Weight

Treatment Group	Patient Randomization Number	Bottle 1		Bottle 2		Total Dose Used (g)
		Weight Dispensed (g)	Weight Collected (g)	Weight Dispensed (g)	Weight Collected (g)	
Desoximetasone 0.25% Shampoo	xxxx	xx	xx	xx	xx	xx

Test Vehicle Shampoo

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L16.2.6.1 Listing of Investigator Global Assessment (IGA)

Treatment Group	Patient Randomization Number	Visit 1	Visit 2	Visit 3 / Early Termination	Clinical Success
Desoximetasone 0.25% Shampoo	xx-xxxx	Mild	Mild	Clear	Yes
	xx-xxxx	Clear	Mild	Mild	No

Test Vehicle Shampoo

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L16.2.6.2 Listing of Percent Scalp Affected with Scalp Psoriasis

Treatment Group	Patient Randomization Number	Visit	Percent Scalp Affected with Scalp Psoriasis	Number of Months or Years the Patient has Suffered from Symptoms of Scalp Psoriasis
Desoximetasone 0.25% Shampoo	xxxx	Visit 1	xxx%	x.xx
		Visit 2	xxx%	
		Visit 3/Early Termination	xxx%	
Test Vehicle Shampoo				

L16.2.7.1 Listing of Adverse Events by Treatment

Test: Desoximetasone 0.25% Shampoo

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?
xx-xxxx	Nervous system disorders / Headache / Headache	No	yyyy-mm-dd / yyyy-mm-dd	Mild	Possible	Recovered	Dose Not Changed	None	No

Table will continue for vehicle group.

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L16.2.7.2 Listing of Skin Irritation Assessment

Treatment Group	Patient Randomization Number	Visit	Dermal Response Score	Other Effects Score
Desoximetasone 0.25% Shampoo	xx-xxxx	Visit 1	1	N
		Visit 2	1	N
		Visit 3/Early Termination	1	N
Test Vehicle Shampoo				

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L16.2.7.3 Listing of Ocular Signs/Symptoms Assessment

Treatment Group	Patient Randomization Number	Visit	Did the patient experience any ocular discomfort?	Signs/ Symptoms	Did the shampoo come into contact with the patient's eye?	Overall Discomfort
Desoximetasone 0.25% Shampoo	xx-xxxx	Visit 2	Yes	Redness/Pain	Yes	Mild
		Visit 3/Early Termination	No		No	
Test Vehicle Shampoo						

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L16.2.7.4 Listing of Positive Pregnancy Test Results

Treatment Group	Patient Randomization Number	Visit	Results
Desoximetasone 0.25% Shampoo	xx-xxxx	Visit 3/Early Termination	Positive

Test Vehicle Shampoo

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L16.2.7.5 Listing of Abnormal Physical Examinations

Treatment Group	Patient Randomization Number	Visit	System	Result
Desoximetasone 0.25% Shampoo	xx-xxxx	Visit 1	xxxxxxx	Abnormal (xxxxx)

Test Vehicle Shampoo

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10. APPENDICES

Appendix A: Investigator's Global Assessment (IGA) of Disease Severity of Scalp Psoriasis

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 B: Skin Assessment (Forehead, Neck and Ears)

At each clinic visit, the Investigator will evaluate the scalp and the adjacent skin (head, neck and ears) for irritation using the following scale:

Dermal Response and Other Effects Scoring

Dermal Response

0 = no evidence of irritation

1 = minimal erythema, barely perceptible

2 = definite erythema, readily visible; minimal edema or minimal papular response

3 = erythema and papules

4 = definite edema

5 = erythema, edema, and papules

6 = vesicular eruption

7 = strong reaction spreading beyond the application site

Other Effects

N = No other observations (numerical score = 0)

A = Slightly glazed appearance (numerical score = 0)

B = Marked glazed appearance (numerical score = 1)

C = Glazing with peeling and cracking (numerical score = 2)

F = Glazing with fissures (numerical score = 3)

G = Film of dried serous exudates covering all or part of the application site (numerical score = 3)

H = Small petechial erosions and/or scabs (numerical score = 3)

Appendix C: Ocular Discomfort Assessment

At Visits 2 and 3 the patient will be asked to assess if any ocular discomfort was experienced, YES or NO, since the last clinic visit.

If YES is reported, the patient will be asked to report the signs and symptoms that apply from the list below or indicate any OTHER signs and symptoms experienced:

Redness	Stinging
Itching	Blur (decrease in vision)
Pain	Increased sensitivity
Swelling	Watery eyes
Burning	Spots, flashes and floaters
Eye Discharge	Foreign body sensation

In addition, the patient will be asked to indicate if the shampoo came into contact with their eye, YES or NO, since the last clinic visit. If YES is reported, the patient will be asked to rate the discomfort at the time of contact as None, Mild, Moderate or Severe.