COVER PAGE

STATISTICAL ANALYSIS PLAN

November 2, 2017

Final Version 1.0

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A Randomized, Double-Blind, Parallel-Design, Multiple-Site Study to Evaluate the Therapeutic Equivalence of Permethrin Cream, 5% (Encube Ethicals) Compared to Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.) in the Treatment of Scabies

Protocol Number: 71675502
Novum Study Number: 71675502

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SAP Final Version Approvals

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Revision History

VERSION	DATE	DESCRIPTION OF REVISIONS	REVISED BY
Draft 1.0	July 26, 2017	New Document	Jianhua Liu
Final 1.0	November 2, 2017	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
HR	Heart Rate
Hg	Mercury
HIV	Human Immunodeficiency Virus
ICF	Informed Consent Form
ICH	International Conference on Harmonization
IND	Investigational New Drug
IWRS	Interactive Web Response System
LOCF	Last Observation Carried Forward
MedDRA	Medical Dictionary for Regulatory Activities
mITT	Modified Intent-to-Treat
LOCF	Last Observation Carried Forward
OGD	The Office of Generic Drugs
PP	Per-Protocol
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SDTM	Study Data Tabulation Model
USA	United States of America

TABLE OF CONTENTS

1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the final Clinical Study Protocol 71675502 [Rev 1] dated 10/31/2017. 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 71675502 [Rev 1] dated 10/31/2017.
- Case Report Form Booklet Version 1.0 for Novum Study No. 71675502

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 objectives of this study are to:

1. Evaluate the therapeutic equivalence of the Test formulation, Permethrin Cream, 5% (Encube Ethicals) to the marketed product, Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.) in patients with scabies.
2. Compare the safety of Test and Reference treatments in patients with scabies.

3. OVERALL STUDY DESIGN

This randomized, double-blind, parallel-design, multiple-site study is designed to evaluate the therapeutic efficacy and safety of a generic Permethrin Cream, 5% (Encube Ethicals) compared to the FDA Reference Listed Drug (RLD), Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.) in patients with scabies.

Before any study-specific procedures are performed, all patients will read and sign the IRB-approved informed consent that meets all criteria of current FDA and International Conference of Harmonisation (ICH) regulations. For patients who are considered minors in the state the study is being conducted (< 18 years in most states) the parent or legal guardian should sign the consent form and the child will be required to sign a patient “assent” form, as appropriate. Patients 11-17 years of age will read and sign an IRB-approved assent form and patients 6-10

years of age will provide verbal assent. Patients 2-5 years of age will be exempt from providing assent based on the child's comprehension and cognitive skills.

Approximately 250 eligible patients, 2 years of age and older with a clinical diagnosis of active scabies based on signs and symptoms and confirmation of microscopic evidence of scabies mites in the skin will be randomized in a 1:1 ratio (Test: Reference) to one of the two study products as follows:

- Test: Permethrin Cream, 5%, (Encube Ethicals)
- Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

Patients will be instructed to self-administer a single dose of study product or, if patient is a child, then parent/guardian will apply study product to him/her on Day 1 according to the dosing instructions provided. A second application may be required if presence of scabies infestation is microscopically demonstrated (i.e., living mites, viable mite eggs, or mite fecal matter present) at Visit 2. The second dose will be self-administered by the patient or if patient is a child, then parent/guardian will apply study product to him/her at Visit 2. Eligible household members and close contacts of the patient will be offered permethrin cream (if they are in need of treatment) as a method to reduce cross-contamination within a household. Additionally, household members will be requested to follow the standard hygiene practices. Patients whose household members are not willing to comply with the standard of care for Scabies management (i.e., use of generic permethrin cream and standard hygiene practices) will not be enrolled in the study.

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

- Visit 1 (Day 1): Screening/Baseline
- Visit 2 (Day 14 ± 4): Interim Visit
- Visit 3 (Day 28 ± 4): End of Study or Early Termination

Final assessments will be carried out at Visit 3 (Day 28 ± 4), which is the test-of-cure visit. The test-of-cure visit will occur 4 weeks (± 4 days) after the end of the single application treatment on study Day 1 or 2 weeks (± 4 days) after the end of a second application, if necessary, on study Visit 2. Therapeutic cure of scabies will be evaluated based on microscopic evidence of absence of scabies infestation (i.e., no living mites, no viable mite eggs, and no mite fecal matter), visual evidence of absence of new lesions and healing of original lesions, regardless of the presence of post-scabetic nodules (i.e., post-scabetic nodules need not be considered as new lesions or persistence of old lesions). The primary statistical analysis of interest is the proportion of patients in each treatment group with therapeutic cure (parasitological cure plus clinical cure) of scabies.

Figure 1 Study Schematic

	Visit 1 Screening/Baseline (Day 1)	**Visit 2** Interim Visit (Day 14 ± 4)	**Visit 3** (Day 28 ± 4) End of Study or Early Termination
Informed Consent	X		
Medical history and Baseline Demographics	X		
Vital Signs	X		X
Adverse Events	X	X	X
Concomitant Medications	X	X	X
Microscopic Examination	X	X	X
Scabies Signs and Symptoms Rating (pruritus, lesion count)	X	X	X
Urine Pregnancy Test	X		X
Review Inclusion/Exclusion Criteria	X		
Collect and Review Diary		X	X
Provide Diary	X	X	
Dispense Study Product	X	X*	
Collect and Weigh Study Product		X	X*

*If retreatment is necessary, the originally dispensed (i.e., at Visit 1) study product will be dispensed at Visit 2 and collected at Visit 3.

4. RANDOMIZATION AND BLINDING

The study product will be randomized, packaged and blinded by an independent packaging company. Randomization will be pre-planned according to a computer-generated randomization schedule. All randomized study products will be blinded and packaged in sealed boxes. Each block will contain two patients' worth of product (1 Test and 1 Reference). Each patient kit will include 1 x 60 gram tube of study product, which should be sufficient for full treatment.

The randomization number will be a unique four-digit number. Patient numbers will be assigned immediately before dispensing of study product and in ascending sequential order, beginning with the lowest available number at the study site. Each patient kit and each dispensed study tube should include the four-digit patient number on the label.

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 schedule 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

For the primary endpoint analysis (proportion of patients in the PP population who are considered to be a Therapeutic Cure on Day 28 ± 4), sample size is estimated for therapeutic equivalence of the Test to the Reference product.

Based on data from a previous bioequivalence study conducted to support approval of the first generic product of permethrin cream, 5%, the therapeutic cure rate (p_R) of the Reference product (Elimite™ permethrin cream 5%) is expected to be about 88% in the PP population. Assuming that the Therapeutic Cure rate for the Test group (p_T) is an absolute difference of 5% lower than the Reference group (i.e., p_T-p_R = -5%), a sample size of 107 patients in each active group in PP population will provide at least 90% power to demonstrate therapeutic equivalence (i.e., the 90% confidence interval [Yates' continuity corrected] on p_T-p_R is within a defined equivalence range [-20%, +20%]).

To allow for approximately 14 % of patients who may drop out from the study or are otherwise non-evaluable, approximately 250 patients (125 in each treatment group) will be randomized, such that there will be an estimated 214 patients (107 per group) in the PP population for statistical evaluation of therapeutic equivalence.

6. STUDY ENDPOINT

The primary efficacy endpoint is the proportion of patients in each treatment group with Therapeutic Cure (parasitological cure plus clinical cure) of scabies at the test-of-cure visit

conducted at Day 28 ± 4. A parasitological cure is defined as failure to demonstrate microscopically the presence of scabies infestation (i.e., no living mites, no viable mite eggs, and no mite fecal matter present). A clinical cure is defined as visual evidence of absence of new lesions and healing of original lesions, regardless the presence of post-scabietic nodules (i.e., post-scabietic nodules need not be considered as new lesions or persistence of old lesions).

Patients who do not respond to the initial treatment and have new lesions or microscopic confirmation of mites, ova, or fecal matter on Day 14 ± 4 will be treated as treatment failure in the final analysis on Day 28.

7. STUDY POPULATIONS

Per-Protocol (PP) Population

The PP population will include:

- Met the inclusion/exclusion criteria as defined in this protocol at Visit 1.
- Did not take any prohibited medications throughout the study.
- Did not have any significant deviations from the protocol. Did not develop any concurrent dermatological condition or illness exhibiting symptoms similar to scabies, or symptoms that in the Investigator's opinion would interfere with endpoint assessments.
- Completed the last study visit (Visit 3) Day 28 ± 4.

Patients will be included in the PP population as treatment failures in the final analysis on Day 28 (provided they had no significant protocol deviations) if they 1) withdrew from the study because of lack of efficacy, 2) show therapeutic cure at Day 14 ± 4 but re-infestation at Day 28 ± 4, or 3) do not respond to the initial treatment and have new lesions or microscopic confirmation of mites, ova, or fecal matter on Day 14 ± 4.

Safety Population

The safety population will include all patients who are randomized who applied at least one dose of the assigned 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 percentage 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 PP and Safety populations.

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

- Age (years)
- Sex (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 severity score of nocturnal itching
- Severity of lesion count infestation pretreatment (mild, moderate, severe)

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 medical history, including acute and chronic medical history and medical history relevant to their scabies.

Medical history data will be listed by treatment and patient.

8.1.4 Concomitant Medications

All concomitant medication use within 6 months of Visit 1 and throughout the study will be recorded.

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 3.

Pregnancy test results will be listed by treatment and patient.

8.2 Efficacy Analyses

8.2.1 Primary Efficacy Analysis

Bioequivalence with Clinical Endpoints Analysis

The proportion of patients in each treatment group with Therapeutic Cure is the primary efficacy endpoint of the study.

The Per Protocol (PP) Population will be used for the analysis of equivalence.

Based on the usual method used in OGD for binary outcomes, the 90% confidence interval for the difference in success proportions between test and reference treatment should be contained within [-0.20, +0.20] (or [-20%, +20%] in percent) in order to establish equivalence.

The compound hypothesis to be tested is:

$H_0: \ P_T - P_R < -20\% \ or \ P_T - P_R > 20\%$ versus

$H_A: -20\% \leq P_T - P_R \leq 20\%$

where P_T = percent cure rate of test treatment
P_R = percent cure rate of reference treatment.

Let

n_T = sample size of test treatment group
cn_T= number of cured patients in test treatment group
n_R = sample size of reference treatment group
cn_R= number of cured patients in reference treatment group

$\hat{P}_T = cn_T/n_T \quad \hat{P}_R = cn_R/n_R,$ and

$$se = \left(\hat{P}_T\,(1-\hat{P}_T)/n_T + \left(\hat{P}_R\,(1-\hat{P}_R)/n_R\right)^{1/2}\right.$$

where $\hat{P}_T$= estimated cure rate (%) of test treatment
$\hat{P}_R$= estimated cure rate (%) of reference treatment.

The 90% confidence interval for the absolute difference between the proportions of patients in test and reference who are considered a therapeutic cure (primary) will be calculated as follows:

$$\mathrm{L} = \left(\hat{P}_T - \hat{P}_R\right) - 1.645\,se$$

$$\mathrm{U} = \left(\hat{P}_T - \hat{P}_R\right) + 1.645\,se$$

If the 90% confidence interval^0 for the absolute difference between the proportion of patients who are considered a therapeutic cure (primary) in the Test and Reference groups is contained within the range [-20% + 20%] then bioequivalence of the Test product to the Reference product will be considered to have been demonstrated for the primary endpoint.

Sensitivity Analysis for Primary Efficacy Endpoint

As a sensitivity analysis, the primary efficacy analysis will be performed on the safety population using LOCF. This analysis will use LOCF such that subjects with no post-dose data will be considered as non-responders.

8.2.2 Supportive Analyses

The following supportive analyses will be performed for the primary endpoint:

1. The primary analysis will be performed including patients who completed Visit 2 within 14 ± 2 days and Visit 3 within 28 ± 4 days.

2. The primary analysis will be performed including patients who completed Visit 2 within 14 ± 2 days and Visit 3 between Day 26 and Day 32, inclusive.
3. The primary analysis will be performed including patients who completed Visit 2 within 14 ± 2 days and Visit 3 within 28 ± 2 days.

To declare therapeutic equivalence of the Test product to the Reference product, therapeutic equivalence must be demonstrated for only the primary analysis.

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 the primary efficacy endpoint in the PP population (for equivalence testing). The treatment-by-site interaction will be evaluated by the Breslow-Day test for homogeneity of the odds ratio at the 5% significance level ($p < 0.05$). 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 PP population at the site with the highest enrolling rate in the PP population. If the treatment-by-site interaction term is found to be statistically significant ($p < 0.05$) for the primary endpoint, then the interaction term will also be assessed for clinical relevance before pooling the data across sites. This will include examination of Therapeutic Cure rates at each site where sample sizes per treatment may be influential in the assessment of the interaction.

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 20.0 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".

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 and Visit 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.

8.4 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.

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

Programming note:

Put Program Name in the footnote where it is stored, Location of Output stored, and Date and time when the output is generated.

T14.1.1 Summary of Patient's Disposition

Patients Randomized	Test N = xxx n (%)	Reference N = xxx n (%)	Total N = xxx n (%)
Completed Study	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Terminated Early	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Adverse Event	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Lack of efficacy	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Protocol Deviation	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Pregnancy	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
etc.			
Other	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N= number of patients randomized in that particular group; n= number of patient with data available for that particular group; total % is based on N

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T14.1.2 Summary of Protocol Deviations

	Test N = xxx n (%)	**Reference N = xxx n (%)**	**Total N = xxx n (%)**
Total Patients with Protocol Deviations	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Total Deviations	xxx	xxx	xxx
Lost to Follow-up	xxx	xxx	xxx
Missed Visit	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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T14.1.3.1 Summary of Patients Excluded from Efficacy Analysis (Population Determination)

	Test N = xxx n (%)	Reference N = xxx n (%)	Total N = xxx n (%)
Safety Population	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Excluded from Safety population	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
PP Population	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Excluded from PP population	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Inclusion/Exclusion criteria not met	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Non-compliant with dosing requirement	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Major protocol deviations	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
etc.	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N= number of patients randomized in that particular group; n= number of patient with data available for that particular group; total % is based on N

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T14.1.3.2 Summary of Patients Included in Analysis Population by Study Center

Site No.	Name	Total Randomized	PP			Safety		
			Test	Reference	Total	Test	Reference	Total
xx	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx
xx	xxxx	xxx	xxx	xxx	xxx	xxx	xxx	xxx

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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T14.1.3.3 Study Timelines (Screened subjects)

	Trial Timelines Date
First Patient First Visit (FPFV)	mm-DDD-YYYY
Last Patient Last Visit (LPLV)	mm-DDD-YYYY
Trial Duration (Days)	xxx

Note: Trial Duration (Days) = (Date of LPLV - Date of FPFV) + 1

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T14.1.4 Summary of Demographic Data and Baseline Characteristics (Safety Population)

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

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N= number of patients randomized in that particular group; n= number of patient with data available for that particular group; total % is based on N

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T14.1.4 Summary of Demographic Data (Safety Population)

		Test N = xxx n (%)	Reference N = xxx n (%)	Total N = xxx n (%)	P-value
Sex	Female	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	x.xxxx
	Male	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	
Baseline Severity Score of Nocturnal Itching Pretreatment	None	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	x.xxxx
	Mild	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	
	Moderate	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	
	Severe	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	
Baseline Severity of Lesion Count Infestation Pretreatment	Mild	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	x.xxxx
	Moderate	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	
	Severe	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N= number of patients randomized in that particular group; n= number of patient with data available for that particular group; total % is based on N

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Similar tables will be created for T14.1.5.

T14.1.5 Summary of Demographic Data (Per-Protocol Population)

T14.1.6 Summary of Microscopic Evaluation of Scabies (Per-Protocol Population)

Visit	Microscopic Evaluation	Statistic	Test N = xxx n (%)	Reference N = xxx n (%)
1 (Baseline)	Microscopic examination result	Positive	xxx (xx.x)	xxx (xx.x)
		Negative	xxx (xx.x)	xxx (xx.x)
	Number of scraped sites	n	xxx	xxx
		Mean ± SD	xx.x ± xx.x	xx.x ± xx.x
		Median	xx.x	xx.x
		Range	xx.x - xx.x	xx.x - xx.x
2	Microscopic examination result	Positive	xxx (xx.x)	xxx (xx.x)
		Negative	xxx (xx.x)	xxx (xx.x)
	Number of scraped sites	n	xxx	xxx
		Mean ± SD	xx.x ± xx.x	xx.x ± xx.x
		Median	xx.x	xx.x
		Range	xx.x - xx.x	xx.x - xx.x
3 (EOS)	Microscopic examination result	Positive	xxx (xx.x)	xxx (xx.x)
		Negative	xxx (xx.x)	xxx (xx.x)
	Number of scraped sites	n	xx	xx
		Mean ± SD	xx.x ± xx.x	xx.x ± xx.x
		Median	xx.x	xx.x
		Range	xx.x - xx.x	xx.x - xx.x

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N= number of patients randomized in that particular group; n= number of patient with data available for that particular group; total % is based on N

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T14.1.7 Summary of Frequency of Scabies Signs and Symptoms Rating (Per-Protocol Population)

Visit	Grade (Lesion Count)	Test N = xxx n (%)	Reference N = xxx n (%)
1	Mild (<50)	xxx (xx.x)	xxx (xx.x)
	Moderate (50 – 100)	xxx (xx.x)	xxx (xx.x)
	Severe (>100)	xxx (xx.x)	xxx (xx.x)
2	Mild (<50)	xxx (xx.x)	xxx (xx.x)
	Moderate (50 – 100)	xxx (xx.x)	xxx (xx.x)
	Severe (>100)	xxx (xx.x)	xxx (xx.x)
3	Mild (<50)	xxx (xx.x)	xxx (xx.x)
	Moderate (50 – 100)	xxx (xx.x)	xxx (xx.x)
	Severe (>100)	xxx (xx.x)	xxx (xx.x)

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N= number of patients randomized in that particular group; n= number of patient with data available for that particular group; total % is based on N

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T14.1.8.1 Summary of Equivalence Analysis Results of Primary Efficacy Endpoint
(Proportion of Patients in each Treatment Group with Therapeutic Cure (Parasitological Cure plus Clinical Cure) of Scabies at Day 28 ± 4)
(Per-Protocol Population)

				Difference Between Treatments	
Treatment Group	**Number of Patients (N)**	**Number of Patients with Therapeutic Cure (n)**	**Proportion of Therapeutic Cure (%)**	**Difference (%)**	**90% CI Evaluation**
Test	Xxx	xxx	xx.x		
Reference	Xxx	xxx	xx.x	xx.x	xx.x – xx.x

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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T14.1.8.2 Sensitivity Analysis Summary of Equivalence Analysis Results of Primary Efficacy Endpoint
(Proportion of Patients in each Treatment Group with Therapeutic Cure (Parasitological Cure plus Clinical Cure) of Scabies at Day 28 ± 4)
(Safety Population)

T14.1.9.1 Supportive Analysis #1: Summary of Equivalence Analysis Results of Primary Efficacy Endpoint (Per-Protocol Population)

				Difference Between Treatments	
Treatment Group	**Number of Patients (N)**	**Number of Patients with Therapeutic Cure (n)**	**Proportion of Therapeutic Cure (%)**	**Difference (%)**	**90% CI Evaluation**
Test	Xxx	xxx	xx.x		
Reference	Xxx	xxx	xx.x	xx.x	xx.x – xx.x

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

The primary analysis will be performed including patients who completed Visit 2 within 14 ± 2 days and Visit 3 within 28 ± 4 days.

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T14.1.9.2 Supportive Analysis #2: Summary of Equivalence Analysis Results of Primary Efficacy Endpoint (Per-Protocol Population)

Note: The primary analysis will be performed including patients who completed Visit 2 within 14 ± 2 days and Visit 3 between Day 26 and Day 32, inclusive.

T14.1.9.3 Supportive Analysis #3: Summary of Equivalence Analysis Results of Primary Efficacy Endpoint (Per-Protocol Population)

Note: The primary analysis will be performed including patients who completed Visit 2 within 14 ± 2 days and Visit 3 within 28 ± 2 days.

T14.1.10 Summary of Frequency of Patient Pruritus Assessment (Per-Protocol Population)

Visit	Grade (Score)	Test N = xxx n (%)	Reference N = xxx n (%)
1	NONE: Complete absence of itching (0)	xxx (xx.x)	xxx (xx.x)
	MILD: Slight itching, no sleep loss (1)	xxx (xx.x)	xxx (xx.x)
	MODERATE: Definitely present, interrupts sleep (2)	xxx (xx.x)	xxx (xx.x)
	SEVERE: Marked, intense, cannot sleep (3)	xxx (xx.x)	xxx (xx.x)
2	NONE: Complete absence of itching (0)	xxx (xx.x)	xxx (xx.x)
	MILD: Slight itching, no sleep loss (1)	xxx (xx.x)	xxx (xx.x)
	MODERATE: Definitely present, interrupts sleep (2)	xxx (xx.x)	xxx (xx.x)
	SEVERE: Marked, intense, cannot sleep (3)	xxx (xx.x)	xxx (xx.x)
3	NONE: Complete absence of itching (0)	xxx (xx.x)	xxx (xx.x)
	MILD: Slight itching, no sleep loss (1)	xxx (xx.x)	xxx (xx.x)
	MODERATE: Definitely present, interrupts sleep (2)	xxx (xx.x)	xxx (xx.x)
	SEVERE: Marked, intense, cannot sleep (3)	xxx (xx.x)	xxx (xx.x)

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N= number of patients randomized in that particular group; n= number of patient with data available for that particular group; total % is based on N

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T14.1.11 Overall Summary of Adverse Events (Safety Population)

Description	Test	Reference	Total
Subjects in Safety Analysis Set	xxx	xxx	xxx
Subjects with at least one AE	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Discontinued study drug due to above AE	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
AEs reported	xxx	xxx	xxx
Mild	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Moderate	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Severe	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Not Related	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Related	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Death	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Serious AE	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

Note: subjects having multiple AEs within same system organ class were counted only once in respective system organ class.
Under any event subjects having multiple AEs with same Preferred Term were counted only once within the respective preferred term.

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T14.1.12 Summary of Frequency of Adverse Events by Body System (Safety Population)

		Test N = xxx		Reference N = xxx		
Body System	**Preferred Term**	**Events**	**Patients n (%)**	**Events**	**Patients n (%)**	**Fisher's p-value**
Patients with at least one AE	Total	xx	xxx (xx.x)	xx	xxx (xx.x)	x.xxxx
Ear and labyrinth disorders	Ear pain	xx	xxx (xx.x)	xx	xxx (xx.x)	x.xxxx
	etc.					
etc.						

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N= number of patients in safety population in that particular group; n= number of patient with data available for that particular group; total % is based on N

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T14.1.13 Summary of Frequency of Adverse Events by Relationship (Safety Population)

Body System	Preferred Term	Test # of Events (N = xxx)		Reference # of Events (N = xxx)	
		Related n (%)	Not Related n (%)	Related n (%)	Not Related n (%)
Total AEs	Total	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Ear and labyrinth disorders	Ear pain	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Hypoacusis	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N = Total number of events in that particular group group; Percentage is based on total number of events.

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T14.1.14 Summary of Frequency of Adverse Events by Severity (Safety Population)

Body System	Preferred Term	Test # of Events (N = xxx)			Reference # of Events (N = xxx)		
		Mild n (%)	Moderate n (%)	Severe n (%)	Mild n (%)	Moderate n (%)	Severe n (%)
Total AEs	Total	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Ear and labyrinth disorders	Ear pain	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Hypoacusis	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N = Total number of events in that particular group group; Percentage is based on total number of events.

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T14.1.15 Summary of Frequency of Serious Adverse Events (Safety Population)

Body System	Preferred **Term**	**Test # Events**	**Reference # Events**
Injury, poisoning and procedural complications	Alcohol poisoning	xxx	xxx

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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T14.1.16 Summary of Vital Signs
(Safety Population)

Vital Signs	Visit	Statistic	Test N = xxx	Reference N = xxx
Systolic Blood Pressure (mmHg)	1	n	xxx	xxx
		Mean ± SD	xxx.x ± xx.x	xxx.x ± xx.x
		Median	xxx.x	xxx.x
		Range	xxx.x – xxx.x	xxx.x – xxx.x
	3			
Diastolic Blood Pressure (mmHg)				
Pulse Rate (beats/min)				
Respiration Rate (breaths/min)				
Temperature (F)				

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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T14.1.17 Summary of Frequency of Patients with Re-Infestation from Day 14 (treatment success) to Day 28 (treatment failure) (Per-Protocol Population)

Test (N = xxx) n (%)	Reference (N = xxx) n (%)
xxx (xx.x)	xxx (xx.x)

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N= number of patients randomized in that particular analysis group; n= number of patient with data available for that particular group; total % is based on N

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T14.1.18 Summary of Frequency of Patients who are Therapeutic Failures on Day 14 ± 4 (Per-Protocol Population)

Test (N = xxx) n (%)	Reference (N = xxx) n (%)
xxx (xx.x)	xxx (xx.x)

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)
N= number of patients randomized in that particular analysis group; n= number of patient with data available for that particular group; total % is based on N

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L16.2.1 Listing of Discontinued Patients

Treatment Group	Patient Randomization Number	Discontinuation Reason	Population
Test	xxxx	Withdrawal by Patient	Per-Protocol
	xxxx	Lost to Follow-up	Safety
Reference			

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.2 Listing of Protocol Deviations

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

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.3 Patients Excluded from the Per-Protocol Population

Treatment Group	Patient Randomization Number	Exclusion Reason
Test	xxxx	Major protocol deviation
Reference		

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.4.1 Listing of Demographic Data

Treatment Group	Patient Randomization Number	Age	Sex	Ethnicity	Race
Test	xxxx	30	Female	Not Hispanic or Latino	Black or African American

Reference

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.4.2 Listing of Medical History

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

Reference

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.4.3 Listing of Concomitant Medication

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

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.4.4 Listing of Treatment for Family Members/Close Contacts

Treatment Group	Patient Randomization Number	Visit Date	How many members in the patient's house-hold (e.g., close personal contacts, and/or family member(s)) are affected with scabies?	Has the patient come into contact with the affected family member(s) and/or close personal contacts?	Have affected family member(s)/close personal contacts of the patient been given prescription generic permethin?
Test	xxxx	yyyy-mm-dd	xxx	Yes	Yes
Reference					

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.5.1 Listing of Visit Date Information

Treatment Group	Patient Randomization Number	Informed Consent Signed	Date Assent Signed	Visit 1	Visit 2	Visit 3 / Early Termination	Safety Population	Per-Protocol Population
Test	xxxx	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	Yes	No

Reference

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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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 Doses Applied	Treatment Compliance*
Test	xxxx	yyyy-mm-dd	yyyy-mm-dd	xx	Yes
Reference					

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

*Treatment compliance will be calculated based off the following criteria: 1.) all patients randomized will have at least 1 dose, confirmed from the study drug administration form via the eCRF. Date of first and last dose and total confirmed doses applied will confirm treatment use. 2.) A patient who is required to dose a second time, compliance will be calculated using criteria 1 and the following data points (via the eCRF) positive microscopic result at Visit 2 and selection of "yes" regarding the question "based on your assessment and microscopic results, is continued treatment required?"

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L16.2.6.1 Listing of Scabies Signs and Symptoms Rating and Microscopic Evaluation of Scabies

Treatment Group	Patient Randomization Number	Visit	Scabies Lesion Count	Are there any new lesions present?	Have all original lesions healed?	Number of scraped sites	Microscopic Examination Result	Clinical Cure	Parasito-logical Cure	Therapeutic Cure
Test	xxxx	1	Moderate	NA	NA	3	Positive (mites, eggs)			
		2	Mild	No	No	3	Positive (eggs)			
		3	Mild	No	Yes	0	Negative	Yes	Yes	Yes
	xxxx	1	Moderate	NA	NA	3	Positive (eggs)			
		2	Mild	No	No	3	Positive (eggs)			
		3	Mild	Yes	Yes	0	Negative	No	Yes	No
Reference										

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.6.2 Listing of Patient Pruritus Assessment

Treatment Group	Patient Randomization Number	Visit 1	Visit 2	Visit 3 / Early Termination	No Itch Persistence
Test	xxxx	1 (Mild)	1 (Mild)	0 (None)	Yes
		2 (Moderate)	1 (Mild)	1 (Mild)	No
Reference					

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.6.3 Listing of Investigator Evaluator Initials On Scabies Signs & Symptoms Rating

Treatment Group	Patient Randomization Number	Visit 1	Visit 2	Visit 3 / Early Termination
Test	xxxx	XYZ	D-G	D-G
Reference				

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.7 Listing of Adverse Events by Treatment

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

Reference

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

L16.2.8.1 Listing of Pregnancy Test Results

Treatment Group	Patient Randomization Number	Visit 1	Visit 3 / Early Termination
Test	xxxx	Negative	Negative
Reference			

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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L16.2.8.2 Listing of Vital Signs

Treatment Group	Patient Randomization Number	Visit	Systolic BP (mmHg)	Diastolic BP (mmHg)	Pulse Rate (beats/min)	Respiration Rate (breaths/min)	Temperature (F)
Test	xxxx	1	120	70	84	18	98.6
		3	140	100 (NCS)	74	18	97.0

Reference

Test: Permethrin Cream, 5%, (Encube Ethicals)
Reference: Elimite™ Cream (permethrin) 5% (Prestium Pharma, Inc.)

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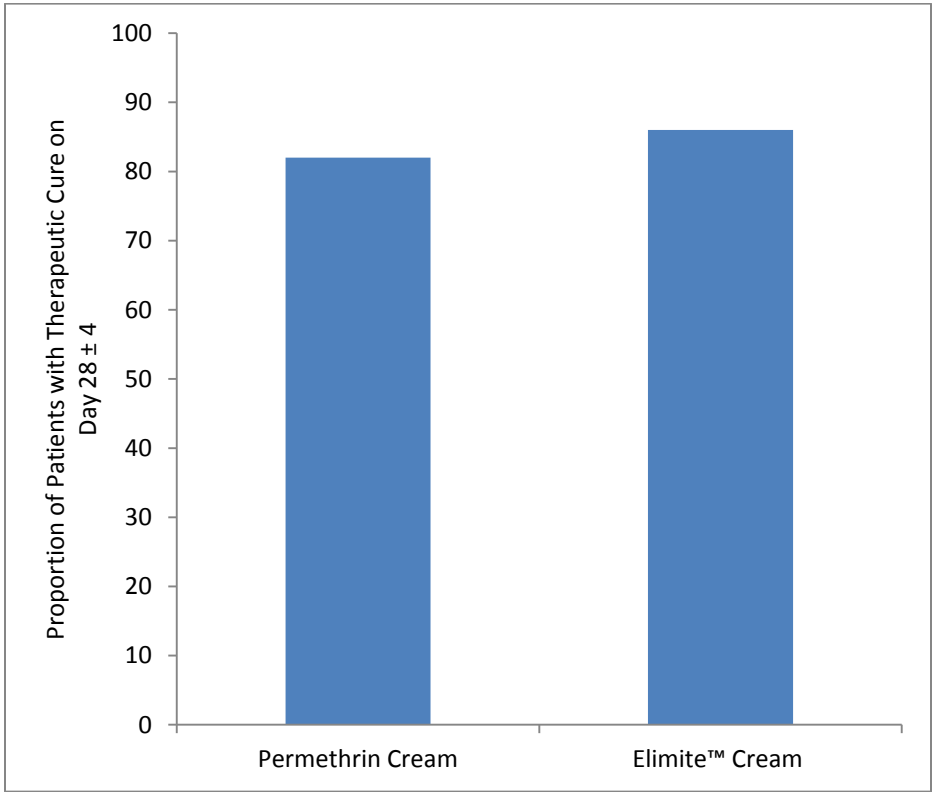
F15.1.1 Histogram of Proportion of Patients with Therapeutic Cure on Day 28 ±4



Reference:

1. FDA Draft Guidance on Malathion, June 2012.