STATISTICAL ANALYSIS PLAN

Protocol Number: HD-MCZ-PHII-DRF062016

Study Title: Dose-Ranging Study of the Efficacy and Safety of Miconazole Oil Used for 7 or 14 Days Compared with Vehicle in the Treatment of Otomycosis

Development Phase of Study: 2

Sponsor: Hill Dermaceuticals, Inc.

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Revisions to the Statistical Analysis Plan described herein must be approved through a formal written amendment with the exception of minor editorial changes to tables, figures, or listing shells, and any necessary textual clarifications for programmers that do not affect the stated analysis variables, study endpoints, or statistical methods.

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1. LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE(s)	adverse event(s)
ATC	Anatomical Therapeutic Chemical
BID	twice daily
CRF(s)	case report form(s)
eCRF(s)	electronic case report form(s)
FDA	Food and Drug Administration
ITT	intent-to-treat
LOCF	last observation carried forward
MedDRA	Medical Dictionary for Regulatory Activities
MIC	Minimum inhibitory concentration
MITT	Modified intent-to-treat
n	number of observations
N	number of subjects (sample size)
OTC	over-the-counter
PP	per-protocol
QST	QST Consultations, Ltd.
SAE(s)	serious adverse event(s)
SAS®	Statistical Analysis System (SAS® Institute Inc., Cary, NC)
SD	standard deviation
SOP(s)	Standard Operating Procedures
TEAE(s)	treatment-emergent adverse event(s)
US	United States
WHO	World Health Organization
WHO-DDE	World Health Organization Drug Dictionary

2. INTRODUCTION

Otomycosis is a fungal otitis associated with organisms from the *Candida* and *Aspergillus* genera. The signs and symptoms of otomycosis are pruritus, debris, the presence of fungal elements, and pain. While antifungal agents including miconazole are used in practice for the treatment of fungal otitis externa (also called otomycosis), there are currently no treatments approved by the United States (US) Food and Drug Administration (FDA) for this indication in humans. Miconazole is an imidazole antifungal agent that has been available by prescription and over the counter (OTC), in different formulations, for many years. It is commonly used for different types of fungal skin infections, such as *Candida*, ringworm, jock itch, athlete's foot, nail fungus, vaginal yeast infections, and oropharyngeal candidiasis. The purpose of this study is to gather preliminary data on the efficacy and safety of 2% miconazole oil after topical otic administration in subjects with otomycosis. The objectives of the study are to obtain preliminary evidence of the efficacy and safety of miconazole oil compared with vehicle over a 14-day treatment duration; and descriptively compare the efficacy and safety of miconazole oil over treatment durations of 7 versus 14 days. Approximately 75 male or female subjects with otomycosis will receive study drug. Subjects will be randomly assigned in a 1:1:1 ratio to receive miconazole oil [administered as 5 drops per ear at ~30 mg per drop instilled into the external ear canal of the ear(s) affected by otomycosis] for 7 or 14 days, or vehicle for 14 days. Efficacy assessments will include fungal culture of the affected ear(s), assessments of clinical signs and symptoms of otomycosis, and a subject global assessment. In cases of bilateral otomycosis, both ears will be treated and evaluated by the investigator, but the ear with the worse infection at Screening/Baseline, as assessed by the investigator by taking into account both clinical signs and symptoms and fungal culture results, will be used as the study ear for efficacy analyses. If both ears are determined by the investigator to have the same degree of infection at Screening/Baseline, the left ear will be used as the study ear for the purposes of efficacy analyses.

Hill Dermaceuticals, Inc. is pursuing the development of Miconazole as a topically applied ergosterol biosynthesis inhibitor for the treatment of otomycosis. The mechanisms of action of miconazole when used topically for the treatment of fungal infections involve its actions against the fungal organisms, rather than their human host. Miconazole targets the cytochrome P450-dependent enzyme 14-α-sterol demethylase, an enzyme that is also involved in mammalian cholesterol synthesis, resulting in inhibition of ergosterol biosynthesis in the cell membrane.

While miconazole has not been FDA-approved for otic administration for any indication in humans, clinical studies in other countries of otically-administered miconazole have been conducted and support the efficacy of miconazole in the treatment of otomycosis. The 2% concentration of miconazole is selected for this study due to the results of an internal study

conducted by the sponsor *in vitro* demonstrating greater zones of inhibition against *Candida* and *Aspergillus* using the 2% concentration compared with the 1% concentration. Furthermore, the 2% miconazole concentration is commonly used for dermatophyte infections, and topical application is expected to be ≥1000-fold the minimum inhibitory concentrations (MICs) of the *Candida* and *Aspergillus* organisms most commonly associated with human otomycosis in the US. Miconazole at a strength of 2.0% has been selected as the concentration to take forward in Phase 2 development.

This study, HD-MCZ-PHII-DRF062016, is one of the confirmatory Phase 2 trials being conducted to assess the efficacy and safety of Miconazole in subjects with otomycosis.

3. STUDY OBJECTIVES

The objective of this study will be to assess the efficacy and safety of Miconazole oil compared to a placebo oil vehicle when applied twice daily (BID) for 14 days in subjects with otomycosis. Descriptively compare the efficacy and safety of miconazole oil over treatment durations of 7 versus 14 days.

4. STUDY DESIGN

4.1. Overall Study Design

This study is a randomized, partially blinded, multiple-dose, parallel-group design study conducted at up to 10 study centers in the US. Approximately 75 male or female subjects with otomycosis will receive study drug. Subjects will be randomly assigned in a 1:1:1 ratio to receive miconazole oil [administered as 5 drops per ear at ~30 mg per drop instilled into the external ear canal of the ear(s) affected by otomycosis] for 7 or 14 days, or vehicle for 14 days. Interim assessments are planned to ensure that there is a sufficient number of subjects within each group for the primary analysis. If deemed necessary the randomization ratio may be adjusted following the interim assessments, see section 6.1.6 for details. For subjects assigned to the 14-day treatment duration with either miconazole oil or vehicle, the contents of the study drug will be blinded to both the subject and the investigator and study staff (i.e., double-blind), but the treatment duration assigned to each subject (7 or 14 days) will be unblinded to both the subject and the investigator and study staff.

At Screening/Baseline (Day 1), the subject will then begin treatment with study drug. All subjects will return to the clinic on Day 8. For subjects randomized to the 7-day treatment duration, this visit will constitute the End of Treatment Visit. Subjects randomized to the 7-day treatment duration will not administer study drug on the day of this visit. All other subjects will

continue to administer the study drug twice per day, up through Day 14, following the same instructions as provided at the Screening/Baseline Visit on Day 1.

All subjects will return to the clinic on Day 15. For subjects randomized to the 7-day treatment duration, this visit will constitute the Test of Cure Visit. For subjects randomized to the 14-day treatment duration, this visit will constitute the End of Treatment Visit. Subjects randomized to the 14-day treatment duration will not administer study drug on the day of this visit. Subjects randomized to the 14-day durations will return to the clinic on Day 22 for the Test of Cure Visit.

Efficacy assessments will include fungal culture of the affected ear(s), assessments of clinical signs and symptoms of otomycosis, and a subject global assessment. In cases of bilateral otomycosis, both ears will be treated and evaluated by the investigator, but the ear with the worse infection at Screening/Baseline, as assessed by the investigator by taking into account both clinical signs and symptoms and fungal culture results, will be used as the study ear for efficacy analyses. If both ears are determined by the investigator to have the same degree of infection at Screening/Baseline, the left ear will be used as the study ear for the purposes of efficacy analyses.

Safety assessments will include AEs.

4.1.1. Schedule of Visits and Assessments

The study schedule can be found in Section 6.1 of the protocol.

4.1.2. Method of Assigning Subjects to Treatment Groups

A randomization schedule will be generated in SAS® using PROC PLAN by a member in the QST Consultations, Ltd. (QST) Statistical Services department who is not associated with the conduct or analysis of the study. The randomization schedule will be stratified by site and separate lists will be produced for each site. Sites will receive sequentially numbered kits randomized in blocks of six in a 1:1:1 ratio.

At the Baseline/Day 1 visit, qualified subjects will be assigned to the lowest numerically available kit at the time of randomization. The assignment of the lowest numerically available kit number must be strictly adhered to as it is the method of randomization for this study. The kit number will be recorded in the electronic case report form (eCRF). Subjects will be randomized in a 1:1:1 ratio to one of three groups: 1) 7-day treatment with miconazole oil; 2) 14-day treatment with miconazole oil; or 3) 14-day treatment with miconazole oil vehicle.

4.1.3. Blinding

The Sponsor, the clinical research organization, the investigator, study site personnel and subjects will be blinded to the treatment assignment if the subject is randomized to a 14-day treatment group. Otherwise subjects in the 7 day treatment group will unblinded. The randomization schedule will be kept strictly confidential and accessible only to authorized persons. Only when the study has been completed, the populations determined, and the study database locked will the randomization schedule be made available for analysis.

The integrity of this clinical study must be maintained by observing the treatment blind. If an adverse event occurs which cannot be managed without knowing whether the subject is receiving active study drug or vehicle solution, the investigator should contact the unblinded sponsor staff to obtain treatment assignment information. The Medical Monitor must be notified whenever study medication is unblinded, preferably prior to unblinding a subject. The duration of treatment will not be blinded. For subjects randomized to the 14-day treatment durations, the contents of the study drug (miconazole oil versus vehicle) will be blinded. Randomized study drug will be packaged in identical bottles and will be labeled with a randomization number rather than the contents of the bottle.

For subjects randomized to the 14-day durations, if it becomes necessary to unblind a subject's treatment assignment in case of emergency, the investigator should contact the unblinded sponsor staff. A person at the sponsor organization who is not otherwise involved with the study will maintain a randomization list that will enable that person to inform the investigator of the subject's treatment allocation. The treatment allocation is to be obtained only if a medical emergency exists and knowledge of the medication being taken will influence the medical management of the subject.

5. EFFICACY AND SAFETY ENDPOINTS

5.1. Efficacy Endpoints

The primary and secondary endpoints will be based on the investigator reporting of signs and symptoms for the study ear. Other efficacy endpoints will be based on the subject reporting of the symptom of pruritus.

5.1.1. Primary Efficacy Endpoints

The primary efficacy endpoint is

- The percentage of subjects at the Test of Cure Visit with "therapeutic cure," defined as a negative mycological [fungal] culture plus "clinical cure" for the study ear. Clinical cure

is defined as the absence of all otomycosis signs and symptoms based on Investigator assessment according to the scales for each individual sign or symptom and with absence defined as a score of 0 on each of the scales for pruritus, debris, fungal elements, and pain.

5.1.2. Secondary Efficacy Endpoints

The secondary efficacy endpoints are as follows:

- Percentage of subjects with clinical cure at the Test of Cure Visit
- Percentage of subjects with a negative fungal culture at the Test of Cure Visit
- Percentage of subjects with a negative fungal culture at the Test of Cure visit as well as individual sign or symptom score of 0 or 1 on each of the scales for pruritus and debris and a score of 0 on each of the scales for fungal elements and pain.
- Percentage of subjects with individual signs or symptoms with a score of 0 or 1 on each of the scales for pruritus and debris and a score of 0 on each of the scales for fungal elements and pain.
- Subject global assessments at Baseline and Test of Cure as well as categorical shifts in the subject global assessment scale scores from the Screening/Baseline to the Test of Cure Visit.

Analyses may also be conducted by fungal organism isolated at Screening/Baseline if a common organism is isolated by at least 5 subjects.

5.1.3. Additional Efficacy Endpoints

Other efficacy endpoints based on subject reporting of pruritus will include the following:

- Subject therapeutic cure (defined as a negative mycological culture plus clinical cure) at the Test of Cure Visit for the study ear based on subject assessment of pruritus. Clinical cure is defined as the absence of all otomycosis signs and symptoms according to the scales for each individual sign or symptom and with absence defined as a score of 0 on each of the scales for pruritus, debris, fungal elements, and pain.

5.2. Safety Endpoints

Safety endpoints will be the percentage of subjects with treatment-emergent AEs, with treatment-emergent defined as occurring upon or after administration of the first dose of study drug.

6. STATISTICAL AND ANALYTICAL PLANS

6.1. General Methodology

All statistical processing will be performed using SAS® unless otherwise stated. No interim analyses are planned.

No formal hypotheses will be tested in this study. Descriptive comparisons will be made between the micronazole oil and the oil vehicle groups for subjects randomized to the 14-day groups. Additionally, descriptive comparisons will be made between the 7-day and 14-day groups for subject's randomized to the miconazole oil treatment.

Descriptive statistics will be used to provide an overview of the efficacy and safety results. For categorical parameters, the number and percentage of subjects in each category will be presented. For continuous parameters, descriptive statistics will include n (number of subjects), mean, standard deviation (SD), median, minimum, and maximum.

The primary method of handling missing efficacy data will be the method of last observation carried forward (LOCF) imputation.

6.1.1. Statistical Analysis

All analyses will be performed by QST using SAS® Version 9.3 or later. All summary tables and data listings will be prepared utilizing SAS® software.

The standard operating procedures (SOPs) of QST will be followed in the creation and quality control of all data displays and analyses.

6.1.2. Baseline Definition

Baseline is defined as the last non-missing assessment prior to first dose of study drug.

6.1.3. Visit Mapping

Data will be summarized based on nominal visit indications with the exception of data captured at early termination and unscheduled visits. Data from early termination and unscheduled visits will be summarized based on mapped visit values. The analysis windows for early termination and unscheduled visits are presented in the following table.

Analysis Windows for Efficacy and Safety Assessments

Scheduled Visit	Target Study Day	Analysis Window (Days)
Day 8	8	4 to 11

Day 15	15	12 to 18
Day 22	22	19 to 30

Data collected at early termination and unscheduled visits prior to study day 4 will not be analyzed, with the exception of those identified as baseline values. Data collected at early termination and unscheduled visits after study day 30 will not be included in the analyses.

The definition for the study day included in each analysis window is defined as below:

Study Day prior to Baseline Visit = Visit Date – Baseline Visit Date

Study Day on or after Baseline Visit = Visit Date – Baseline Visit Date + 1

If an assessment's mapped visit is a visit at which the subject has data from a scheduled visit, or if no analyses are planned for the assessment at the mapped visit, the data collected at the early termination or unscheduled visit will not be included in analyses.

In the event of multiple values from unscheduled or early termination assessments within an analysis window, the value closest to the scheduled visit target study day will be used for analyses. If two values tie as closest to the time point (for example, one value is before and the other value is after the time point), then the later value will be selected.

Data collected at all visits will be included in the data listings with visit presented as reported by the site.

6.1.4. Adjustments for Covariates

Not applicable to this study.

6.1.5. Handling of Dropouts or Missing Data

Missing values from the Test of Cure visit from which the dichotomized Therapeutic Cure is derived will be imputed using LOCF method.

6.1.6. Interim Analyses and Data Monitoring

An interim assessment of the treatment allocation will be performed to ensure that there is a sufficient number of subjects within and across treatment arms. A subject's MITT status (specifically positive fungal culture at baseline) is determined only after randomization which may result in an imbalance between treatment groups. Therefore, at least one assessment during the conduct of the study is planned to ensure that there is a sufficient number of subjects within each group for the primary analysis. Once at least 10 MITT subjects have been enrolled in the 7-Day active group, the numbers of MITT subjects in the 14-Day active group and the 14-Day

vehicle group will be determined by an unblinded statistician; no persons involved in the day to day conduct of the study will be unblinded. Randomization allocation for future subjects may be adjusted if deemed necessary to achieve minimum number of subjects within each arm. At the time of the assessment, the 7-Day active kits will be removed from the randomization schedule for future subjects and the table below will be used as a guide for adjustments to the randomization allocation of 14-Day kits for future subjects. This assessment may be repeated in order to ascertain that a minimum enrollment of MITT subjects is met for each treatment group before study end.

14-Day Active	14-Day Vehicle	Action
≥ e + 3	≤ e – 3	Skip 14-Day Active kits
≥ e + 2	e - 2	Skip 14-Day Active kits with the exception of one kit at each site. One of the four lowest 14-Day Active kit numbers will be selected at random to remain in the schedule for each site.
e – 1 to e + 2	e – 1 to e + 2	No action
e - 2	≥ e + 2	Skip 14-Day Vehicle kits with the exception of one kit at each site. One of the four lowest 14-Day Active kit numbers will be selected at random to remain in the schedule for each site.
≤ e - 3	≥ e + 3	Skip 14-Day Vehicle kits
Note: e represents the expected number of subjects based on a 1:1 ratio and the current number of MITT subjects between the 14-Day active and 14-Day vehicle groups. e = ½ * (Current number of MITT subjects between the 14-Day groups), non-integer results will be rounded down to the nearest integer. When determining an action the conditions of both the 14-Day Active and 14-Day Vehicle columns must be met.		

6.1.7. Multicenter Studies

Not applicable to this study.

6.1.8. Multiple Comparisons/Multiplicity

No adjustments for multiple comparisons or multiplicity will be made.

6.1.9. Use of an Efficacy Subset of Subjects

Subjects with a clinical diagnosis of otomycosis confirmed by a positive fungal culture, who are randomized to study drug, have received at least one dose of study medication, and who do not have major protocol deviations will form the Per Protocol (PP) Population. The major protocol deviations will be defined at the time of evaluability evaluation, the time between the database soft lock and hard lock before unblinding.

Excluding subjects who have major protocol deviations will decrease the variability in treatment response and will allow for a better determination of dose-response relationship of miconazole.

6.1.10. Active-Control Studies Intended to Show Equivalence

Not applicable to this study.

6.1.11. Examination of Subgroups

Not applicable to this study.

6.2. Disposition of Subjects

The number of subjects included in each analysis population (randomized, ITT, MITT, safety, PP) will be summarized by treatment group. The number of subjects who completed and discontinued (including the reasons for discontinuation) will be summarized for each treatment group.

The ear being treated (Left, Right, Both) will be summarized by treatment group as well as an indication of worse ear if "Both" is selected for the ear being treated.

Subjects who are excluded from an analysis population will be summarized by the reasons for exclusion based on primary reason for exclusion.

6.3. Protocol Deviations

Protocol deviations will not be entered into the database. Deviations leading to exclusion from analysis populations will be identified. Protocol deviations will be presented in a by-subject listing.

6.4. Data Sets Analyzed

Subjects will be summarized based on the primary reason for exclusion. Below is the order to be used in summaries:

6.4.1. Intent-to-Treat (ITT) Population

All subjects who were randomized and dispensed study drug will be included in the ITT population.

6.4.2. Modified Intent-to-Treat (MITT) Population

All subjects in the ITT population with a clinical diagnosis of otomycosis confirmed by positive fungal culture will be included in the MITT population and analyzed according to the treatment group they were randomized. All efficacy analyses will be presented using the MITT population.

6.4.3. Per-Protocol (PP) Population

The PP population will be a subset of the MITT population and will include all subjects who complete the Test of Cure visit without any major protocol violations. The PP population will include subjects in the MITT population who did not meet any of the following criteria:

- Violated the inclusion/exclusion criteria
- Used an interfering concomitant medication
- Did not attend the Test of Cure visit
- Did not attend the End of Treatment visit
- Have not been compliant with the dosing regimen (i.e., subjects must have received 80%-120% of the expected applications of study medication in the study ear during participation in the study)
- Out of visit window at the Test of Cure Visit (-1/+8 days)

Subjects who discontinue from the study due to an adverse event related to study treatment, documented lack of treatment effect, or worsening of condition will be included in the PP population. Prior to breaking the blind, other additional criteria may be added to the list to accommodate for unforeseen events that occurred during the conduct of the trial that result in noteworthy study protocol violations.

All efficacy analyses will be performed on the PP population.

6.4.4. Safety Population

All subjects in the ITT population who received at least one dose of the study drug and had at least one post-Baseline safety assessment will be included in the safety population and analyzed

according to the treatment group they received. All safety analyses will be performed using the safety population.

6.5. Demographic and Other Baseline Characteristics

All demographic and baseline characteristic summaries will be done for the MITT, PP, and safety populations.

Sex, race, and ethnicity will be summarized by counts and percentages. Age will be summarized with descriptive statistics.

Baseline mycological culture, signs and symptoms of otomycosis, and subject global assessment will be summarized with descriptive statistics.

Medical histories will be coded using the Medical Dictionary for Regulatory Activities (MedDRA) dictionary and presented in a by-subject listing.

6.6. Prior and Concomitant Medications

Concomitant medications will be coded to preferred name and Anatomical Therapeutic Chemical (ATC) classification of ingredients using the World Health Organization (WHO) Drug dictionary (WHO-DDE)

Counts and percentages will be provided to summarize the use of medications other than the study drug reported throughout the study. The number and percent of subjects who took other therapy will be shown by ATC level 2 term and preferred name. Medications which start prior to first dose will be considered prior medications. Ongoing medications and medications ending after the date of first dose will be considered concomitant medications. Medications which are both prior and concomitant will be included in both summaries. Incomplete start and end dates which could be either prior to first dose or after first dose will be considered prior to first dose.

A by-subject listing of all prior and concomitant medications will be presented.

6.7. Analysis of Efficacy

6.7.1. Primary Efficacy Analysis

The primary population for all efficacy analyses will be the MITT population. Efficacy endpoints will also be summarized for the PP population and will be considered supportive.

The percentage of subjects who demonstrate a positive outcome for each efficacy endpoint will be presented for the primary efficacy parameter as well as all secondary efficacy parameters.

In cases of bilateral otomycosis, the ear with the worse infection at Screening/Baseline, as assessed by the investigator by taking into account both clinical signs and symptoms and fungal culture results, will be used as the study ear for efficacy analyses. If both ears are determined by the investigator to have the same degree of infection at Screening/Baseline, the left ear will be used as the study ear for the purposes of efficacy analyses.

The Test of Cure Visit is scheduled to occur on Day 15 for subjects randomized to the 7-day treatment duration, or on Day 22 for subjects randomized to the 14-day treatment durations.

The percentage of subjects with "therapeutic cure" at the Test of Cure Visit will be presented by treatment group. Subjects are defined as reaching "therapeutic cure" if they have a negative mycological culture plus "clinical cure" for the study ear, where "clinical cure" is defined as the absence of all otomycosis signs and symptoms based on Investigator assessment according to the scales for each individual sign or symptom and with absence defined as score of 0 on each of the scales for pruritus, debris, fungal elements, and pain.

In addition otomycosis signs and symptoms will be presented as the percentage of subjects with occurrences by treatment arm, assessor type (subject or investigator assessment), and visit. Subject assessments will be summarized for pruritus only.

6.7.2. Secondary Efficacy Analysis

The percentage of subjects with clinical cure at the Test of Cure visit will be presented by treatment group.

The same analysis will be done for the following endpoints:

- Percentage of subjects with a negative fungal culture at the Test of Cure Visit
- Percentage of subjects with a negative fungal culture at the Test of Cure visit as well as individual sign or symptom score of 0 or 1 on each of the scales for pruritus and debris and a score of 0 on each of the scales for fungal elements and pain.
- Percentage of subjects with individual signs or symptoms with a score of 0 or 1 on each of the scales for pruritus and debris and a score of 0 on each of the scales for fungal elements and pain.
- Frequency counts and percentages will be presented for the subject global assessments at Screening/Baseline and Test of Cure by treatment group. A categorical shift analysis (with categories of None, Minor, and Moderate) in the subject global assessment scale scores from the Screening/Baseline to the Test of Cure Visit will also be presented similarly. Only subjects with results at both the Screening/Baseline and the Test of Cure Visit will be considered in the shift analysis.

In addition the subject global assessment will be presented in frequency counts and percentages for all study visits.

If feasible, analyses may also be conducted by fungal organism isolated at Screening/Baseline.

The secondary efficacy analysis will be presented on both the MITT and PP populations.

6.7.3. Other Efficacy Analysis

The counts and percentages of subjects with "subject therapeutic cure" at the Test of Cure Visit will be presented by treatment group. Subjects are defined as reaching "subject therapeutic cure" if they have a negative mycological culture plus "subject clinical cure" for the study ear, where "subject clinical cure" is defined as the absence of all otomycosis signs and symptoms based on subject assessed pruritus.

6.8. Safety Evaluation

6.8.1. Extent of Exposure

The extent of exposure to study drug in each treatment group will be summarized by total number of days of exposure, total number of applications, number of missed applications and number and percentage of subjects who are compliant. A subject will be considered compliant with the dosing regimen if the subject applied 80% to 120% of the expected number of applications while enrolled in the study.

Days of exposure = Date of last study application – Date of first study application + 1

Total Number of Applications:

2*(Date of Last Application – Date of First Application + 1) – (Number of doses missed as collected on the case report form (CRF)) + (Number of extra doses as collected on the CRF)

Total Number of Expected Applications:

2*(End of Treatment Visit Date – Date of Randomization).

If the total number of expected applications exceeds 14 for the 7-Day treatment group then the total number of expected applications will be set to 14. If the total number of expected applications exceeds 28 for the 14-Day treatment group then the total number of expected applications will be set to 28.

Compliance will be calculated as a percentage as 100 times the total number of applications divided by the total number of expected applications.

6.8.2. Medical History

Medical history results will only be shown in a by-subject listing.

6.8.3. Adverse Events

All AEs that occur during the study will be recorded and classified on the basis of MedDRA terminology. Treatment-emergent AEs (TEAEs) are defined as AEs with an onset on or after the date of the first study drug application.

TEAEs will be summarized by treatment group, the number of subjects reporting a TEAE, system organ class, preferred name, severity, relationship to study drug (causality), and seriousness. When summarizing AEs by severity and relationship, each subject will be counted once within a system organ class or a preferred term by using the event with the highest severity and greatest relationship within each classification.

Serious AEs (SAEs) will be summarized by treatment group, severity and relationship to study drug, and individual SAEs will be listed by subject. In addition, a list of subjects who prematurely discontinue from the study due to an AE will be provided.

No statistical inference between treatments will be performed on adverse events.

Listings will be presented for all adverse events as well as for serious adverse events, and adverse events leading to discontinuation from the study.

6.8.4. Clinical Laboratory Evaluation

Urine pregnancy test results will only be shown in a by-subject listing.

6.8.5. Physical Examination

Physical examination data will be presented in a by-subject listing.

7. DETERMINATION OF SAMPLE SIZE

The sample size for this study is not based on statistical considerations and is instead intended to be a reasonable number of subjects upon which to gather preliminary information on the efficacy and safety of miconazole oil when administered via the otic route to subjects with otomycosis.

8. CHANGES IN THE PLANNED ANALYSES

There are no changes in the conduct of the study or planned analyses.

9. INDEX OF PLANNED TABLES

Table 14.0.1: Summary of Subject Enrollment and Evaluability

	7-Day Miconazole Oil	14-Day Miconazole Oil	14-Day Vehicle Oil
Number of Subjects Randomized	xx	xx	xx
Number of Subjects Excluded from the ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the MITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the MITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Included in the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.0.2: Summary of Subjects Excluded from Analyses
(Randomized Subjects)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Number of Subjects Excluded from the ITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the ITT Population			
Not Dispensed Study Drug	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the MITT Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the MITT Population			
Not Dispensed Study Drug	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No Positive Otomycosis Diagnosis	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the Safety Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the Safety Population			
Not Dispensed Study Drug	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No Post Baseline Assessment	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number of Subjects Excluded from the PP Population	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Exclusion from the PP Population			
Not Dispensed Study Drug	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No Positive Otomycosis Diagnosis	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Violated the inclusion/exclusion criteria	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Used an interfering concomitant medication	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Did not attend the Test of Cure Visit	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Have not been compliant with the dosing regimen	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Out of visit window at the Test of Cure Visit	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.0.3: Summary of Subject Treatment Completion/Discontinuation
(Randomized Subjects)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Completed Study			
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Reason for Discontinuation			
Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Lost To Follow-Up	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pregnancy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Protocol Deviation	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Subject	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Withdrawal by Parent/Guardian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Physician Decision	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Study Terminated by Sponsor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Other[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing 16.2.1.2 for other discontinuation reasons.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.1: Summary of Subject Demographics
(Modified Intent-To-Treat Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Age (years)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Sex			
n	xx	xx	xx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity			
n	xx	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race			
n	xx	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or 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[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing 16.2.4.1 for a complete list of all other races.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.2: Summary of Subject Demographics
(Per-Protocol Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Age (years)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Sex			
n	xx	xx	xx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity			
n	xx	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race			
n	xx	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or 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[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing 16.2.4.1 for a complete list of all other races.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.1.3: Summary of Subject Demographics
(Safety Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Age (years)			
n	xx	xx	xx
Mean	xx.x	xx.x	xx.x
SD	xx.xx	xx.xx	xx.xx
Median	xx.x	xx.x	xx.x
Min. to Max.	xx to xx	xx to xx	xx to xx
Sex			
n	xx	xx	xx
Male	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Female	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Ethnicity			
n	xx	xx	xx
Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Hispanic or Latino	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Race			
n	xx	xx	xx
American Indian or Alaska Native	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Asian	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Black or 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[a]	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] See Listing 16.2.4.1 for a complete list of all other races.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Subject Baseline Characteristics
(Modified Intent-To-Treat Population)
(Page 1 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Otomycosis Mycological Culture			
n	xx	xx	xx
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pruritus			
Subject Assessed			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Investigator Assessed			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Table only includes assessments of the study ear.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.1: Subject Baseline Characteristics
(Modified Intent-To-Treat Population)
(Page 2 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Debris			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Scant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heavy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Presence of Fungal Elements			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pain			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subject Global Assessment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Table only includes assessments of the study ear.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.2: Subject Baseline Characteristics
(Per-Protocol Population)
(Page 1 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Otomycosis Mycological Culture			
n	xx	xx	xx
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pruritus			
Subject Assessed			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Investigator Assessed			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Table only includes assessments of the study ear.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.2: Subject Baseline Characteristics
(Per-Protocol Population)
(Page 2 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Debris			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Scant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heavy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Presence of Fungal Elements			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pain			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subject Global Assessment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Table only includes assessments of the study ear.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.3: Subject Baseline Characteristics
(Safety Population)
(Page 1 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Otomycosis Mycological Culture			
n	xx	xx	xx
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pruritus			
Subject Assessed			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Investigator Assessed			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Table only includes assessments of the study ear.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.1.2.3: Subject Baseline Characteristics
(Safety Population)
(Page 2 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Debris			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Scant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heavy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Presence of Fungal Elements			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Pain			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Subject Global Assessment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Table only includes assessments of the study ear.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.1: Summary of Primary Efficacy Endpoint: Therapeutic Cure at Test of Cure
(Modified Intent-to-Treat Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Therapeutic Cure [a] at Test of Cure			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Therapeutic Cure is defined as a negative mycological culture plus Clinical Cure for the study ear. Clinical Cure is defined as the absence of all otomycosis signs and symptoms based on Investigator assessment according to the scales for each individual sign or symptom and with absence defined as a score of 0 on each of the scales for pruritus, debris, fungal elements, and pain.

Note: Last observation carried forward (LOCF) used to impute missing values.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.1.2: Summary of Primary Efficacy Endpoint: Therapeutic Cure at Test of Cure
(Per-Protocol Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Therapeutic Cure [a] at Test of Cure			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Therapeutic Cure is defined as a negative mycological culture plus Clinical Cure for the study ear. Clinical Cure is defined as the absence of all otomycosis signs and symptoms based on Investigator assessment according to the scales for each individual sign or symptom and with absence defined as a score of 0 on each of the scales for pruritus, debris, fungal elements, and pain.

Note: Last observation carried forward (LOCF) used to impute missing values.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.1: Summary of Secondary Efficacy Endpoints: Mycological Culture and Individual Signs and Symptoms
(Modified Intent-to-Treat Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Clinical Cure [a] at Test of Cure			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative Mycological Culture at Test of Cure			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative Mycological Culture and Individual Sign or Symptom Score of 0 or 1 on each of the Scales for Pruritus and Debris and a Score of 0 on each of the Scales for Fungal Elements and Pain at Test of Cure.			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Individual Sign or Symptom Score of 0 or 1 on each of the Scales for Pruritus and Debris and a Score of 0 on each of the Scales for Fungal Elements and Pain at Test of Cure.			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Clinical Cure is defined as the absence of all otomycosis signs and symptoms based on Investigator assessment according to the scales for each individual sign or symptom and with absence defined as a score of 0 on each of the scales for pruritus, debris, fungal elements, and pain.
Note: Last observation carried forward (LOCF) used to impute missing values.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.1.2: Summary of Secondary Efficacy Endpoints: Mycological Culture and Individual Signs and Symptoms Endpoints
(Per-Protocol Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Clinical Cure [a] at Test of Cure			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative Mycological Culture at Test of Cure			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative Mycological Culture and Individual Sign or Symptom Score of 0 or 1 on each of the Scales for Pruritus and Debris and a Score of 0 on each of the Scales for Fungal Elements and Pain at Test of Cure.			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Individual Sign or Symptom Score of 0 or 1 on each of the Scales for Pruritus and Debris and a Score of 0 on each of the Scales for Fungal Elements and Pain at Test of Cure.			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Clinical Cure is defined as the absence of all otomycosis signs and symptoms based on Investigator assessment according to the scales for each individual sign or symptom and with absence defined as a score of 0 on each of the scales for pruritus, debris, fungal elements, and pain.
Note: Last observation carried forward used to impute missing values.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.2.1: Summary of Secondary Efficacy Endpoint: Subject Global Assessment
(Modified Intent-to-Treat Population)

	7-Day Miconazole Oil (N=xx)		14-Day Miconazole Oil (N=xx)		14-Day Vehicle Oil (N=xx)	
Subject Global Assessment	Baseline	Test of Cure	Baseline	Test of Cure	Baseline	Test of Cure
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	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%)	xx (xx.x%)	xx (xx.x%)

	7-Day Miconazole Oil (N=xx) Test of Cure			14-Day Miconazole Oil (N=xx) Test of Cure			14-Day Vehicle Oil (N=xx) Test of Cure		
Baseline	None	Minor	Moderate	None	Minor	Moderate	None	Minor	Moderate
None	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%)
Minor	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%)
Moderate	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%)

Note: No imputation of missing values.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.2.2: Summary of Secondary Efficacy Endpoint: Subject Global Assessment
(Per-Protocol Population)

	7-Day Miconazole Oil (N=xx)		14-Day Miconazole Oil (N=xx)		14-Day Vehicle Oil (N=xx)	
Subject Global Assessment	Baseline	Test of Cure	Baseline	Test of Cure	Baseline	Test of Cure
n	xx	xx	xx	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	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%)	xx (xx.x%)	xx (xx.x%)

	7-Day Miconazole Oil (N=xx)			14-Day Miconazole Oil (N=xx)			14-Day Vehicle Oil (N=xx)		
	Test of Cure			Test of Cure			Test of Cure		
Baseline	None	Minor	Moderate	None	Minor	Moderate	None	Minor	Moderate
None	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%)
Minor	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%)
Moderate	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%)

Note: No imputation of missing values.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.1: Otomycosis Mycological Culture Through Time
(Modified Intent-To-Treat Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Otomycosis Mycological Culture			
Baseline			
n	xx	xx	xx
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
Positive		xx (xx.x%)	xx (xx.x%)
Negative		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Test of Cure			
n	xx	xx	xx
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.3.2: Otomycosis Mycological Culture Through Time
(Per-Protocol Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Otomycosis Mycological Culture			
Baseline			
n	xx	xx	xx
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
Positive		xx (xx.x%)	xx (xx.x%)
Negative		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Test of Cure			
n	xx	xx	xx
Positive	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Negative	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.4.1: Investigator Assessed Pruritus Through Time
(Modified Intent-To-Treat Population)
(Page 1 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Investigator Assessed Pruritus			
Baseline			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
None		xx (xx.x%)	xx (xx.x%)
Mild		xx (xx.x%)	xx (xx.x%)
Moderate		xx (xx.x%)	xx (xx.x%)
Severe		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.4.1: Investigator Assessed Pruritus Through Time
(Modified Intent-To-Treat Population)
(Page 2 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Investigator Pruritus			
Test of Cure			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.4.2: Investigator Assessed Pruritus Through Time
(Per-Protocol Population)
(Page 1 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Investigator Assessed Pruritus			
Baseline			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
None		xx (xx.x%)	xx (xx.x%)
Mild		xx (xx.x%)	xx (xx.x%)
Moderate		xx (xx.x%)	xx (xx.x%)
Severe		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.4.2: Investigator Assessed Pruritus Through Time
(Per-Protocol Population)
(Page 2 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Investigator Pruritus			
Test of Cure			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.5.1: Debris Through Time
(Modified Intent-To-Treat Population)
(Page 1 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Debris			
Baseline			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Scant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heavy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
None		xx (xx.x%)	xx (xx.x%)
Scant		xx (xx.x%)	xx (xx.x%)
Moderate		xx (xx.x%)	xx (xx.x%)
Heavy		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Scant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heavy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.5.1: Debris Through Time
(Modified Intent-To-Treat Population)
(Page 2 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Debris			
Test of Cure			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Scant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heavy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.5.2: Debris Through Time
(Per-Protocol Population)
(Page 1 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Debris			
Baseline			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Scant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heavy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
None		xx (xx.x%)	xx (xx.x%)
Scant		xx (xx.x%)	xx (xx.x%)
Moderate		xx (xx.x%)	xx (xx.x%)
Heavy		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Scant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heavy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.5.2: Debris Through Time
(Per-Protocol Population)
(Page 2 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Debris			
Test of Cure			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Scant	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Heavy	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.6.1: Presence of Fungal Elements Through Time
(Modified Intent-To-Treat Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Presence of Fungal Elements			
Baseline			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
Absent		xx (xx.x%)	xx (xx.x%)
Present		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Test of Cure			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.6.2: Presence of Fungal Elements Through Time
(Per-Protocol Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Presence of Fungal Elements			
Baseline			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
Absent		xx (xx.x%)	xx (xx.x%)
Present		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Test of Cure			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.7.1: Pain Through Time
(Modified Intent-to-Treat Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Pain			
Baseline			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
Absent		xx (xx.x%)	xx (xx.x%)
Present		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Test of Cure			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.7.2: Pain Through Time
(Per-Protocol Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Pain			
Baseline			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
Absent		xx (xx.x%)	xx (xx.x%)
Present		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Test of Cure			
n	xx	xx	xx
Absent	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Present	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.8.1: Subject Global Assessment Through Time
(Modified Intent-To-Treat Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Subject Global Assessment			
Baseline			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
None		xx (xx.x%)	xx (xx.x%)
Minor		xx (xx.x%)	xx (xx.x%)
Moderate		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Test of Cure			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.2.8.2: Subject Global Assessment Through Time
(Per-Protocol Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Subject Global Assessment			
Baseline			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
None		xx (xx.x%)	xx (xx.x%)
Minor		xx (xx.x%)	xx (xx.x%)
Moderate		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Test of Cure			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Minor	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1.1: Summary of Other Efficacy Endpoint: Subject Therapeutic Cure at Test of Cure
(Modified Intent-to-Treat Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Subject Therapeutic Cure [a] at Test of Cure			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Therapeutic Cure is defined as a negative mycological culture plus Clinical Cure based on subject assessment of pruritus for the study ear. Clinical Cure is defined as the absence of all otomycosis signs and symptoms based on Investigator assessment according to the scales for each individual sign or symptom and with absence defined as a score of 0 on each of the scales for pruritus, debris, fungal elements, and pain.

Note: Last observation carried forward used to impute missing values.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.1.2: Summary of Other Efficacy Endpoint: Subject Therapeutic Cure at Test of Cure
(Per-Protocol Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Subject Therapeutic Cure [a] at Test of Cure			
Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Not Achieved	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Therapeutic Cure is defined as a negative mycological culture plus Clinical Cure based on subject assessment of pruritus for the study ear. Clinical Cure is defined as the absence of all otomycosis signs and symptoms based on Investigator assessment according to the scales for each individual sign or symptom and with absence defined as a score of 0 on each of the scales for pruritus, debris, fungal elements, and pain.

Note: Last observation carried forward used to impute missing values.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2.1: Subject Assessed Pruritus Through Time
(Modified Intent-To-Treat Population)
(Page 1 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Subject Assessed Pruritus			
Baseline			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
None		xx (xx.x%)	xx (xx.x%)
Mild		xx (xx.x%)	xx (xx.x%)
Moderate		xx (xx.x%)	xx (xx.x%)
Severe		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2.1: Subject Assessed Pruritus Through Time
(Modified Intent-To-Treat Population)
(Page 2 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Subject Assessed Pruritus (cont.)			
Test of Cure			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2.2: Subject Assessed Pruritus Through Time
(Per-Protocol Population)
(Page 1 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Subject Assessed Pruritus			
Baseline			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
On Treatment			
n	NA	xx	xx
None		xx (xx.x%)	xx (xx.x%)
Mild		xx (xx.x%)	xx (xx.x%)
Moderate		xx (xx.x%)	xx (xx.x%)
Severe		xx (xx.x%)	xx (xx.x%)
End of Treatment			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.2.3.2.2: Subject Assessed Pruritus Through Time
(Per-Protocol Population)
(Page 2 of 2)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Subject Assessed Pruritus (cont.)			
Test of Cure			
n	xx	xx	xx
None	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Subjects in the 14-day treatment duration will have the follow-up visit schedule On Treatment – Day 8, End of Treatment – Day 15, and Test of Cure – Day 22. Subjects in the 7-day treatment durations will have the follow-up visit schedule End of Treatment – Day 8, and Test of Cure – Day 15.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.1: Summary of Extent of Exposure
(Modified Intent-To-Treat Population)

	Total Amount of Study Drug Used (g)	Total Number of Days of Exposure	Total Number of Applications	Total Number of Missed Applications	Compliant[a]
7-Day Miconazole Oil (N=xx)					
n	xx	xx	xx	xx	Yes xx (xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x	No xx (xx.x%)
SD	xx.x	xx.x	xx.x	xx.x	
Median	xx.xx	xx.xx	xx.xx	xx.xx	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
14-Day Miconazole Oil (N=xx)					
n	xx	xx	xx	xx	Yes xx (xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x	No xx (xx.x%)
SD	xx.x	xx.x	xx.x	xx.x	
Median	xx.xx	xx.xx	xx.xx	xx.xx	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
14-Day Vehicle Oil (N=xx)					
n	xx	xx	xx	xx	Yes xx (xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x	No xx (xx.x%)
SD	xx.x	xx.x	xx.x	xx.x	
Median	xx.xx	xx.xx	xx.xx	xx.xx	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	

[a] A subject was considered compliant with the dosing regimen if the subject applied at least 80% but no more than 120% of the expected applications while enrolled in the study.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.2: Summary of Extent of Exposure
(Per-Protocol Population)

	Total Amount of Study Drug Used (g)	Total Number of Days of Exposure	Total Number of Applications	Total Number of Missed Applications	Compliant[a]	
7-Day Miconazole Oil (N=xx)						
n	xx	xx	xx	xx	Yes	xx (xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x	No	xx (xx.x%)
SD	xx.x	xx.x	xx.x	xx.x		
Median	xx.xx	xx.xx	xx.xx	xx.xx		
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx		
14-Day Miconazole Oil (N=xx)						
n	xx	xx	xx	xx	Yes	xx (xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x	No	xx (xx.x%)
SD	xx.x	xx.x	xx.x	xx.x		
Median	xx.xx	xx.xx	xx.xx	xx.xx		
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx		
14-Day Vehicle Oil (N=xx)						
n	xx	xx	xx	xx	Yes	xx (xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x	No	xx (xx.x%)
SD	xx.x	xx.x	xx.x	xx.x		
Median	xx.xx	xx.xx	xx.xx	xx.xx		
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx		

[a] A subject was considered compliant with the dosing regimen if the subject applied at least 80% but no more than 120% of the expected applications while enrolled in the study.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.1.3: Summary of Extent of Exposure
(Safety Population)

	Total Amount of Study Drug Used (g)	Total Number of Days of Exposure	Total Number of Applications	Total Number of Missed Applications	Compliant[a]
7-Day Miconazole Oil (N=xx)					
n	xx	xx	xx	xx	Yes xx (xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x	No xx (xx.x%)
SD	xx.x	xx.x	xx.x	xx.x	
Median	xx.xx	xx.xx	xx.xx	xx.xx	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
14-Day Miconazole Oil (N=xx)					
n	xx	xx	xx	xx	Yes xx (xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x	No xx (xx.x%)
SD	xx.x	xx.x	xx.x	xx.x	
Median	xx.xx	xx.xx	xx.xx	xx.xx	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	
14-Day Vehicle Oil (N=xx)					
n	xx	xx	xx	xx	Yes xx (xx.x%)
Mean	xx.x	xx.x	xx.x	xx.x	No xx (xx.x%)
SD	xx.x	xx.x	xx.x	xx.x	
Median	xx.xx	xx.xx	xx.xx	xx.xx	
Min. to Max.	xx to xx	xx to xx	xx to xx	xx to xx	

[a] A subject was considered compliant with the dosing regimen if the subject applied at least 80% but no more than 120% of the expected applications while enrolled in the study.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)
(Page 1 of 4)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Number (%) of Subjects Reporting At Least One Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Discontinued Study Drug due to Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
By Subject			
Maximum Severity			
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%)
Strongest Relationship to Study Drug			
Not Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
By Subject			
Maximum Severity within Relationship to Study Drug			
Not Suspected			
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%)
Suspected			
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%)

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)
(Page 3 of 4)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Number Events Reported	xx	xx	xx
By Event			
Serious			
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Death			
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Discontinuation of Study Drug			
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severity			
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%)
Relationship to Study Drug			
Not Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.1: Summary of Treatment-Emergent Adverse Event Characteristics
(Safety Population)
(Page 4 of 4)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
By Event			
Severity within Relationship to Study Drug			
Not Suspected			
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%)
Suspected			
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%)

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.2: Summary of Treatment-Emergent Adverse Events Leading to Permanent Withdrawal of Study Drug and/or Early Discontinuation From Study
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.
Note: MedDRA dictionary (Version 20.1)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.3: Summary of Treatment-Emergent Adverse Events
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.
Note: MedDRA dictionary (Version 20.1)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.4: Summary of Treatment-Emergent Adverse Events by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
System Organ Class	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%)
Preferred Term	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%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.
Note: MedDRA dictionary (Version 20.1)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.2.5: Summary of Treatment-Emergent Adverse Events by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
System Organ Class	Not Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Not Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the strongest reported relationship.

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.
Note: MedDRA dictionary (Version 20.1)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 1 of 4)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Number (%) of Subjects Reporting At Least One Serious Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Died	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Number (%) of Subjects who Discontinued Study Drug due to Adverse Event	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
By Subject			
Maximum Severity			
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%)
Strongest Relationship to Study Drug			
Not Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 2 of 4)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
By Subject			
Maximum Severity within Relationship to Study Drug			
Not Suspected			
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%)
Suspected			
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%)

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 3 of 4)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Number of Serious Events Reported	xx	xx	xx
By Event			
Death			
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Discontinuation of Study Drug			
No	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Yes	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Severity			
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%)
Relationship to Study Drug			
Not Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.1: Summary of Treatment-Emergent Serious Adverse Event Characteristics
(Safety Population)
(Page 4 of 4)

	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
Severity within Relationship to Study Drug			
By Event			
Not Suspected			
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%)
Suspected			
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%)

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.2: Summary of Treatment-Emergent Serious Adverse Events
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
System Organ Class	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once.

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.
Note: MedDRA dictionary (Version 20.1)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.3: Summary of Treatment-Emergent Serious Adverse Events by Severity
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Severity	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
System Organ Class	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%)
Preferred Term	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%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the greatest reported severity.

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.
Note: MedDRA dictionary (Version 20.1)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

Table 14.3.3.4: Summary of Treatment-Emergent Serious Adverse Events by Relationship to Study Drug
(Safety Population)
(Page 1 of xx)

System Organ Class[a] Preferred Term	Relationship	7-Day Miconazole Oil (N=xx)	14-Day Miconazole Oil (N=xx)	14-Day Vehicle Oil (N=xx)
System Organ Class	Not Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
Preferred Term	Not Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Suspected	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

[a] Counts reflect numbers of subjects reporting one or more adverse events that map to MedDRA. At each level of summarization (System Organ Class or Preferred Term) subjects are counted once under the strongest reported relationship.

Note: Treatment-emergent adverse events are those with an onset on or after the date of first study drug application.
Note: MedDRA dictionary (Version 20.1)

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE,TIME)

10. INDEX OF PLANNED LISTINGS

Listing 16.1.7: Randomization Scheme
(Page xx of yy)

Subject	Age/Sex	Eval	Randomization Date	Assigned Arm	Treated Ear(s)	Worse Ear
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx	xxxx	xxx xxxxx xxxx xxxx xxxxx xxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx	xxxxx	
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxx	xxxx	

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.1.1: End of Study Information
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date of First Dose of Study Drug	Date of Last Dose of Study Drug	Reason for End of Treatment	Reason for Study Completion/ Discontinuation	Date of Study Completion/ Discontinuation (Day)[1]
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxx xx xxxxxxxxx	xxxx xx xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxx xxxxxxxxx x xxx xxxxxxxxxx	xxxxxxxx xxxxxxxxx x xxx xxxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx

[1] Day is calculated as date - date of first dose for dates prior to first dose. Otherwise, day is calculated as date - date of first dose + 1 for dates on or after first dose.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.1.2: Discontinued Subjects
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date of First Dose of Study Drug	Date of Last Dose of Study Drug	Reason for End of Treatment	Reason for Study Completion/ Discontinuation	Date of Study Completion/ Discontinuation (Day)[1]
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxx xx xxxxxxxxx	xxxx xx xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxx xxxxxxxxx x xxx xxxxxxxxxx	xxxxxxxx xxxxxxxxx x xxx xxxxxxxxxx	xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx xxxx

[1] Day is calculated as date - date of first dose for dates prior to first dose. Otherwise, day is calculated as date - date of first dose + 1 for dates on or after first dose.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.1.3: Screen Failures
(Page xx of yy)

Subject	Age/Sex	Date of Screen Failure	Failed Inclusion/ Met Exclusion Criteria	Criteria	Other Reason for Screen Failure
xxxxxx	xxxxxxxx	xxxxxxxxxx	xxx	xxxxxxxxx xxxxxxxx x	
xxxxxx	xxxxxxxx	xxxxxxxxxx	xx		xxxxx xxxx xxxx xx xxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.2.1: Inclusion/Exclusion Criteria Violations
(Page xx of yy)

Subject	Age/Sex	Eval	Date Assessed	Criteria Failed	Description
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxx	xxxxx xxx xx xxxxxxxx xxxx xxxx x xxxxxxxx xxxxxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxx	xxxxx xx xxxxxxxxx xx xxxxxx xxx xx xxxxxxxx xxxx xxxxxxxxxxxxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.3: Analysis Populations
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Population	Included	Reason(s) Excluded	Exceptions
xxxxxx	xxxx	Intent-to-Treat	xxx		
		Modified Intent-to-Treat	xxx		
		Per-Protocol	xxx		
		Safety	xxx		
xxxxxx	xxxx	Intent-to-Treat	xxx		
		Modified Intent-to-Treat	xxx		
		Per-Protocol	xx	xxxx xxxxxxxxx xxxxx xxx xx xxxxxx xxxxxx	
		Safety	xxx		
xxxxxx	xxxx	Intent-to-Treat	xxx		
		Modified Intent-to-Treat	xxx		
		Per-Protocol	xxx		
		Safety	xxx		
xxxxxx	xxxx	Intent-to-Treat	xxx		
		Modified Intent-to-Treat	xxx		
		Per-Protocol	xxx		
		Safety	xxx		
xxxxxx	xxxx	Intent-to-Treat	xxx		
		Modified Intent-to-Treat	xxx		
		Per-Protocol	xxx		
		Safety	xxx		
xxxxxx	xxxx	Intent-to-Treat	xxx		
		Modified Intent-to-Treat	xxx		
		Safety	xxx		
		Per-Protocol	xxx		

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.4.1: Subject Demographic Information
Treatment Arm
(Page xx of yy)

Subject	Eval	A: Age S: Sex	R: Race E: Ethnicity	Date of Birth	C: Childbearing Potential B: Method of Contraception	P: Protocol Version I: Informed Consent Date A: Informed Assent Date
xxxxxx	xxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxxxxxxx xx xxxxxx	xxxxxxxxxx	C: xx B:	P: xxxxxxx x I: xxxxxxxxxx A: xx
xxxxxx	xxxxxxxxx	A: xx S: xxxxxx	R: xxxxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx	C: xxx B: xxxx xxxxxxxxx	P: xxxxxxx x I: xxxxxxxxxx A: xx
xxxxxx	xxxxxxxxx	A: xx S: xxxx	R: xxxxx E: xxx xxxxxxxx xx xxxxxx	xxxxxxxxxx	C: xx B:	P: xxxxxxx x I: xxxxxxxxxx A: xx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.4.2.1: Unique Medical History Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Condition or Surgery Verbatim Term
xxxxx xxx xxxxxxxxx xxxxxx xxxxxxxxx	xxxx xxxxxxxxxx xxxxxxx	xxxx xxxxxxxxxx xxxxxx
	xxxxxxxxxxxxxxx	xxxxxxxxxxxxxxx
xxxxxxx xxxxxxxxx	xxxxxxxxxx	xxxxxxx xxxxxxxxx
	xxxxxx xxxxxxxxxxxx	xxxxxx xxxxxxxxxx
		xxxxxx xxxxxxxxxxxx
	xxxxxxxxxxxxxxxx xxxxx xxxxx xxxxxx	xxx xxxxxx xx xxxxx
	xxxxxx xxxxxx xxxxx xxxxx	xxxxx xxxxxx xxxxxx xxxxx
	xxxxxxx xxxxxxx xxxxxxxxxx	xxxxxxxxxx xxxxx xxxxxxx
	xxxxxxxxxxxxxx xxxxxxxx	xxxxxxxxxxxxxx xxxxxxxx
	xxxxxxxx xxxxxx xxxxxxx	xxxxxxxx xxxxxx xxxxxxx
	xxxxxxxxxx xxxxxxxxxx	xxxxxxxxxx xxxxxxx
		xxxxxxxxxx xxxxxxxxxx
	xxxxxxxxxxx xxxxxxxx	xxxxxxxxxxx xxxxxxxx xxxxxxxx xx xxxxxxxxxxx xxxxxx
	xxxxxxxxx xxxxx xxxxxxxxxxxx	xxxx xxxxxxxxx xxxxxxxxxxxxx
xxxxxxxxxxx xxxxxxxx xxx xxxxxxx xxxxxxxxx	xxxxxxxxxxxxxxxxxx xxxxxxxx xxxxxxxxx	xxxxx xxxxxxxx xxxxxxx xxxxxxxx xxxxxxxxx
	xxxxxxxx xxxxxxxxxx xxxxxxxx	xxxxxxxxxx
xxx xxx xxxxxxxxx xxxxxxxxx	xxxxxxxx	xxxxxxx xxxx

Note: System Organ Class and Preferred Term from MedDRA Version 20.1.

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.4.2.2: Medical History
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Condition or Surgery Verbatim Term	Physical Exam Finding	P: MedDRA Preferred Term S: MedDRA System Organ Class	S: Start Date E: End Date
xxxxxx	xxxx	xxxxxxxxxx	xxxxxx	xxx	P: xxxxxx S: xxxxxxxxxxxx xxxxxxxx xxx xxxxxxxxxxx xxxxxxxxx	S: xxxx E: xxxxxxx
			xxxxxxx xxxxxx	xx	P: xxxxxxx S: xxxxxxxxxx xxx xxxxxxxxx xxxxxxxxx	S: xxxxxxx E: xxxxxxx
			xxxxxxxxxxxxxx	xx	P: xxxxxxxxxxxxx S: xxxxxx xxxxxxxxxxxxx	S: xxxx E: xxxxxxx
			xxxxxxxxx	xx		S: xxxx E: xxxxxxx
xxxxxx	xxxx	xxxxxxxxxx	xxxx xxxxxxxxxxx	xxx	P: xxxxx xxxxxxxxxxx xxxxxxxxx S: xxxxxxxxxxxxxx	S: xxxx E: xxxxxxx
			xxxxxxxxx	xx		S: xxxx E: xxxxxxx
			xxxxxxxx xxxxxxxxx	xx	P: xxxxxxxx xxxxxxx S: xxxxxx xxxxxx xxxxxxxxx	S: xxxx E: xxxxxxx
			xxxxxxxxx	xx	P: xxxxxxxxx S: xxxxxxxx xxx xxxxxxx xxxxxxxxxx	S: xxxx E: xxxx
xxxxxx	xxxx	xxxxxxxxxx	xxxxxxxxxxxxxxxx xxxxx xxx	xx	P: xxxxxx xxxxxxxxx S: xxxxxxxx xxx xxxxxxx xxxxxxxxxx	S: xxxx E: xxxx
			xxxx xxxxxx xxxxxxx xxxx xxxx	xx	P: xxxxxxx xxxx xxxxxxxx S: xxxxxxxxxxxxxx xxx xxxxxxxxxx xxxxxx xxxxxxxxx	S: xxxx E: xxxx

Note: System Organ Class and Preferred Term from MedDRA Version 20.1.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Verbatim Term, Start Date, and End Date.

Listing 16.2.4.3: Physical Examination
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Physical Exam Performed
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxx	xxx
			xxxxxxxxxxx	xxxxxxxxxx	xx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxxxxxx	xx
			xxxxxxxxxxx	xxxxxxxxxx	xxx
			xxxxxxxxxxx	xxxxxxxxxx	xxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.4.3.1: Unique Medication Names Coded to WHO-DDE ATC Level 2 Terms and Preferred Names
(Page xx of yy)

ATC Level 2 Term	Standardized Medication Name	Medication Name	I: Indication R: Route
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
xxxxxxxxxxxxxx	xxxxxxxxxxxxxx	xxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx
		xxxxxxxxx	I: xxxxxxxxxxx R: xxxxxxxxxxx

Note: Standardized Medication Name and ATC Level 2 Term map to the WHO-DDE (Version March 1, 2017).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by ATC Level 2 Term, Standardized Medication Name, Medication Name, Indication, and Route.

Listing 16.2.4.3.2: Prior and Concomitant Medications
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	M: Medication Name I: Indication A: Applied at Dosing Site	P: Standardized Medication Name A: ATC Level 2 Term	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1]	D: Dose U: Units F: Frequency O: Route
S: xxxxxx A: xxxx E: xxxxxxxxx	M: xxxxxxxxxxxxx I: xxxxxxxx A: xx	P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxx	D: xx U: xx F: xxxx O: xxxxxx
	M: xxxxxxxxxxxxx I: xxxxxxxx A: xxx	P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxx	D: xxxxx U: xx F: xx O: xxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	M: xxxxxxxxxxxxx I: xxxxxxxx A: xx	P: xxxxxxxxxxxxx A: xxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxx	D: xxx U: xx F: xx O: xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
Note: Standardized Medication Name and ATC Level 2 Term map to the WHO-DDE (Version March 1, 2017).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, Medication Name, Indication, and Route.

Listing 16.2.4.4: Prior and Concomitant Procedures/Therapies
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date of First Dose	Procedure/ Theraphy	Indication	Applied at Dosing Site	S: Start Date (Day)[1] E: End Date (Day)[1]
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxxxx	xxxxxxxx	xx	S: xxxxxxxxxx xxxx E: xxxxxxx
				xxxxxxxxxxxx	xxxxxxxx	xxx	S: xxxxxxxxxx xxxx E: xxxxxxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxxxxxx	xxxxxxxx	xx	S: xxxxxxxxxx xxxx E: xxxxxxx xxxx

[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, Medication Name, Indication, and Route.

Listing 16.2.5.1: Study Visit Compliance
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Visit Date	Study Day[1]	Within Visit Window	Visit Not Done/ Reason for Unscheduled Visit	Ear(s) Cleaned
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx	xxx		xxxxx xxxxxx
			xxxxxxxx	xxxxxxxxxx	xx	xxx		xxxx
			xxxxxx	xxxxxxxxxx	xx	xxx		xxxx
xxxxxx	xxxx	xxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xx	xxx		xxxxxx xxxxx
			xxxxxxxx	xxxxxxxxxx	xx	xxx		xxxx
			xxxxxx	xxxxxxxxxx	xx	xxx		xxxxx
			xxxxxx	xxxxxxxxxx	xx	xxx		xxxxx

[1] Day is calculated as date - baseline date for dates prior to baseline visit. Otherwise, day is calculated as date - Baseline date + 1 for dates on or after baseline visit.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.5.2: Subject Dosing Compliance
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	F: Date of First Dose L: Date of Last Dose	Number of Days of Exposure	Calculated[1] Number of Applications	Amount of Study Drug Used (g)	Percent Compliant	Compliant?[2]
xxxxxx	xxxx	xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xx	xx	xxxx	xxx	xxx
xxxxxx	xxxx	xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xx	xx	xxxx	xxx	xxx
xxxxxx	xxxx	xxxxxxxxx	F: xxxxxxxxxx L: xxxxxxxxxx	xx	xx	xxxx	xxx	xxx

[1] The number of applications will be calculated by
2*(Date of Last Dose – Date of First Dose + 1) – (Number of Doses Missed) + (Number of Extra Doses).
[2] A subject was considered compliant with the dosing regimen if the subject applied 80% to 120% of the total number of expected doses during the treatment period.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing Format May Be Altered on Confirmation of Dosing Data Capture.

Listing 16.2.5.3: Missed/Extra Doses
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date of First Dose	Treatment Ear(s)	Date of Missed/ Extra Dose	Number of Missed Doses	Number of Extra Doses
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	x	
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxxx	xxxxxxxxxx		x
				xxxx	xxxxxxxxxx	x	
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxxx	xxxx	xxxxxxxxxx	x	
				xxxx	xxxxxxxxxx	x	
				xxxx	xxxxxxxxxx		x

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.5.4: Study Drug Dispensing and Return
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Kit Number	Bottle Number	Date Dispensed	Dispense Weight	Return Date	Return Weight
xxxxxx	xxxx	xxxxxxxxx	xxxxx	x	xxxxxxxxxx	xxx	xxxxxxxxxx	xxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	x	xxxxxxxxxx	xxxxx	xxxxxxxxxx	xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	x	xxxxxxxxxx	xxxxx	xxxxxxxxxx	xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	x	xxxxxxxxxx	xxxxx	xxxxxxxxxx	xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	x	xxxxxxxxxx	xxxxx	xxxxxxxxxx	xxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	x	xxxxxxxxxx	xxx	xxxxxxxxxx	xxx xxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	x	xxxxxxxxxx	xxxxx	xxxxxxxxxx	xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	x	xxxxxxxxxx	xxxxx	xxxxxxxxxx	xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	x	xxxxxxxxxx	xxxxx	xxxxxxxxxx	xxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	x	xxxxxxxxxx	xxxxx	xxxxxxxxxx	xxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.6.1: Otomycosis Signs and Symptoms
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	V: Visit D: Date	Assesor	Investigator Initals	Ear	Pruritus	Debris	Presence of Fungal Elements	Pain
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxx D: xxxxxxxxxx	xxxxxxx		xxxx	xxxxxxxx			
	V: xxx xx D: xxxxxxxxxx	xxxxxxxxxxx	xxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxx	xxxxxxxx
	V: xxx xx D: xxxxxxxxxx	xxxxxxxxxxx	xxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxx	xxxxxxxx
S: xxxxxx A: xxxx E: xxxxxxxxx	V: xxxxxxxxxx D: xxxxxxxxxx	xxxxxxx		xxxx	xxxxxxxx			
	V: xxx xx D: xxxxxxxxxx	xxxxxxxxxxx	xxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxx	xxxxxxxx
	V: xxx xx D: xxxxxxxxxx	xxxxxxxxxxx	xxx	xxxx	xxxxxxxx	xxxxxxxx	xxxxxx	xxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.6.2: Subject Global Assessment
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Date	Visit	Ear	Subject Global Assessment
xxxxxx	xxxxx	xxxxxxxxxxxx	xxxxxxxxxx	xxxxxxxx	xxxx	x x xxxxxxxx
					xxxxx	x x xxxxxxxx
			xxxxxxxxxx	xxxxxxxx	xxxx	x x xxxxxxxx
					xxxxx	x x xxxxxxxx
			xxxxxxxxxx	xxx xx	xxxx	x x xxxxxxxx
					xxxxx	x x xxxxxxxx
			xxxxxxxxxx	xxx xx	xxxx	x x xxxxxxxx
					xxxxx	x x xxxxxxxx
xxxxxx	xxxxx	xxxxxxxxxxxx	xxxxxxxxxx	xxxxxxxx	xxxx	x x xxxxxxxx
					xxxxx	x x xxxxxxxx
			xxxxxxxxxx	xxxxxxxx	xxxx	x x xxxxxxxx
					xxxxx	x x xxxxxxxx
			xxxxxxxxxx	xxx xx	xxxx	x x xxxxxxxx
					xxxxx	x x xxxxxxxx
			xxxxxxxxxx	xxx xx	xxxx	x x xxxxxxxx
					xxxxx	x x xxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.7.2.1: Unique Adverse Events Coded to MedDRA System Organ Classes and Preferred Terms
(Page xx of yy)

MedDRA System Organ Class	MedDRA Preferred Term	Adverse Event
xxxxx xxxxx xxxxx	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx
	xxxxx xxxxx xxxxx	xxxxxxxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx
	xxxxxxxxxx	xxxxx xxxxx xxxxx
		xxxxxxxx xxxxxxxx xxxxxxxxxx
		xxxxxxxx xxxxxxxxx xxxxxxxxxxxxxxx

Note: System Organ Class and Preferred Term map to MedDRA (Version 20.1).
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by MedDRA System Organ Class, Preferred Term, and Adverse Event.

Listing 16.2.7.2.2: Pre-Treatment Adverse Events
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	A: Adverse Event Description C: System Organ Class P: Preferred Term	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1] B: When Did The AE Begin	E: Occur on the Ear D: Occur at Dosing Site S: Severity R: Relationship to Study Drug O: Outcome	S: Serious A: Action Taken T: Other Action D: Cause Discontinuation
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx B: xxxxxxxxxxx xxxxx xxxx xx xxxxx xxxx	E: xxxxxxxx xxx xxx xxxxx xx xx xxx xxxx D: xx S: xxxxxxxx R: xxx xxxxxxxxx O: xxxxxxxxxxxxxxxxxx xxxx xxxxxxxx	S: xx A: xxxx xxx xxxxxxx T: xxxxxxxxxxx xxxxx xxxxx D: xx

Note: System Organ Class and Preferred Term map to MedDRA (Version 20.1).
[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event Description.

Listing 16.2.7.2.3: Treatment-Emergent Adverse Events
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	A: Adverse Event Description C: System Organ Class P: Preferred Term	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1] B: When Did The AE Begin	E: Occur on the Ear D: Occur at Dosing Site S: Severity R: Relationship to Study Drug O: Outcome	S: Serious A: Action Taken T: Other Action D: Cause Discontinuation
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx B: xxxxxxxxxxx xxxxx xxxx xx xxxxx xxxx	E: xxxxxxxx xxx xxx xxxxx xx xx xxx xxxx D: xx S: xxxxxxxx R: xxx xxxxxxxxx O: xxxxxxxxxxxxxxxxxx xxxx xxxxxxxx	S: xx A: xxxx xxx xxxxxxx T: xxxxxxxxxxx xxxxx xxxxx D: xx

Note: System Organ Class and Preferred Term map to MedDRA (Version 20.1).
[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event Description.

Listing 16.2.7.2.4: Serious Adverse Events
Treatment Arm
(Page xx of yy)

S: Subject A: Age/Sex E: Eval	A: Adverse Event Description C: System Organ Class P: Preferred Term	F: Date of First Dose S: Start Date (Day)[1] E: End Date (Day)[1] B: When Did The AE Begin	E: Occur on the Ear D: Occur at Dosing Site S: Severity R: Relationship to Study Drug O: Outcome	S: Serious A: Action Taken T: Other Action D: Cause Discontinuation
S: xxxxxx A: xxxx E: xxxxxxxxx	A: xxxxxxxxxxxxxxx C: xxxxxxxxxxxxxxx P: xxxxxxxxxxxxxxx	F: xxxxxxxxxx S: xxxxxxxxxx E: xxxxxxxxxx B: xxxxxxxxxxx xxxxx xxxx xx xxxxx xxxx	E: xxxxxxxx xxx xxx xxxxx xx xx xxx xxxx D: xx S: xxxxxxxx R: xxx xxxxxxxxx O: xxxxxxxxxxxxxxxxxx xxxx xxxxxxxx	S: xxx A: xxxx xxx xxxxxxx T: xxxxxxxxxxx xxxxx xxxxx D: xx

Note: System Organ Class and Preferred Term map to MedDRA (Version 20.1).
[1] Day is calculated as date – date of first dose for dates prior to first dose. Otherwise, day is calculated as date – date of first dose + 1 for dates on or after first dose.
SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Start Date, End Date, and Adverse Event Description.

Listing 16.2.8.1.1: Urine Pregnancy Test Results
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Visit	Date	Results
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxx	xxxxxxxxxx	xxx xxxx
			xxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxxxxxxxxxx	xxxxxxxxxx	xxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxx	xxxxxxxxxx	xxxxxxxx
			xxxxxxxxxxxxxx	xxxxxxxxxx	xxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing 16.2.8.2.1: Microbial Culture Results
Treatment Arm
(Page xx of yy)

Subject	Age/Sex	Eval	Ear	Date	Visit	Culture Type	Results
xxxxxx	xxxx	xxxxxxxxx	xxxxx	xxxxxxxxxx	xxxxxxxx	xxxxxx	xxxxx xxxxxxx xxxx xxxxx
						xxxxxxxx	xxxxx xxxxxxx xxxx
				xxxxxxxxxx	xxx xx xxxxxxxxx	xxxxxx	xx xxxxx xxxxxxxxx
xxxxxx	xxxx	xxxxxxxxx	xxxxx	xxxxxxxxxx	xxxxxxxx	xxxxxxxxx	xxxxx xxxxxxx xxxx xxxxx
						xxxxxxxx	xxxxx xxxxxxx xxxx
				xxxxxxxxxx	xxx xx xxxxxxxxx	xxxxxxxxx	xxxxx xxxxxxx xxxx xxxxx
				xxxxxxxxxx	xxx xx xxxxxxxxx	xxxxxx	xx xxxxx xxxxxxxxx

SOURCE: USERNAME\SPONSOR\PROJECT\JOBNAME (DATE, TIME)

Listing sorted by Subject, Visit, Date, Category, and Lab Test.