Statistical Analysis Plan with Amendment 02

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multiple-Site Clinical Study to Evaluate the Therapeutic Equivalence and Safety of Ivermectin Lotion 0.5% (Actavis Laboratories UT, Inc.) to SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC) in the Treatment of Human Head Lice Infestation

Study Number 71691702

NCT03301649

Statistical Analysis Plan with Amendment 02 Approval Date: 12 January 2018

STATISTICAL ANALYSIS PLAN

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multiple-Site Clinical Study to Evaluate the Therapeutic Equivalence and Safety of Ivermectin Lotion 0.5% (Actavis Laboratories UT, Inc.) to SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC) in the Treatment of Human Head Lice Infestation

Protocol Number: 71691702
[redacted] 71691702

Sponsor:
Actavis LLC
400 Interpace Parkway
Morris Corporate Center III
Parsippany, NJ 07054

Contract Research Organization:
[redacted]

January 12, 2018

Draft Version 2.0

[redacted]

STATISTICAL ANALYSIS PLAN

Ivermectin Lotion 0.5% **Protocol / Study No. 71691702**

SAP FINAL VERSION APPROVALS

A Randomized, Double-Blind, Placebo-Controlled, Parallel-Design, Multiple-Site Clinical Study to Evaluate the Therapeutic Equivalence and Safety of Ivermectin Lotion 0.5% (Actavis Laboratories UT, Inc.) to SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC) in the Treatment of Human Head Lice Infestation

Written By: Signature: _____ [redacted]	Date: _____
Reviewed By: Signature: _____ [redacted]	Date: _____
Approved By: Signature: _____ [redacted] Actavis LLC	Date: _____

[redacted]

STATISTICAL ANALYSIS PLAN

Ivermectin Lotion 0.5% **Protocol / Study No. 71691702**

Revision History

VERSION	DATE	DESCRIPTION OF REVISIONS	REVISED BY
Draft 1.0	December 06, 2017	New Document	[redacted]
Draft 2.0	January 12, 2018	Incorporate client comments	

List of Abbreviations and Definition of Terms

ADaM	Analysis Data Model
AE	Adverse Event
ANOVA	Analysis of Variance
C	Celsius
CDISC	Clinical Data Interchange Standards Consortium
CMH	Cochran-Mantel-Haenszel
CRF	Case Report Form
CRO	Contract Research Organization
EOS	End of Study
F	Fahrenheit
FDA	Food and Drug Administration
GLM	Generalized Linear Model
Hg	Mercury
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IWRS	Interactive Web Response System
LOCF	Last Observation Carried Forward
MedDRA	Medical Dictionary for Regulatory Activities
mITT	modified Intent-to-Treat Population
OGD	Office of Generic Drugs
PP	Per-Protocol Population
RLD	Reference Listed Drug
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SAS	Statistical Analysis System
SD	Standard Deviation
SDTM	Study Data Tabulation Model

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1. INTRODUCTION

This Statistical Analysis Plan (SAP) is based on the final Clinical Study Protocol 71691702 Rev. 0 dated 06/21/2017. 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 71691702 Rev.0 dated 06/21/2017
- Final eCRF Version 1.0 for Study No. 71691702

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, Ivermectin Lotion 0.5% (Actavis Laboratories UT, Inc.) to the Reference product, SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC) in the treatment of active head lice infestation.
2. Demonstrate the superiority of the Test and Reference (active) treatments over Placebo treatment in patients with active head lice infestation.
3. Compare the safety of Test, Reference and Placebo treatments in patients with active head lice infestation.

3. OVERALL STUDY DESIGN

This randomized, double-blind, placebo-controlled, parallel-design, multiple-site clinical study has been designed to evaluate the efficacy and safety of a generic Ivermectin Lotion 0.5% (Actavis Laboratories UT, Inc.) compared to the Food and Drug Administration (FDA) Reference Listed Drug (RLD) SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals,

LLC) in patients with active head lice infestation. Additionally, both the Test and Reference (i.e., the RLD) treatments will be tested for superiority to a Placebo.

Before any study-specific procedures are performed, all patients will read and sign the IRB-approved informed consent form (ICF). In addition, patients who are considered minors in the state the study is being conducted (< 18 years of age in most states), must have a signed parental/guardian ICF, indicating approval to participate, as well as a signed assent to participate 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 6 months-5 years of age will be exempt from providing assent based on the child's comprehension and cognitive skills.

Males and females, 6 months of age and older with an active head lice infestation will be randomized [redacted] to one of the three study products as follows:

- **Test**: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
- **Reference**: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
- **Placebo**: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

[redacted]

Patients, [redacted] will be instructed to administer a single application of the study product to the hair on the day of or the day after enrollment into the study, leave the study product on the hair and scalp for 10 minutes, and then rinse off with warm water. Patients and infested household members will be instructed to apply the study product at home. The day of dosing will be considered Day 1.

Patients will attend the following four scheduled clinics visits:

- Visit 1 (Day -1 to 1): Screening/Baseline
- Visit 2 (Day 2): Interim Visit
- Visit 3 (Day 8 ± 2): Interim Visit
- Visit 4 (Day 15 ± 2): End of Study

At Visit 2 (Day 2), [redacted] enrolled [redacted] will return the study product to the clinic. Visit 2 must occur the day after dosing. [redacted] At Visits 2, 3, and 4, patients will be examined for the presence of live head lice (i.e., live adults

and/or nymphs). Louse examination should be conducted for 15 minutes or longer, unless any live lice are detected in less time. Duration of examination should be recorded. [redacted] Unscheduled visits will be allowed as deemed necessary by the Investigator or Sponsor to ensure patient safety or to perform other study-related procedures.

At Visit 2, patients will be questioned about any ocular discomfort associated with the study product. Also at Visits 2, 3, and 4, patients will be questioned about any adverse events (AEs), application site reactions (Appendix A), and any new concomitant medication use.

Definitions

- [redacted]
- [redacted]
- Non-index patient: Any household member who has agreed to participate in the study but is not the youngest member of the household.
- Index patient: The youngest household member who is randomized into the study.

Therapeutic equivalence will be assessed by evaluating the proportion of index patients in each treatment group who are considered a Treatment Success on Day 15 ± 2. Treatment Success is defined as the absence of live lice. The proportion of all patients (i.e., index + non-index) who are considered a Treatment Success on Day 15 ± 2 will be evaluated as a secondary endpoint. The analysis of superiority will compare both active treatment groups to the Placebo group for the same primary and secondary endpoints.

Study Schematic

PROCEDURE	VISIT 1 (Day -1 to 1)* Screening/Baseline	VISIT 2 (Day 2)† Interim Visit	VISIT 3 (Day 8 ± 2 Days) Interim Visit	VISIT 4 (Day 15 ± 2 Days) End of Study
Informed Consent/Assent	X			
Medical History and Demographics	X			
Concomitant Medication	X	X	X	X
Adverse Events	X	X	X	X
Vital Signs	X	X	X	X
Pregnancy Test‡	X	X	X	X
Louse Examination	X	X	X	X
Inclusion/Exclusion	X			
Application Site Reactions	X	X	X	X
Ocular Irritation Assessment		X		
Dispense Study Product	X			
Collect Study Product		X		
Provide Patient Diary	X	X	X	
Collect and Review Patient Diary		X	X	X

*Study product will be administered on Day 1.
†Visit 2 must occur the day after patient dosing.
‡For females of childbearing potential

4. RANDOMIZATION AND BLINDING

The study product will be randomized, packaged and blinded by an independent packaging company (Actavis, SLC site). The randomization will be pre-planned according to a computer-generated randomization schedule. All enrolled members of a household will be randomized to the same treatment arm.

Using [redacted] Interactive Web Response Technology System (IWRS), all eligible and non-eligible patients who are consented and screened into the study will be assigned a patient number. The patient number is assigned after a patient is consented. It is the only identifier for screened patients. [redacted] The system will also assign a study product kit number (based on the randomization schedule created by an independent biostatistician). The study product kit number is the identifying number listed on the study product dispensed to eligible patients. The study product kit number is a five-digit number. This will be the identifier used for randomized patients (i.e., randomization number). Both the patient number and randomization number will be entered into the patient's eCRF. 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 index patients in the PP population who are considered to be a Treatment Success on Day 15 ± 2), sample size is estimated for therapeutic equivalence of the Test to the Reference product and superiority of each of the active treatments groups over Placebo. The sample size estimations are based on data reported in the product label for SKLICE® (ivermectin) Lotion, 0.5%.

[redacted]

[redacted]

Under the above assumptions, [redacted] approximately 364 index patients may be randomized [redacted]

6. ANALYSIS POPULATION

Per-Protocol Population (PPP)

The PP population will include all randomized patients who:

- Meet all inclusion and exclusion criteria.
- [redacted]
- [redacted]
- Have no significant protocol deviations.
- Apply the study product as instructed on Day 1.

[redacted]

Modified Intent-to-Treat Population (mITT)

The mITT population will include all randomized patients who meet all inclusion/exclusion criteria, apply the study product as instructed, and return for at least one post-baseline evaluation visit.

Safety Population

The Safety population will include all patients who are randomized and received study product.

7. EFFICACY ENDPOINTS

Primary Efficacy Endpoint

The primary efficacy endpoint is the proportion of index patients in each treatment group who are considered a Treatment Success on Day 15 ± 2. Treatment Success is defined as the absence of live lice.

Secondary Efficacy Variable

The secondary efficacy endpoint is the proportion of all randomized patients (i.e., index + non-index) who are considered a Treatment Success on Day 15 ± 2. Treatment Success is defined as the absence of live lice.

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, efficacy variables 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 number of observations, 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). ADaM datasets will include but not limited to ADSL, ADEFF, ADAE, ADVS, ADCM and ADMH.

8.1 Baseline Characteristics

8.1.1 Baseline Comparability

Baseline characteristics will be evaluated separately for the PP, mITT and Safety populations.

Demographic information collected at baseline includes the following:

- 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)
- Number of live lice

Summary tables by treatment group will be presented. Continuous variables will be summarized using descriptive statistics (number of observations, median, minimum, maximum, mean and standard deviation). Categorical variables will be summarized using frequencies and percentage. Baseline treatment comparisons will be presented using Chi-Square test for the categorical variables, and Analysis of Variance (ANOVA) for the continuous variables.

All data will be listed by treatment and patient.

8.1.2 Medical History

At Visit 1, each patient will be required to provide basic demographic information: date of birth, gender, ethnicity and race. Patients will also be questioned about medical history, including acute and chronic medical history and medical history relevant to their head lice.

Medical history data will be listed by treatment and patient.

8.1.3 Concomitant Medications

At Visit 1, patients will be questioned about current and previous medication use over the last four weeks. At all subsequent visits, patients will be questioned about ongoing or new concomitant medication use.

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

8.1.4 Pregnancy Test

All females of childbearing potential will have a urine pregnancy test performed at each visit.

Pregnancy test results will be listed by treatment and patient.

8.2 Efficacy Analyses

8.2.1 Primary and Secondary Endpoint Analysis

Therapeutic Bioequivalence Analysis

The primary measure of therapeutic equivalence will be evaluated using the Per-Protocol population.

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] in order to establish equivalence.

The compound hypothesis to be tested is:

$H_0: P_T - P_R \leq -.20 \text{ or } P_T - P_R \geq .20$ versus

$H_A: -.20 < P_T - P_R < .20$

where P_T = success rate of test treatment
P_R = success rate of reference treatment.

Let

n_T = sample size of test treatment group
cn_T = number of subjects considered as Treatment Success in test treatment group
n_R = sample size of reference treatment group
cn_R = number of subjects considered as Treatment Success in reference treatment group
$\hat{P}_T = cn_T/n_T$ $\hat{P}_R = cn_R/n_R$, and

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

The 90% confidence interval for the difference in proportions between test and reference will be calculated as follows:

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

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

If the 90% confidence interval for the absolute difference between the proportion of patients who are considered a Treatment Success in the Test and Reference groups is contained within the range [-20%, +20%] then therapeutic equivalence of the Test product to the Reference product will be considered to have been demonstrated.

The same statistical approach will be conducted for analysis of the secondary endpoint in the PP population.

To declare therapeutic equivalence of the Test product to the Reference product, therapeutic equivalence must be demonstrated for only the primary endpoint in the PP population.

Superiority to Placebo Analysis

Superiority of the Test and Reference products against the Placebo for the primary endpoint will be tested at the 5% significance level ($p < 0.05$; two-sided, CMH test, stratified by clinical site) in the mITT population using last observation carried forward (LOCF). If the proportions of patients who are considered a Treatment Success in the Test and Reference groups are numerically and statistically superior to that of the Placebo ($p < 0.05$; using two-sided, CMH test stratified by clinical site), then superiority of the Test and Reference products over Placebo will be concluded.

The same statistical approach will be conducted for analysis of the secondary endpoint in the mITT population.

To declare superiority of the Test and Reference products over Placebo, their superiority must be demonstrated for only the primary endpoint in the mITT population.

8.2.2 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 ($p < 0.05$) then the interaction term will also be assessed for clinical relevance before pooling the data

across sites. This will include examination of Treatment Success rates at each site where sample sizes per treatment may be influential in the assessment of the interaction.

8.3 Safety Analysis

All safety analyses will be based on the 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.

The total number and percentage of patients with at least one AEs, discontinued study drug due to AEs, AE severity and AEs related to investigational product, serious AEs and death will be summarized by treatment groups.

A summary table of the number and percent of patients with AEs by system organ class, preferred term, and treatment group 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 group 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 group will be presented. Relationship to a study drug will be classified as “Related” or “Not Related”.

Adverse event frequencies will be compared between treatments using Fisher’s exact test. If the overall Fisher’s test is statistically significant, a pairwise test will be conducted for Test and Reference to determine if the difference in AEs is related to the active product.

8.3.2 Application Site Reactions

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

Signs and Symptoms:
Erythema
Pyoderma

Excoriation
Pain
Pruritus
Edema

Grading Scale:

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

Application site reactions and ocular discomfort will be compared descriptively among treatment groups. A frequency summary table comparing the application site reactions for each treatment group will be presented by visit.

8.3.3 Vital Signs

Vital signs will be recorded (pulse, blood pressure, temperature and respiration rate) at each visit.

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

T16.1.9.1 Summary of Discontinued Patients

Patients	Test	Reference	Placebo	Total
Randomized	xxx	xxx	xxx	xxx
Completed Study	xxx	xxx	xxx	xxx
Terminated Early	xxx	xxx	xxx	xxx
Lost to Follow-Up	xxx	xxx	xxx	xxx
Withdrew Consent	xxx	xxx	xxx	xxx
Randomized in Error	xxx	xxx	xxx	xxx
etc.				

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)

Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)

Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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T16.1.9.2 Summary of Protocol Deviations

	Test	Reference	Placebo	Total
Total Patients with Protocol Deviations	xxx	xxx	xxx	xxx
Total Deviations	xxx	xxx	xxx	xxx
Outside Visit Window	xxx	xxx	xxx	xxx
Randomized in Error	xxx	xxx	xxx	xxx
Missed Visit	xxx	xxx	xxx	xxx
Restricted Medication	xxx	xxx	xxx	xxx
etc	xxx	xxx	xxx	xxx
Other	xxx	xxx	xxx	xxx

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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T16.1.9.3.1 Summary of Patients Excluded from Efficacy Analysis

		Test	Reference	Placebo	Total
Randomized	Total	xxx	xxx	xxx	xxx
Safety Population	Total	xxx	xxx	xxx	xxx
Excluded from Safety	Total	xxx	xxx	xxx	xxx
	Not randomized or did not received study product	xxx	xxx	xxx	xxx
mITT Population	Total	xxx	xxx	xxx	xxx
Excluded from mITT	Total	xxx	xxx	xxx	xxx
	Did not dose	xxx	xxx	xxx	xxx
	etc.				
PP Population	Total	xxx	xxx	xxx	xxx
Excluded from Excluded from PPP	Total	xxx	xxx	xxx	xxx
	Restricted Medication	xxx	xxx	xxx	xxx
	etc.				

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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

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

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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T16.1.9.4 Summary of Demographic Data and Baseline Characteristics (Safety Population)

		Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)	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	
Race	White	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xxxx
	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%)	
	Asian	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	American Indian or Alaska Native	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
	Other	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	
Gender	Female	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	x.xxxx
	Male	xxx (xx.x%)	xxx (xx.x%)	xxx (xx.x%)	

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

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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T16.1.9.4 Summary of Demographic Data and Baseline Characteristics (Safety Population)

		Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)	P-value
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%)	
Number of live lice	n	xxx	xxx	xxx	x.xxxx
	Mean ± SD	xx.x ± x.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	

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

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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Similar tables will be created for T16.1.9.5 and T16.1.9.6

T16.1.9.5 Summary of Demographic Data and Baseline Characteristics (modified Intent-to-Treat Population)

T16.1.9.6 Summary of Demographic Data and Baseline Characteristics (Per-Protocol Population)

T16.1.9.7 Summary of Analysis Results of Primary Efficacy Endpoint (Proportion of Index Patients with Treatment Successes between Treatment Groups)

Equivalence: Per-Protocol Population

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

Superiority: modified Intent-to-Treat Population

Treatment Group	**Number of Patients (N)**	**Number of Treatment Successes (n)**	**Proportion of Treatment Successes (%)**	**P-value**
Placebo	xxx	xxx	xx.x	
Test	xxx	xxx	xx.x	x.xxxx
Reference	xxx	xxx	xx.x	x.xxxx

Superiority of Active treatments over Placebo were tested using a two-sided Cochran-Mantel-Haenszel (CMH) test, stratified by clinical site, at the 5% significance level.
The superiority testing include patients in the mITT population using last observation carried forward (LOCF).
Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

T16.1.9.8 Summary of Analysis Results of Secondary Efficacy Endpoint (Proportion of All Randomized Patients with Treatment Successes between Treatment Groups)

Equivalence: Per-Protocol Population

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

Superiority: modified Intent-to-Treat Population

Treatment Group	Number of Patients (N)	Number of Treatment Successes (n)	Proportion of Treatment Successes (%)	P-value
Placebo	xxx	xxx	xx.x	
Test	xxx	xxx	xx.x	x.xxxx
Reference	xxx	xxx	xx.x	x.xxxx

Superiority of Active treatments over Placebo were tested using a two-sided Cochran-Mantel-Haenszel(CMH) test, stratified by clinical site, at the 5% significance level.
Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

T16.1.9.9 Overall Summary of Adverse Events (Safety Population)

Description	Test	Reference	Placebo	Total
Patients Randomized	xxx	xxx	xxx	xxx
Patients with at least one AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Discontinued study drug due to above AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
AEs reported	xxx	xxx	xxx	xxx
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Related	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Serious AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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Created on: ddmmmyy hh:mm

T16.1.9.10 Summary of Frequency of All Adverse Events by Body System (Safety Population)

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

Comparison of treatment groups is with respect to the number of patients with at least one occurrence of the AE.

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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T16.1.9.11 Summary of Frequency of All Adverse Events by Severity (Safety Population)

		Test # Events (N=xx)			Reference # Events (N=xx)			Placebo # Events (N=xx)		
Body System	**MedDRA Term**	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**
Total AEs	Total AEs	xx(xx.x%)	xx(xx.x%)	xx (xx.x%)	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%)	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%)	xx (xx.x%)

etc.

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

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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

		Test # Events (N=xx)		Reference # Events (N=xx)		Placebo # Events (N=xx)	
Body System	**MedDRA Term**	**Related**	**Not Related**	**Related**	**Not Related**	**Related**	**Not Related**
Total AEs	Total AEs	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%)
	etc.						
etc.							

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

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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T16.1.9.13 Summary of Frequency of Serious Adverse Events (Safety Population)

Body System	MedDRA Term	Test # Events	Reference # Events	Placebo # Events
Injury, poisoning and procedural complications	Alcohol poisoning	xx	xx	xx

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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T16.1.9.14 Summary of Frequency of Application Site Reaction (Safety Population)

Signs and Symptoms	Visit	Statistic	Placebo (N = xxx)	Test (N = xxx)	Reference (N = xx)
Edema	Visit 1	Absent	xxx (x.x%)	xxx (x.x%)	xxx (x.x%)
		Mild	xxx (x.x%)	xxx (x.x%)	xxx (x.x%)
		Moderate	xxx (x.x%)	xxx (x.x%)	xxx (x.x%)
		Severe	xxx (x.x%)	xxx (x.x%)	xxx (x.x%)
	Visit 2				
	Visit 3				
	Visit 4				
Erythema					
Excoriation					
Pain					
Pruritus					
Pyoderma					

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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T16.1.9.15 Summary of Vital Signs (Safety Population)

Vital Signs	Visit	Statistic	Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)
Systolic Blood Pressure (mmHg)	Visit 1	n	xxx	xxx	xxx
		Mean ± SD	xxx.x ± xxx.x	xxx.x ± xxx.x	xxx.x ± xxx.x
		Median	xxx.x	xxx.x	xxx.x
		Range	xxx.x – xxx.x	xxx.x – xxx.x	xxx.x – xxx.x
	Visit 2				
	Visit 3				
	Visit 4				
Diastolic Blood Pressure (mmHg)					
Heart Rate (beats/min)					
Respiration Rate (breaths/min)					
Temperature (F)					

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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T16.1.9.16 [redacted]

(Safety Population)

Visit	Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)
[redacted]	xxx (x.x%)	xxx (x.x%)	xxx (x.x%)
[redacted]	xxx (x.x%)	xxx (x.x%)	xxx (x.x%)

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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T16.1.9.17 [redacted]
(Safety Population)

Test (N = xxx)	Reference (N = xxx)	Placebo (N = xxx)
xxx (x.x%)	xxx (x.x%)	xxx (x.x%)

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)
Re-infestation is defined as treatment success at Visit 2 and treatment failure at either Visit 3 or 4, or treatment success at Visits 2 and 3 and treatment failure at Visit 4.

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L16.2.1 Listing of Discontinued Patients

Treatment Group	Patient Number	Discontinuation Reason	Population
Test	xxx-xxx-xx	Withdrew Consent	mITT
	xxx-xxx-xx	Lost to Follow-up	Safety
Reference			
Placebo			

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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L16.2.2 Listing of Protocol Deviations

Treatment Group	Patient Number	Protocol Deviation Summary	Population
Test	xxx-xxx-xx	Outside Visit Window	Safety
Reference			
Placebo			

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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L16.2.3.1 Listing of Patients Excluded from the Per-Protocol Population

Treatment Group	Patient Number	Exclusion Reason
Test	xxx-xxx-xx	Patient did not meet IE criterion.
	xxx-xxx-xx	Patient took prohibited medications
Reference		
Placebo		

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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L16.2.3.2 Listing of Patients Excluded from the Modified Intent-to-Treat Population

Treatment Group	Patient Number	Exclusion Reason
Test	xxx-xxx-xx	Patient did not have at least one post-randomization evaluation
	xxx-xxx-xx	Patient did not have at least one post-randomization evaluation
Reference		
Placebo		

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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L16.2.4.1 Listing of Demographic Data

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

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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L16.2.4.2 Listing of Medical History

Treatment Group	Patient Number	System	Diagnosis or Surgical Procedure	Start Date	End Date	Ongoing
Test	xxx-xxx-xx	Gynecologic	Menopause	2003	2003	
Reference						
Placebo						

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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L16.2.4.3 Listing of Concomitant Medications

Treatment Group	Patient Number	Medication	TX Area	Dosage	Frequency	Route	Start/End Date	Indication
Test	xxx-xxx-xx	LISINOPRIL	Yes	20 MG	QD	PO	yyyy-mm-dd/ yyyy-mm-dd	HYPERTENSION
Reference								
Placebo								

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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L16.2.5 Listing of Visit Date Information

Treatment Group	Patient Number	Informed Consent Date	Visit 1	Visit 2	Visit 3	Visit 4 or Discontinuation
Test	xxx-xxx-xx	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd	yyyy-mm-dd

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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L16.2.6 Listing of Louse Examination Results

Treatment Group	Patient Number	Visit	Were Live Head Lice Present?	Number of Live Head Lice	Treatment Success	Duration of Louse Examination (minutes)
Test	xxx-xxx-xx	Visit 1	Yes	6		xx
		Visit 2	Yes	5		xx
		Visit 3	Yes	2		xx
		Visit 4	No	0	Yes	xx
	xxx-xxx-xx	Visit 1	Yes	6		xx
		Visit 2	Yes	5		xx
		Visit 3	Yes	2		xx
		Visit 4	Yes	2	No	xx
	etc					
Reference						
Placebo						

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

L16.2.7.1 Listing of Adverse Events by Treatment Group

Treatment group	Patient Number	Body System/ MedDRA Term/ AE Term	TX Area	Start /End Date	Severity	Relationship to Study Drug	Outcome	Action Taken with Study Drug/ Other Action Taken	SAE?
Test	xxx-xxx-xx	Nervous system disorders/ headache/ Headache	No	yyyy-mm-dd / yyyy-mm-dd	Mild	Not Related	Recovered	Drug withdrawn/ None	No
Reference									
Placebo									

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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L16.2.7.2 Listing of Application Site Reactions

Treatment Group	Patient Number	Visit	Edema	Erythema	Excoriation	Pain	Pruritus	Pyoderma
Test	xxx-xxx-xx	Visit 1	0	0	0	1	0	0
		Visit 2	0	1	0	0	0	0
		Visit 3	0	0	0	1	0	0
		Visit 4	0	0	0	1	0	0
Reference								
Placebo								

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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L16.2.8.1 Listing of Pregnancy Test Results

Treatment Group	Patient Number	Visit 1	Visit 2	Visit 3	Visit 4 or Discontinuation
Test	xxx-xxx-xx	Negative	Negative	Negative	Negative
Reference					
Placebo					

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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Created on: ddmmmyy hh:mm

L16.2.8.2 Listing of Vital Signs

Treatment Group	Patient Number	Visit	Systolic BP (mmHg)	Diastolic BP (mmHg)	Pulse Rate (beats/min)	Respiration Rate (breaths/min)	Temperature (F)
Test	xxx-xxx-xx	Visit 1	120	70	84	18	98.6
		Visit 2	140	80	74	18	97
		Visit 3	120	70	84	18	98.6
		Visit 4	140	80	74	18	97
Reference							
Placebo							

Test: Ivermectin Lotion, 0.5% (Actavis Laboratories UT, Inc.)
Reference: SKLICE® (ivermectin) Lotion, 0.5% (Arbor Pharmaceuticals, LLC)
Placebo: Placebo (vehicle) lotion (Actavis Laboratories UT, Inc.)

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