STATISTICAL ANALYSIS PLAN

PROTOCOL ADB244-001

A Prospective, Vehicle Controlled, Double Blinded, Multicenter, Randomized, Phase II Study of B244 Delivered as a Topical Spray to Determine Safety and Efficacy in Subjects with Mild to Moderate Atopic Dermatitis

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Methodology:	Prospective, Vehicle Controlled, Double Blinded, Multicenter, Randomized, 2-Arm
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APPROVAL SIGNATURE PAGE

Protocol Title:	A Prospective, Vehicle Controlled, Double Blinded, Multicenter, Randomized, Phase II Study of B244 Delivered as a Topical Spray to Determine Safety and Efficacy in Subjects with Mild to Moderate Atopic Dermatitis
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Sponsor Approval:

By signing this document, I acknowledge that I have read the document and approve of the planned statistical analyses described herein. I agree that the planned statistical analyses are appropriate for this study, are in accordance with the study objectives, and are consistent with the statistical methodology described in the protocol, clinical development plan, and all applicable regulatory guidances and guidelines.

I have discussed any questions I have regarding the contents of this document with the biostatistical author.

I also understand that any subsequent changes to the planned statistical analyses, as described herein, may have a regulatory impact and/or result in timeline adjustments. All changes to the planned analyses will be described in the clinical study report.

Sponsor Signatory:

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Date: 10/30/2018

REVISION HISTORY

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LIST OF ABBREVIATIONS AND DEFINITION OF TERMS

Abbreviation	Definition
AD	Atopic Dermatitis
AE	Adverse event
AOB	Ammonia oxidizing bacteria
ATC	Anatomic therapeutic class
CI	Confidence interval
CRF	Case report form
CSR	Clinical study report
CTCAE	Common Terminology Criteria for Adverse Events
DLT	Dose-limiting toxicity
EASI	Atopic Deramtitis Area Severity Index
ECG	Electrocardiogram
eCRF	Electronic case report form
FDA	Food and Drug Administration
ICH	International Conference on Harmonisation
IGA	Investigator Global Assessment
ITT	Intent-to-treat
MedDRA	Medical Dictionary for Regulatory Activities
Msec	Millisecond
NO/NO_x	Nitric oxide
PP	Per protocol
PT	Preferred Term
Rel Day	Relative study day
SAE	Serious adverse event
SAP	Statistical analysis plan
SC	Subcutaneous
SD	Standard deviation
SD	Standard error of the mean
SOC	System organ class
TEAE	Treatment-emergent adverse event
VAS	Visual Analog Scale

1. INFORMATION FROM THE STUDY PROTOCOL

1.1. Introduction and Objectives

1.1.1. Introduction

B244 is a purified a strain of *Nitrosomonas eutropha* originally isolated from soil samples. Based on *in vitro* co-culture studies, B244 was able to reduce survival of pathogenic bacteria. Nitrite generation from ammonia concurrently with medium acidification by B244 led to strong antibacterial effects and a marked reduction (~100-fold) in viable counts of methicillin-resistant *Staphylcoccus aureus* and *Pseudomonas aeruginosa*, two pathogens frequently isolated from infected skin and wound sites. B244 has been developed as a topical application of a natural source of Ammonia oxidizing bacteria (AOB) and nitric oxide (NO/NO_x) to the human skin. The active ingredient in B244 is available to consumers as a cosmetic product.

Eczema or Atopic Dermatitis (AD) is an inflammatory skin condition that affects nearly 20% of children and 2-10% of adults (Williams et al, 1999). Disease prevalence has steadily grown in the last 30 years, resulting in a growing field of atopic dermatitis research (Diepgen, 2000). The disease is characterized by pruritus, scratching, and eczematous lesions. The chronic condition may be associated with thickening and pigmentary changes. Onset of the disease occurs mostly between 3 and 6 months, but in 90% of children, the disease occurs by age of 5. Staphylococcus aureus is consistently found in eczematous skin lesions in patients with AD. Correlation between the severity of the disease and presence of Staphylococcus aureus has been well established and it has been shown that presence of bacteria is an important factor in skin aggravation. The goal of therapy for AD is to restore the epidermal barrier function and reduce skin inflammation. However, systemic antibiotic use is controversial.

The purpose of this study is to evaluate the safety and efficacy of B244 in treating patients with Atopic Dermatitis (AD).

1.1.2. Study Objectives

1.1.2.1. Primary Objectives

- To evaluate the safety and tolerability of B244 in subjects with mild to moderate Atopic Dermatitis.

1.1.2.2. Secondary Objectives

- To assess the efficacy of B244 versus vehicle by the change in Atopic Dermatitis Area Severity Index (EASI) Score from baseline to post-baseline visits.

1.1.2.3. Exploratory Objectives

- To assess the efficacy of B244 versus vehicle by the change in Visual Analog Scale (VAS) Score from baseline to post-baseline visits.
- To assess the efficacy of B244 versus vehicle by observing the change in the Skindex 16 Score from baseline to post-baseline visits.
- To assess the efficacy of B244 versus vehicle by observing the change in the Investigator Global Assessment (IGA) Score from baseline to post-baseline visits.

- ☐ To assess the efficacy of B244 versus vehicle by the change in Actigraphy Movement Count per Hour and sleep quality during nighttime from baseline to post-baseline visits.
- ☒ To evaluate if B244 administration on the skin twice daily for 28 days will affect the levels of immune biomarkers.
- ☒ To explore microbial content baseline and Day 28.

This statistical analysis plan (SAP) is designed to outline the methods to be used in the analysis of study data in order to answer the study objective(s). Populations for analysis, data handling rules, statistical methods, and formats for data presentation are provided. The statistical analyses and summary tabulations described in this SAP will provide the basis for the results sections of the clinical study report (CSR) for this trial.

This SAP will also outline any differences in the currently planned analytical objectives relative to those planned in the study protocol.

1.2. Study Design

1.2.1. Synopsis of Study Design

This is a prospective, vehicle controlled, double blind, multicenter, randomized Phase II trial comparing the effect of twice daily B244 application for 28 days versus vehicle application on treatment of mild to moderate AD.

Subjects who have clinically confirmed diagnosis of mild to moderate AD are eligible for enrollment. Subjects must be in general good health as determined by a thorough medical history, physical examination, and vital signs.

It is estimated that approximately 130 subjects will be randomized in order to provide 104 subjects for inclusion in the primary analysis, assuming a 20% drop-out rate.

After screening and recruitment, subjects will be randomized 1:1 to B244 or vehicle application for 28 days. Subjects will apply a total of 8 pumps of investigational product (IP) per application to all affected areas twice-a-day for 28 days.

Clinical assessments of response to treatment will be made at Baseline, Study Days 14 and 28. Subject will come back for the final visit on Study Day 42.

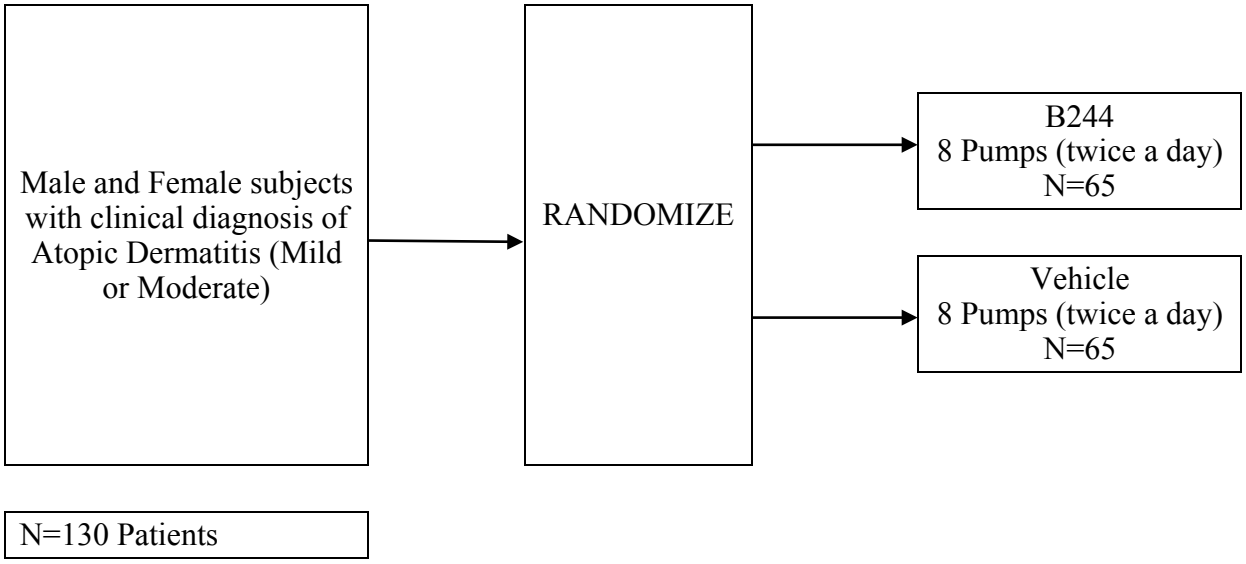
Safety evaluations will consist of review of subject's medical history at screening and on-going assessment of adverse events reported throughout the study duration.

1.2.1.1. Randomization Methodology

Randomization will be evenly allocated across 2 treatments (B244 or vehicle), so that equal numbers of subjects will be treated in each of the 2 treatment groups of the study. Randomization will occur during the baseline period for the study. All B244 randomized subjects will be treated at the dose of 4×10^9 cfu/ml. Details of the randomization scheme are provided in a separate document – "Randomization Plan".

The study schema is illustrated in Figure 1.

Figure 1: Study Schema



1.2.2. Stopping Rules and Unblinding

A subject may withdraw from the study at any time at his/her own request, or may be withdrawn at any time at the discretion of the Investigator. Reasons for withdrawal (subjects who refuse to complete any remaining study visits) or discontinuation (subjects who prematurely stop the application) at any time during the study may include, but are not limited, to the following:

- For safety reasons, either at the discretion of the Investigator or at the subject's request
- For protocol violations at the discretion of AOBiome
- Due to concomitant therapy that could interfere with the results of the study (the Investigator will report all such information on the CRFs and decide, in accordance with AOBiome, whether the subject is to be withdrawn).

The reason for subject study withdrawal will be recorded in the electronic Case Report Form (eCRF). Data from subjects withdrawing from the study will be considered evaluable up to the point at which they are withdrawn using the same criteria for evaluability as for subjects who complete the study.

The Investigator may unblind a subject's treatment assignment only in the case of emergency or in the event of a serious medical condition when knowledge of the study treatment is essential for the appropriate clinical management or welfare of the subject, as determined by the Investigator. It is preferred (but not required) that the Investigator first contact the Medical Monitor to discuss options before unblinding the part subject's treatment assignment. The Investigator must notify the Sponsor as soon as possible when a subject's treatment assignment is unblinded without revealing the treatment assignment of the unblinded subject unless that information is deemed important for the safety of subjects currently in the study. The date and reason for the unblinding must be documented in the subject's study record.

The Medical Monitor may unblind the treatment assignment for any subject with a serious adverse event (SAE). If the SAE requires that an expedited regulatory report be sent to 1 or more regulatory agencies, a copy of the report, identifying the subject's treatment assignment, may be sent to clinical investigators in accordance with local regulations and/or sponsor policy.

1.2.3. Study Procedures

The schedule of assessments, as outlined in the study protocol, is presented in Table 1.

The study flow is presented in Figure 2.

Table 1: Schedule of Assessments

Visit Name	Screening	Washout Phase[16]	Baseline	Week 2 Day 14	Week 4 Day 28	Week 6 Final Visit (EOS) Day 42	Early Temination Visit
Visit Window in Days	**-21 to -14**	**-14 to -1**	**-1 to 0**	**+/-1**	**+/-1**	**+/-1**	
Informed Consent	X						
Inclusion/Exclusion Criteria[21]			X				
Demographics							
Medical History							
Hanifin and Rajka criteria	X		X				
Concomitant Medications			X	X			
Smoking Status	X						
Physical Exam	X					X	X
Body Weight	X			X	X	X	X
Height	X						
In Office BP and HR[13]	X		X	X	X	X	X
Urine Pregnancy Test for WOCBP[1]	X						
Oral Hygiene	X			X	X	X	X
EASI	X		X	X	X	X	X
VAS	X		X	X	X	X	X
Skindex 16 Questionnaire	X		X	X	X	X	X
IGA	X		X	X	X	X	X
Clinical Chemistry[11]	X			X	X	X	X[18]
Blood for Biomarkers[12]			X	X	X	X	X[18]
Skin Swabs			X		X	X	X[18]
Micobial Composition[21]	X		X		X		
IWRS			X				
Dispense Investigational Product to Patient			X	X			

Visit Name	Screening	Washout Phase[16]	Baseline	Week 2 Day 14	Week 4 Day 28	Week 6 Final Visit (EOS) Day 42	Early Temination Visit
Visit Window in Days	**-21 to -14**	**-14 to -1**	**-1 to 0**	**+/-1**	**+/-1**	**+/-1**	
Collect Investigational product from Patient				X	X		
Investigational Product Application[7]			X	X	X		X[15]
Investigational Product Compliance[6]			X	X	X		X[15]
Call to Subjects to Initiate Washout Phase[16]		X[17]					
Actigraphy Watch[10]			X		X[19]		X[15]
Counseling[4]		X	X	X	X		
Study Cleanser[2]	X	X	X	X	X[9]		X[15]
Moisturizer[14]	X	X	X	X	X		X[15]
Study Diary[3]			X	X	X		X[15]
AE Monitoring[8]	X	X	X	X	X	X	X

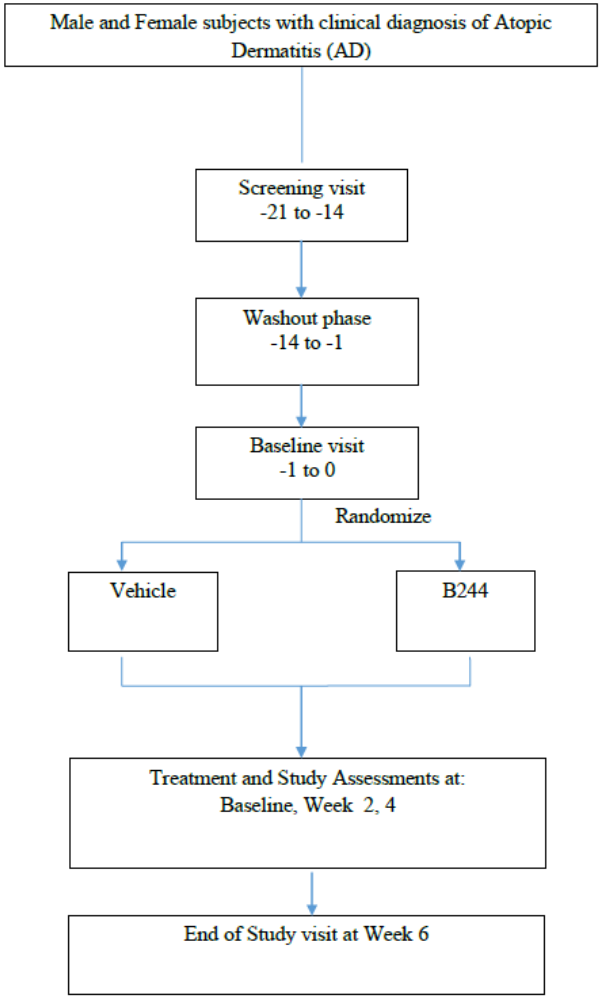
Abbreviations: AE=Adverse event, BP=Blood pressure, EASI= Eczema Area and Severity Index, EOS=End of Study, IGA=Investigator Global Assessment, VAS=Visual Analog Scale, IWRS=Interactive web response system, HR=Heart rate, IP=Investigational product, WOCBP=Woman of child-bearing potential.

1. Urine pregnancy test for WOCBP will be done at Screening.
2. Subjects are to be provided cleanser and moisturizer at Screening visit to start using it as the start of the Washout phase. However, cleanser, and moisturizer are available upon request in the event that subjects run out of their initial supplies.
3. Subjects will be asked to fill out study diary for the duration of the study (Baseline-Day 28).
4. Subjects will be counseled on the use of study medication, diary and answer any questions subject may have.
5. Skin swabs will be obtained during the office visit and will be kept in the refrigerator until shipped monthly to the storage lab.
6. Weight of an IP kit will be obtained at the at the Baseline visit. Study staff will be asked to weigh 2 bottles without the carton box PRE FIRST DOSE. Weightwill be recorded in grams. Subjects will be asked to bring both bottles back for the Week 2 and Week 4 visit. Upon return for the study visit, 2 bottles will be weighted again.
7. Subjects will be asked to apply the IP twice daily. First IP application will happen in the office under medical supervision.
8. AEs will be monitored throughout the trial, starting with the time ICF has been signed.
9. Cleanser and moisturizer should be returned to the study coordinator. Subjects will be asked to go back to their regular routine.

10. Actigraphy watch is dispensed at the Baseline visit. Subjects will be asked to wear one watch on each wrist startimg at Baseline and through Day 28 visit. Subjects are allowed to take watches off during bathing/ swimming/ showering but will be asked to put watches back once these procedures are completed.
11. Patients should fast for at least 8 hours before the test. Blood for clinical chemistry will be shipped to the central lab for processing. Chemistry, Hematology, HbA1C, Lipid Panel and Angiotensin converting enzyme tests will be done at Screening, Week 2, Week 4 and Week 6.. Serology will only be done at Screening. Kits will be provided by the Cenetron Labs.
12. Blood samples for biomarkers will be collected and processed on site within 5 minutes of collection. Patients should fast for at least 8 hours before the test. Samples will then be frozen onsite and shipped on monthly bases to the Central lab for storage.
13. Blood pressure readings will be obtained at every visit. Subject should be allowed to rest for > 5 minutes sitting, then serial clinic BP measurements and heart (x3) rate will be performed, using the non-dominant arm with a calibrated electronic sphygmomanometer. The average of the second and third readings will be documented.
14. Moisturizer to be used for the duration of the trial will be provided to all subjects starting with the Washout eriod. . Subjects will be asked to refrain, if possible, from using any other moisturizer and apply the provided product while they are participating in the trial. Any left over moisturizer will be collected at Week 4 visit.
15. If patient's Early Termination Visit happens before Week 4, subject will be asked to return the Actigraphy watch, soap, shampoo, moisturizer and IP to the study staff. Weigh of an IP will need to be taken.
16. Subjects will not need to come in to the clinic in order to start the Washout phase. Once all of the Screening procedures have been completed and subject becomes eligible for the study, supplies will be issued to the patient. However, the patient will be asked to hold off starting with the Washout period until results of chemistry and serology become available. At that point, subject will then be notified via the phone that they may proceed with the Washout period. Start of the Washout period will be recorded in the CRF by the study staff. Subjects will be instructed to start using the provided cleanser and moisturizer if necessary.
17. Call to subjects to alert them to initiate the 2-week Washout phase and explain the procedures.
18. If patient's Early Termination Visit happens before Week 4, blood for biomarkers, clinical chemistry and skin swab will need to be collected.
19. Return Actigraphy watches
20. At Baseline, study staff will examine subject's body surface area affected by AD and will be asked to identify only one area to be sampled. Once the area is identified, study staff will sample this particular treatment area. Sampling area should be noted in subject's record, so that the same treatment area is then sampled at Week 4 visit.

21. Medical records from patient's dermatologist or primary care physician to confirm the diagnosis of Atopic Dermatitis are optional. Verbal confirmation of the diagnosis present for $\geq$12 months is sufficient in order to fulfill this criterion.

Figure 2: Study Flow



1.2.4. Efficacy, Safety and Exploratory Parameters

1.2.4.1. Efficacy Parameters

The efficacy endpoint includes:

- Difference in Atopic Dermatitis Area Severity Index (EASI)

The following exploratory endpoints are considered as part of the efficacy analyses:

- Difference in Visual Analog Scale (VAS) Score for Pruritus from baseline to post-baseline visits.
- Difference in the Skindex 16 Score from Baseline to post-baseline visits.
- Difference in the IGA Score from Baseline to post-baseline visits.
- Difference in Actigraphy Movement Count per Hour and sleep quality during the night from Baseline to Day 28
- Difference in biomarkers between active and vehicle groups
- Composition of microbiome
- Difference in skin microbiodata from Baseline to Day 28 between active and vehicle groups.
- Observing a difference in Staphylococcus aureus and a more diverse microbial collection on the patient's skin.

1.2.4.2. Safety Parameters

Safety and tolerability endpoints will consist of all adverse events (AEs) reported during the study duration from the date of randomization through 28 days after the last dose of study drug.

Specific AEs are defined below.

Treatment-Emergent Adverse Events (TEAE): Any AE with onset after the first dose of study medication through 28 days after the last dose of study medication.

Serious Adverse Event (SAE): An AE occurring at any dose that results in any of the following outcomes: death, a life-threatening AE, in-patient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect.

Associated with Use of the Study Drug: There is a reasonable possibility that the experience may have been caused by the study drug. If the Investigator does not know whether or not study drug caused the event, then the event will be handled as "related to study drug" for reporting purposes. The determination of whether an AE is related to study drug is as follows:

- Related: The AE has a missing, unknown, possible, probable or definite relationship to the study medication.
- Not related: The AE is unlikely or definitely unrelated to the study drug.

2. SUBJECT POPULATION

2.1. Population Definitions

The following subject populations will be evaluated and used for presentation and analysis of the data:

- Intent-to-Treat (ITT) Population: Includes all randomized subjects. Subjects will be analyzed according to the treatment assigned by the randomization schedule. The ITT population will be the primary population for efficacy analyses.
- Safety Population: Includes all subjects who received at least 1 dose of study medication. Subjects will be analyzed according to the study drug received.
- Per Protocol (PP) Population: Includes subjects who administered at least 50% of IP, have at least one baseline and post baseline Day 28 visit and did not have any major protocol violations. The PP population will be used for supportive summaries of efficacy data.

The ITT population is the primary population for the analysis of efficacy parameters. A subset of efficacy parameters will be evaluated for the PP population (see Section 4.3). The Safety population is the primary population for the analysis of safety endpoints.

2.2. Protocol Deviations

Deviations will be summarized on the ITT patient population and may include:

- Inclusion or exclusion criteria not satisfied.
- Deviations related to the Investigational Product administration
- Not permitted concomitant medications.

At the discretion of the Sponsor, major protocol deviations, as determined by a review of the data prior to unblinding of the study results and the conduct of statistical analyses, may result in the removal of a subject's data from the PP population. The Sponsor or designee will be responsible for producing the final protocol deviation file (formatted as a Microsoft Excel file), in collaboration with Veristat and the data monitoring group as applicable. This file will include a description of the protocol deviation and clearly identify whether or not this violation warrants exclusion from the PP population.The file will also classify the deviations as major vs minor deviations. This file will be finalized prior to hard database lock.

All protocol deviations will be presented in a data listing.

3. GENERAL STATISTICAL METHODS

3.1. Sample Size Justification

A total sample size of 130 randomized subjects, allows for a dropout rate of 20%.

A sample size of 52 per group achieves >80% power to reject the null hypothesis of equal PHDQVZKHQWKHSRSXODWLRQPHDQGLIIHUHQFHLV(-5.3) = 3.9 with a standard deviation for both groups of 7.0 and with a significance level (alpha) of 0.025 using a one-sided two sample equal-variance t-test.

The power calculation assumes baseline treatment group means of 14 in EASI score. The change from baseline to Day 28 is assumed to be -1.4 for the vehicle group and -5.3 for the active group; this represents approximately a 38% reduction in EASI score for the active group and 10% reduction in EASI score for the placebo group.

3.2. General Methods

The analyses will be conducted on all subject data when the trial ends. Data will be presented by treatment group and overall except where noted. Listings will be sorted by treatment group and subject.

All data listings that contain an evaluation date will contain a relative study day (Rel Day). Pre-treatment and on-treatment study days are numbered relative to the day of the first dose of study medication which is designated as Relative Day 1. The preceding day is Relative Day -1, the day before that is Relative Day -2, etc. The last day of study medication is designated with an "L" (e.g., Relative Day 14L). Post-treatment study days are numbered relative to the last dose and are designated as Relative Day 1P, Relative Day 2P, etc.

All output will be incorporated into Microsoft Word or Excel files, or Adobe Acrobat PDF files, sorted and labeled according to the International Council for Harmonisation (ICH) recommendations, and formatted to the appropriate page size(s).

Tabulations will be produced for appropriate demographic, baseline, efficacy, and safety parameters. For categorical variables, summary tabulations of the number and percentage of subjects within each category (with a category for missing data) of the parameter will be presented. For continuous variables, the number of subjects, mean, median, standard deviation (SD), minimum, and maximum values will be presented.

Formal statistical hypothesis testing will be performed on the primary and secondary efficacy endpoints with all tests conducted at the one-sided, 0.025 level of significance unless otherwise specified. Summary statistics will be presented, as well as one-sided 95% confidence intervals for the difference in treatment groups means, as described in the sections below. P-values will be rounded to 4 decimal places. P-values that round to 0.0000 will be presented as <0.0001, and p-values that round to 1.00 will be presented as >0.9999.

3.3. Computing Environment

All descriptive statistical analyses will be performed using SAS v9.4 or later unless otherwise noted. Medical history and AEs will be coded using MedDRA v20.0. Concomitant medications will be coded using the World Health Organization (WHO) Drug Dictionary March 2017

3.4. Baseline Definitions

For all analyses, baseline will be defined as the most recent measurement prior to the first administration of study drug. The day of first dose of study medication is Day 0 in the Schedule of Assessments (SOA) and will be considered Relative Study Day 1.

3.5. Methods of Pooling Data

Subjects will be pooled across all sites. Data will be presented by treatment group and overall.

3.6. Adjustments for Covariates

No formal statistical analyses that adjust for possible covariate effects are planned.

3.7. Multiple Comparisons/Multiplicity

Analyses will not be adjusted for multiple endpoints.

3.8. Subpopulations

EASI, IGA,VAS, and Skindex 16 Scores will be reported separately for Black versus Non Black subjects, subjects $\geq$ 30 years versus < 30 years and male vs female subjects. Some of the parameters will also be presented by number of atopic dermatitis sites.

3.9. Withdrawals, Dropouts, Loss to Follow-up

Subjects who dropout after enrollment but prior to randomization will be replaced.

3.10. Missing, Unused, and Spurious Data

In general, there will be no substitutions made to accommodate missing data points. All data recorded on the case report form will be included in data listings that will accompany the clinical study report.

When tabulating adverse event data, partial dates will be handled as follows. If the day of the month is missing, the onset day will be set to the first day of the month unless it is the same month and year as study treatment. In this case, in order to conservatively report the event as treatment-emergent, the onset date will be assumed to be the date of treatment. If the onset day and month are both missing, the day and month will be assumed to be January 1, unless the event occurred in the same year as the study treatment. In this case, the event onset will be coded to the day of treatment in order to conservatively report the event as treatment-emergent. A missing onset date will be coded as the day of treatment.

In all cases, the resulting date will be compared to the AE end date, if present. If the imputed start date is later than the AE end date, then the start date will be set equal to the end date. The imputed start date is used only for determining treatment emergence; data listings will present the partial date as recorded on the CRF.

Missing AE severities will not be imputed and will be considered missing in any tabulations of AE severity. When relation of AEs to the study drug is missing, the AE will be considered "related" to study drug.

3.11. Visit Windows

It is expected that all visits should occur according to the protocol schedule. All data will be tabulated per the evaluation visit as recorded on the CRF even if the assessment is outside of the visit window. In data listings, the relative day of all dates will be presented.

3.12. Interim Analyses

No interim analyses are planned for this study.

4. STUDY ANALYSES

4.1. Subject Disposition

A tabulation of the disposition of subjects will be presented by treatment assignment and overall. The number screened, the number randomized, the number treated in each arm, and the reasons for study discontinuation will be reported. Summaries of the number in each analysis set will be presented. Entry criteria and protocol deviations will be listed. Screen failures will be listed.

A by-subject data listing of study completion information including the reason for premature study withdrawal, if applicable, will be presented.

4.2. Demographics and Baseline Characteristics

Demographic and baseline characteristic data summarization will be performed in order to descriptively assess the comparability of treatments. Summaries will be generated for the ITT, Safety and PP populations. Data to be tabulated will include age (continuous and classified <30/>=30), sex, child-bearing potential (for females only), race, ethnicity, height, weight, BMI (continuous and classified as underweight (<20), normal (20-<25), overweight (25-<30), and obese (>=30))and smoking history as well as baseline characteristics related to medical history. Weight, BMI, and age will be analyzed as a continuous variable using descriptive statistics (number of subjects, mean, SD, median, minimum, and maximum). Age category, sex, race, ethnicity, BMI category, and smoking status will be summarized by frequency (count and percent). Selected baseline variables will be compared to assess the balance of characteristics across the treatment groups. Age and BMI will be compared using ANCOVA.

Demography, general medical history, and smoking history will be presented in data listings.

Medical history will be coded using MedDRA v20.0, and the number and percentage of patients experiencing at least 1 such diagnosis by MedDRA System Organ Class (SOC) and preferred term (PT) will be reported.

4.3. Efficacy Evaluation

Efficacy analyses will be conducted using the ITT and PP populations. In the event that these two populatioins are the same, only the ITT tables will be produced.

4.3.1. EASI, IGA, VAS

EASI, IGA, and VAS scores will be summarized using descriptive statistics at Baseline, Day 14, Day 28, and Day 42 for actual values and change-from-baseline values. Tabulations will be produced for both the ITT and PP populations.

The difference in treatment groups in change-from-baseline values at post-baseline visits will be analyzed using a mixed model Analysis of Variance with one between-subject variable (active group vs. vehicle group) and one within-subject variable (Day 14, Day 28, and Day 42).

The interaction between within-subject and between-subject variable will be included in the mixed model to test if any difference in treatment groups at post-baseline visits.
The model will include treatment group, siteid and visit as the independent effects and the interaction term treatment group*visit*siteid. Outputs from the analysis will include the p-value

for the treatment group and interaction factor separately. The p-value should be evaluated at a significance level of 0.05.
Mixed model ANOVA will be implemented using PROC GLM in SAS using the REPEATED option.

Additionally, a one-sided two-sample equal-variance t-test will be performed as a supportive test to analyze the differences in mean change in scores from baseline between treatment groups at each post baseline visit (Day 14, Day 28, Day 42). Output from the analysis will include a one sided 95% confidence interval and p-value. The p-value should be evaluated at a one-sided significance level of 0.025.
The above analysis will also be performed by subgroups – age, gender, and race for the ITT Population.
An exploratory analysis will also be conducted by the number of AD sites (1, 2 and >2) the subjects had.

At each visit, based on the score, subjects will be categorized into the below categories.

EASI score.
0 = clear
0.1 – 1.0 = almost clear
1.1 – 7.0 = mild
7.1 – 21.0 = moderate
21.1 – 50.0 = severe
50.1 – 72.0 = very severe

VAS score:
0 = no pruritus
>0 – <4 points = mild pruritus
>4 – <7 points = moderate pruritus
>7 – <9 points = severe pruritus
>9 points = very severe pruritus

IGA score:
0 = Clear
1 = Almost Clear
2 = Mild Disease
3 = Moderate Disease
4 = Severe Disease

A shift table for baseline to each post baseline visit by treatment group will also be created for EASI, VAS, and IGA scores.Shift tables will also be presented by subgroups.
The proportion of subjects with improvement in EASI. IGA and VAS from Baseline to Day 14, Day 28 and Day 42 in the B244 and Vehicle groups will be tabulated. The proportions will be compared using Pearson's Chi-square test of independence. The p-value should be evaluated at

a significance level of 0.05. The proportion of subjects with no improvement and the proportion of subjects whose score worsened will also be tabulated for each visit and for each score.

4.3.2. Skindex 16 score:

The Skindex 16 score – average of all 16 items in the scale will be summarized using descriptive statistics at Baseline, Day 14, Day 28, and Day 42 for actual values and change-from-baseline values for both ITT and PP populations.

The three subscores – Symptom subscale (average of items 1-4), Emotional subscale (average of items 5 -11), Functional subscale (average of items 12 -16) will also be summarized similarly.

The difference in treatment groups in change-from-baseline values at post-baseline visits will be analyzed using a mixed model Analysis of Variance similar to as described for the EASI score.The above analysis will also be performed by subgroups - age, race, and gender for the ITT population.

4.3.3. Actigraphy Watch

The actigraphy data will be used to determine the estimates of actigraphy movement count per hour, total sleep time (TST), total wake time (TWT), total number of scratching events, scratching events per hour and sleep efficiency(%) each night for only 'Major Rest' periods. 'Rest' periods will not be analayzed as they may or may not indicate the sleep time of the subject. Night averages will be calculated for each parameter from hourly readings. Weekly averages for each parameter will be calculated from the nightly averages. Change in all the three parameters – weekly averages from baseline to week 1, 2, 3 and 4 will be summarized by treatment group and visit. One-sided two-sample equal-variance t-test will be performed to analyze the differences in treatment group means in change from baseline at each post baseline week for each parameter. Non parametric Mann-Whitney U test will also be performed to account for any concerns about the normality of the data.

4.4. Pharmacokinetic Evaluation

No pharmacokinetic analyses will be conducted.

4.5. Safety Analyses

Safety analyses will be conducted using the Safety population.

4.5.1. Study Drug Exposure

The cumulative amount of study drug exposure will be estimated by calculating the difference between the weight of the 4 bottles of drug at the time the drug was dispensed and the weight of the 4 bottles at the last visit. The amount of product used per day will be estimated by dividing the change by the number of days the subject was on treatment. These weights will be compared to the weight of the product that would be used if the subject was compliant with the protocol and used the spray 16 times per day (8 sprays BID) for 28 days.

Percent compliance will be summarized for each subject from date of first dose through the treatment period based on the net weight of the product administered. Net weight is calculated as the weight collected at Day 28 minus the weight at Day 1. Based on information provided by AOBiome, the expected amount of study drug used per week is approximately 15.68 g/week for 16 sprays/application per day.

$$\text{Percent Compliance} = \frac{(NetWeightofstudydrug)*100}{(2.24g/day*28daysoonstudy)}$$

The number of days the subject administered study drug, the amount of product used, and the percent compliance will be summarized by treatment group and presented in a by-subject data listing. The subject listing will also include by-visit IP weights. Percent compliance will be calculated only for subjects who returned the study drug at Day 28. In the listing, subjects who withdrew from the study early will be flagged.

4.5.2. Adverse Events

Adverse events will be analyzed in terms of treatment-emergent adverse events (TEAEs) which are defined as any AEs that begin or worsen on or after the start of study drug through 28 days after the last dose of study drug.

A treatment-related TEAE is defined as a TEAE that was considered by the Investigator to be at least possibly related to the study drugs.

If a subject experiences the same AE more than once with different toxicity grades, the event with the highest grade will be tabulated in the "by grade" tables. If a subject experiences multiple AEs under the same preferred term (SOC), the subject will be counted only once for that preferred term (SOC). In addition, AEs with a missing severity will be presented in the summary table as an intensity category of "Missing."

An overall summary table presenting the number of subjects who experienced the following will be presented by treatment arm: any TEAE, any related TEAE, any Grade 3 or 4 TEAE, any related Grade 3 or 4 TEAE, any serious TEAE, any serious related TEAE, any TEAE leading to discontinuation of treatment, any TEAE leading to study discontinuation, and any TEAE leading to death.

The incidence of TEAEs will be summarized by MedDRA SOC and preferred term. Tables summarizing the incidence of TEAEs will be generated for each of the following:

- x All TEAEs
- x TEAEs reported as treatment-related
- x Severe or Grade 3/4 TEAEs
- x Related Grade 3/4 TEAEs
- x Serious TEAEs
- x Related Serious TEAEs

If no subjects experience any of the events in the overall summary table, the corresponding table by SOC and preferred term will not be produced.

No formal hypothesis-testing analysis of AE incidence rates will be performed.

All AEs occurring on-study will be listed in subject data listings.

By-subject listings also will be provided for the following: subject deaths, serious AEs, and AEs leading to withdrawal.

4.5.3. Laboratory Data

Clinical laboratory values will be expressed in SI units reported by the central laboratory.

The actual value and change from screening will be summarized for each clinical chemistry, hematology and lipid panel parameters and by each visit. In the event of repeat values, the last non-missing value per visit will be used.

Sample for Serology was collected only at Baseline. Hence Serology data will be only provided in a listing.

All laboratory data will be also provided in data listings. Values outside of the lab parameter's normal range will be flagged as high, low, or abnormal based on the range of the test.

4.5.4. Vital Signs and Physical Examination

Vital sign measurements will be presented for each subject in a data listing. Systolic blood pressure, diastolic blood pressure, heart rate, and weight will be summarized as actual value and change from baseline by visit.

All physical examination findings will be presented in a data listing.

4.5.5. Concomitant Medications

Concomitant medications will be coded using the WHO Drug Dictionary. Results will be tabulated by anatomic therapeutic class (ATC) and preferred term.

Concomitant medications will be tabulated by treatment group, where any medications that did not end prior to first dose will be included. If an end date is missing or the medication is ongoing, the medication will be included.

The use of concomitant medications will be included in a by-subject data listing.

5. CHANGES TO PLANNED ANALYSES

The definition of per protocol population was changed to be more specific and it would now include only subjects who have the post baseline Day 28 visit instead of any post baseline visit.

Biomarker data and Microbial data will not be analysed at this stage. These are a part of exploratory analysis and would be done later.

6. REFERENCES

Williams, H, Robertson, C, Stewart, A, et al: Worldwide variations in the prevalence of symptoms of atopic eczema in the international study of asthma and allergies in childhood. J Allergy Clin Immunol 1999 103: 125–138.

Diepgen, TL: Is the prevalence of atopic dermatitis increasing? In: Williams HC ed. Atopic Dermatitis: the Epidemiology, Causes and Prevention of Atopic Eczema. 2000 Cambridge: Cambridge University Press

7. STATISTICAL OUTPUT

7.1. List of Statistical Output

STATISTICAL TABLES

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Table 14.1.1

Subject Enrollment and Disposition (All Enrolled Subjects)

Disposition	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Total Number of Subjects				
Screened	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Screen Failures [1]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Enrolled	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Randomized [1]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Treated [2]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Completed the Study [3]	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Discontinued	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Study Population [4]				
Safety	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Intent-to-Treat (ITT)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Per Protocol (PP)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Reason for Early Study Discontinuation				
Death	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Lost to follow-up	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Withdrawal of consent by subject	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Investigator's decision	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Percentage based on the number screened.
[2] Percentage based on the number randomized.
[3] Percentage and all subsequent percentages based on the number treated.
[4] Safety Population: All subjects who received at least 1 dose of study medication, analyzed according to drug received.
Intent-to-Treat (ITT) Population: all randomized subjects, analyzed according to treatment assigned.
Per Protocol (PP) Population: Subjects who were administered at least 50% of , have baseline and at least 1 post-baseline in-clinic visit, and did not have any major protocol violations which could potentially compromise interpretation of results.
Source: Listing xxx

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: DDMMMYYYY HH:MM

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Table 14.1.2.1A

Demographics and Baseline Characteristics (ITT Population)

Parameter	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Age (years)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	p-value [1]			x.xxxx
Age Category (years)				
<30	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=30	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Sex				
Female	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Male	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Chile bearing potential (for females)				
Yes				
No	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Race				
American Indian or Alaska Native	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Asian	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Black	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Native Hawaiian or Other Pacific Islander	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
White	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Other	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ethnicity				
Hispanic/Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Not Hispanic/Latino	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Unknown	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] p-value is from ANCOVA model.
Source:□/□□□□□□□□

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Table 14.1.2.1A

Demographics and Baseline Characteristics (ITT Population)

Parameter	Statistic	B244 (N=xx)	Plcebo (N=xx)	Overall (N=xx)
Weight (kg)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Height (meters)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
BMI (kg/m^2)	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
	p-value [1]			x.xxxx
BMI Category (kg/m^2)				
<20	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
20-<25	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
25-<30	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
>=30	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Smoking History				
Never	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Former	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Current	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] p-value is from ANCOVA model.
Source:□/LVWLQ□□

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Repeat for:
Table 14.1.2.1B Demographics and Baseline Characteristics (Safety Population)
Table 14.1.2.1C Demographics and Baseline Characteristics (PP Population)

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Table 14.1.3.1

Concomitant Medication by Anatomic Therapeutic Class and Preferred Term (Safety Population)

ATC Class Preferred Term	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
ATC 1				
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.				
ATC 2				
PT 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
PT 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.				
Etc.				

Note: Concomitant medications are any medications that did not end prior to first dose. If an end date is missing or the medication is ongoing, the medication is included.
Note: Concomitant medications anatomic therapeutic class (ATC) and preferred term (PT) are coded using the WHO Drug Dictionary version March 2017.
Source: [illegible]

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Table 14.1.4.1

Medical History by MedDRA System Organ Class and Preferred Term (Safety Population)

System Organ Class Preferred Term	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Patients with Medical History	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1				
Preferred Term 1		xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 2				
Preferred Term 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.				

Note: If a subject experiences multiple occurrences in the same PT/SOC, the subject will be counted only once for that PT/SOC.
Note: Medical history is coded using MedDRA v20.0.
Source: /LVWLD

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Table 14.1.5.1A

Summary of Drug Exposure (ITT Population)

Parameter	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Cumulative Study Drug Exposure (g) [1]	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Amount of Product Used per Day (g) [2]	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Days of Study Drug Administration	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx
Percent Compliance [3]	n	xx	xx	xx
	Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
	Median	xx.x	xx.x	xx.x
	Min, Max	xx, xx	xx, xx	xx, xx

[1] Cumulative study drug exposure = weight of the 4 drug bottles at last visit - weight of the 4 drug bottles at first dispense.
[2] Amount of product used per day = change / number of days the subject was on treatment.
[3] Percent compliance = (Net weight of study drug) / (Expected net weight for 28 days of use) × 100.
Source: /LVWLQJ

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Repeat for:
Table 14.1.5.1B Summary of Drug Exposure (Safety Population)
Table 14.1.5.1C Summary of Drug Exposure (PP Population)

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Table 14.2.1.1

Summary of Values and Change from Baseline for EASI Score (ITT Population)

Visit	Actual/ Change	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Baseline	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Day 14	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	Change	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
		p-value [1]	x.xxxx		
		p-value [2]	x.xxxx		
		95% CI [2]	xx.xx, xx.xx		

[1] p-value is from Mixed model ANOVA.
[2] p-value is from t- test.
Source: /LVWLD[[[

Programming Note: Repeat for all visits

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Repeat Table 14.2.1.1 for the following tables:

Table 14.2.1.2 Summary of Values and Change from Baseline for EASI Score (PP Population)
Table 14.2.1.3 Summary of Values and Change from Baseline for EASI Score by Gender (ITT Population)
Table 14.2.1.4 Summary of Values and Change from Baseline for EASI Score by Age Category (ITT Population)
Table 14.2.1.5 Summary of Values and Change from Baseline for EASI Score by Race (ITT Population)
Table 14.2.1.6 Summary of Values and Change from Baseline for EASI score by Number of Atopic Dermatitis Sites (ITT Population)

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Table 14.2.2.1

Shift table for EASI Score (ITT Population)

		Day 14							
Treatment	Baseline	Clear	Almost Clear	Mild	Moderate	Severe	Very Severe	Missing	Total
B244	Clear	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Almost Clear	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Mild	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)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Very Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Placebo	Clear	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Almost Clear	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Mild	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)
	Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Very Severe	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: /LVWLQJ

Programming Note: Repeat for all visits.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY
Repeat Table 14.2.2.1 for the following tables:

Table 14.2.2.2 Shift table for EASI Score (PP Population)
Table 14.2.2.3 Shift table for EASI Score by Gender (ITT Population)
Table 14.2.2.4 Shift table for EASI Score by Age Category (ITT Population)
Table 14.2.2.5 Shift table for EASI Score by Race (ITT Population)

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Table 14.2.3.1

Summary of Values and Change from Baseline for VAS Score (ITT Population)

Visit	Actual/ Change	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Baseline	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Day 14	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	Change	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
		p-value [1]	x.xxxx		
		p-value [2]	x.xxxx		
		95% CI [2]	xx.xx, xx.xx		

[1] p-value is from Mixed model ANOVA.
[2] p-value is from t- test.
Source:□/LVWLD[][]

Programming Note: Repeat for all visits

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Repeat Table 14.2.3.1 for the following tables:

Table 14.2.3.2 Summary of Values and Change from Baseline for VAS Score (PP Population)
Table 14.2.3.3 Summary of Values and Change from Baseline for VAS Score by Gender (ITT Population)
Table 14.2.3.4 Summary of Values and Change from Baseline for VAS Score by Age Category (ITT Population)
Table 14.2.3.5 Summary of Values and Change from Baseline for VAS Score by Race (ITT Population)
Table 14.2.3.6 Summary of Values and Change from Baseline for VAS Score by Number of Atopic Dermatitis Sites (ITT Population)

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Table 14.2.4.1

Shift table for VAS Score (ITT Population)

		Day 14						
Treatment	Baseline	No Pruritus	Mild Pruritus	Moderate Pruritus	Severe Pruritus	Very Severe Pruritus	Missing	Total
B244	No Pruritus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Mild Pruritus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate Pruritus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe Pruritus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Very Severe Pruritus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Placebo	No Pruritus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Mild Pruritus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate Pruritus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe Pruritus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Very Severe Pruritus	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source:

Programming Note: Repeat for all visits.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Repeat Table 14.2.4.1 for the following tables:

Table 14.2.4.2 Shift table for VAS Score (PP Population)
Table 14.2.4.3 Shift table for VAS Score Score by Gender (ITT Population)
Table 14.2.4.4 Shift table for VAS Score by Age Category (ITT Population)
Table 14.2.4.5 Shift table for VAS Score by Race (ITT Population)

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Table 14.2.5.1

Summary of Values and Change from Baseline for IGA Score (ITT Population)

Visit	Actual/ Change	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Baseline	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Day 14	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	Change	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
		p-value [1]	x.xxxx		
		p-value [2]	x.xxxx		
		95% CI [2]	xx.xx, xx.xx		

[1] p-value is from Mixed model ANOVA.
[2] p-value is from t-test.
Source: Listing xxx

Programming Note: Repeat for all visits

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Repeat Table 14.2.5.1 for the following tables:

Table 14.2.5.2 Summary of Values and Change from Baseline for IGA Score (PP Population)
Table 14.2.5.3 Summary of Values and Change from Baseline for IGA Score by Gender (ITT Population)
Table 14.2.5.4 Summary of Values and Change from Baseline for IGA Score by Age Category (ITT Population)
Table 14.2.5.5 Summary of Values and Change from Baseline for IGA Score by Race (ITT Population)
Table 14.2.5.6 Summary of Values and Change from Baseline for IGA Score by Number of Atopic Dermatitis Sites (ITT Population)

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Table 14.2.6.1

Shift table for IGA Score (ITT Population)

		Day 14						
Treatment	Baseline	Clear	Almost Clear	Mild Disease	Moderate Disease	Severe Disease	Missing	Total
B244	Clear	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Almost Clear	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Mild Disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate Disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe Disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Placebo	Clear	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Almost Clear	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Mild Disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Moderate Disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Severe Disease	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Source: /LVWLQJ

Programming Note: Repeat for all visits.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

Repeat Table 14.2.6.1 for the following tables:

Table 14.2.6.2 Shift table for IGA Score (PP Population)
Table 14.2.6.3 Shift table for IGA Score Score by Gender (ITT Population)
Table 14.2.6.4 Shift table for IGA Score by Age Category (ITT Population)
Table 14.2.6.5 Shift table for IGA Score by Race (ITT Population)

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Table 14.2.7.1

Subjects showing Improvement from Baseline on the EASI Score (ITT Population)

Visit	Number of subjects showing	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Day 14	Improvement in score compared to Baseline	N (%)	xx (xx.xx)	xx (xx.xx)	xx (xx.xx)
		p-value [1]	x.xxxx		
	No change in score compared to Baseline				
	Worsening of score compared to Baseline				
Day 28					
Day 42					

[1] p-value is from Chi square test
Source: Listing xxx

Programming Note: Repeat for all visits.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Repeat Table 14.2.7.1 for the following tables:

Table 14.2.7.2 Subjects showing Improvement from Baseline on the VAS Score (ITT Population)
Table 14.2.7.3 Subjects showing Improvement from Baseline on the IGA Score (ITT Population)
Table 14.2.7.4 Subjects showing Improvement from Baseline on the EASI Score(PP Population)
Table 14.2.7.5 Subjects showing Improvement from Baseline on the VAS Score(PP Population)
Table 14.2.7.6 Subjects showing Improvement from Baseline on the IGA Score(PP Population)

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Table 14.2.8.1

Summary of Values and Change from Baseline for Skindex 16 Score (ITT Population)

Parameter: Total Skindex 16 Score

Visit	Actual/ Change	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Baseline	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Day 14	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	Change	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
		p-value [1]	x.xxxx		
		p-value [2]	x.xxxx		
		95% CI [2]	xx.xx, xx.xx		

[1] p-value is from Mixed model ANOVA.
[2] p-value is from t-test.
Source: Listing xxx

Programming Note: Repeat for the three subcategories and for all visits.

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Repeat Table 14.2.8.1 for the following tables:
- Table 14.2.8.2 Summary of Values and Change from Baseline for Skindex 16 Score (PP Population)
- Table 14.2.8.3 Summary of Values and Change from Baseline for Skindex 16 Score by Gender (ITT Population)
- Table 14.2.8.4 Summary of Values and Change from Baseline for Skindex 16 Score by Age Category(ITT Population)
- Table 14.2.8.5 Summary of Values and Change from Baseline for Skindex 16 Score by Race (ITT Population)
- Table 14.2.8.6 Summary of Values and Change from Baseline for Skindex 16 Score by Number of Atopic Dermatitis Sites (ITT Population)

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Table 14.2.9.1

Summary of Values and Change from Baseline for Actigraphy Movement (ITT Population)

Parameter: Total Sleep Time

Visit	Actual/ Change	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Baseline	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Week 1	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	Change	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
		p-value [1]	x.xxxxx		
		p-value [2]	x.xxxx		

[1] p-value is from t-test.
[2] p-value is from Mann-Whitney U test.
Source:

Programming Note: Repeat for parameters: Total Wake time, Average movement count, Total Number of scratching events, Scratching events per hour, sleep efficiency (%) and for all weeks (week 1, 2,3 and 4).

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX DATE: HH:MM/DDMMMYYYY

Repeat Table 14.2.9.1 for the following tables:

Table 14.2.9.2 Summary of Values and Change from Baseline for Actigraphy Movement (PP Population)

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Table 14.3.1.1

Overall Summary of Treatment-Emergent Adverse Events (Safety Population)

	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Subjects with at Least 1 Treatment-Emergent Adverse Event (TEAE)	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with at Least 1 Treatment-Related TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with at Least 1 Grade 3 or 4 TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with at Least 1 Treatment-Related Grade 3 or 4 TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with at Least 1 Serious TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with at Least 1 Treatment-Related Serious TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with at Least 1 TEAE that led to Treatment Discontinuation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with at Least 1 TEAE that led to Study Discontinuation	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Subjects with 1 TEAE that led to Death				

If a subject experiences multiple occurrences in the category of Adverse event , the subject will be counted only once for that PT/SOC.
If a subject experiences the same AE more than once with different CTCAE grades, the event with the highest grade will be tabulated.
TEAE is defined as any AEs that begin or worsen on or after the start of study drug through 30 days after the last dose of study drug.
Treatment-related TEAE is defined as TEAE that was considered by the Investigator to be at least possibly related to the study drug.
Severity will be graded based on the NCI CTCAE, Version 4.03.
Adverse events are coded using MedDRA v20.0.
Source:

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

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Table 14.3.1.2

Treatment-Emergent Adverse Events (TEAE) by MedDRA System Organ Class and Preferred Term (Safety Population)

System Organ Class Preferred Term	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Any TEAE	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 1				
Preferred Term 1		xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
System Organ Class 2				
Preferred Term 1	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Preferred Term 2	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.	n (%)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Etc.				

TEAE is defined as any AEs that begin or worsen on or after the start of study drug through 30 days after the last dose of study drug.
If a subject experiences multiple occurrences in the same PT/SOC, the subject will be counted only once for that PT/SOC.
Adverse events are coded using MedDRA v20.0.
Source: /LVWLQJ[[

PROGRAM NAME: XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX | DATE: HH:MM/DDMMMYYYY

Repeat Table 14.3.1.2 for the following tables:

Table 14.3.1.3 Treatment-Related Treatment-Emergent Adverse Events (TEAE) by MedDRA System Organ Class and Preferred Term (Safety Population)
PROGRAMMING NOTE: filter for at least possibly related to the study drug. Add footnote "Treatment-related TEAE is defined as TEAE that was considered by the Investigator to be at least possibly related to the study drug."

Table 14.3.1.4 Grade 3 or 4 Treatment-Emergent Adverse Events (TEAE) by MedDRA System Organ Class and Preferred Term (Safety Population)
PROGRAMMING NOTE: filter for grade = 3 or 4. Add footnote "Severity will be graded based on the NCI CTCAE, Version 4.03." AND "If a subject experiences the same AE more than once with different CTCAE grades, the event with the highest grade will be tabulated."

Table 14.3.1.5 Treatment-Related Grade 3 or 4 Treatment-Emergent Adverse Events (TEAE) by MedDRA System Organ Class and Preferred Term (Safety Population)
PROGRAMMING NOTE: filter for grade = 3 or 4 and at least possibly related to the study drug. Add footnote "Treatment-related TEAE is defined as TEAE that was considered by the Investigator to be at least possibly related to the study drug." AND "Severity will be graded based on the NCI CTCAE, Version 4.03." AND "If a subject experiences the same AE more than once with different CTCAE grades, the event with the highest grade will be tabulated."

Table 14.3.1.6 Serious Treatment-Emergent Adverse Events (TEAE) by MedDRA System Organ Class and Preferred Term (Safety Population)
PROGRAMMING NOTE: filter for SERIOUS = YES.

Table 14.3.1.7 Treatment-Related Serious Treatment-Emergent Adverse Events (TEAE) by MedDRA System Organ Class and Preferred Term (Safety Population)
PROGRAMMING NOTE: filter for SERIOUS = YES and at least possibly related to the study drug. Add footnote "Treatment-related TEAE is defined as TEAE that was considered by the Investigator to be at least possibly related to the study drug."

Repeat Listing 16.2.7.1 for the below table listings.

Table 14.3.2.1 Serious Adverse Events
PROGRAMMING NOTE: filter for SERIOUS = YES and remove Serious Column.

Table 14.3.2.2 Adverse Events Leading to Early Discontinuation
PROGRAMMING NOTE: filter for subjects who discontinued early.

Table 14.3.2.3 Subject Deaths
PROGRAMMING NOTE: filter for subject deaths, remove Outcome column and accompanying footnote and renumber other footnotes accordingly.

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Table 14.3.3.1

Summary of Values and Change from Baseline for Hematology Parameters (Safety Population)

Parameter:

Visit	Actual/ Change	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Screening	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Week 2	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	Change	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Etc.					

Source: ADLBHM

Programming Note: Continue for all parameters and visits.

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Table 14.3.3.2

Summary of Values and Change from Baseline for Chemistry Parameters (Safety Population)

Parameter:

Visit	Actual/ Change	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Screening	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Week 2	Actual	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	Change	n	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Etc.					

Source:□/LVWLQ□□

Programming Note: Continue for all parameters and visits.

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Repeat Table 14.3.3.2 for the below table.

Table 14.3.3.3 Summary of Values and Change from Baseline for Lipid Parameteres (Safety Population)

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Table 14.3.4

Summary of Values and Change from Baseline for Vital Signs (Safety Population)

Parameter: Systolic Blood Pressure

Visit	Actual/ Change	Statistic	B244 (N=xx)	Placebo (N=xx)	Overall (N=xx)
Screening	Actual	N	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Week 2	Actual	N	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
	Change	N	xx	xx	xx
		Mean (SD)	xx.x (xx.xx)	xx.x (xx.xx)	xx.x (xx.xx)
		Median	xx.x	xx.x	xx.x
		Min, Max	xx, xx	xx, xx	xx, xx
Etc.					

Source:□/LVWLD□□

Programming Note: Continue for all parameters and visits.

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LISTING SHELLS

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Listing 16.2.2.1

Inclusion/Exclusion Criteria Not Met

Treatment Group:

Subject Number	Did the Subject Meet All Eligibility Criteria?	Criterion ID Not Met	Was a Waiver Provided so the Subject can CContinue on the Trial?	Date of Waiver
		Inclusion 1	Yes	YYYY-MM-DD
		Inclusion 2	No	
		Etc.		

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Listing 16.2.2.2

Protocol Deviations

Treatment Group:

Subject Number	Date	Visit	Deviation Type	Description
			Major	
			Minor	

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Listing 16.2.4.1

Demographics and Baseline Information

Treatment Group:

Subject Number	Age (years)	Sex	Race	Ethnicity	Height (metres)	Weight (kg)	BMI (kg/m^2)	Is Female Subject of Child-Bearing Potential?	If Yes, Form of Birth Control	If No, Reason
			American Indian or Alaska Native Asian Black or African-American Native Hawaiian or Other Pacific Islander White Other	Hispanic or Latino Not Hispanic or Latino Not Reported Unknown				Yes No	Condom (w/spermicide) Oral Patch Cervical Cap (w/spermicide) Vaginal Ring Vasectomized Partner Abstinence Diaphragm (w/spermicide) IUD Other	Post-Menopausal Surgically Sterile Hysterectomy Tubal Ligation Other, Specify

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Listing 16.2.4.2

Smoking History

Treatment Group:

Subject Number	Subject Have Smoking History	Type of Product Smoked	Date Subject Started to Smoke	Still Smoking?	Date Stopped Smoking	Number of Packs Per Day (Tobacco Products)	Number of Times Smoking Occurs per Week (non-tobacco products)
	Yes	Tobacco Products		Yes			
	No	Non-Tobacco Products		No			
		Both					

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Listing 16.2.4.3

Medical History

Treatment Group:

Subject Number	Medical History Condition/Event Description	MedDRA System Organ Class	Preferred Term	Date Diagnosed	Ongoing at Screening?	End Date	Currently Being Treated with Concomitant Medication?
							Yes
							No

Medical history is coded using MedDRA v20.0.

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Listing 16.2.5.1

Dosing Data

Treatment Group:

Subject Number	Visit	Date/Time of Dispense (Rel Day)	Weight of Investigational Product (mg)

Rel Day = Relative to first dose of study medication, Day 1.

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Listing 16.2.5.2

Extent of Exposure

Treatment Group:

Subject Number	Baseline Weight of Study Drug [1]	Week 4 Weight (g)	Amount of Product Used (g) [2]	Expected Weight	Percent Compliance [3]

[1] Cumulative study drug exposure = weight of the 4 drug bottles at last visit - weight of the 4 drug bottles at first dispense.
[2] Amount of product used per day = change / number of days the subject was on treatment.
[3] Percent compliance = (Net weight of study drug)/(Expected weight for 28 days of use)×100.

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Listing 16.2.6.1

EASI, VAS, IGA and Skindex Scores

Treatment Group:

Subject Number	Visit	Date	Rel Day	EASI	VAS	IGA	Total Skindex 16 Score	Symptom Subscale Score	Emotional Subscale Score	Functional Subscale Score

Rel Day = Relative to first dose of study medication, Day 1.

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Listing 16.2.6.2

Actigraphy Watch Readings

Treatment Group:

Subject Number	Date	Rel Day	Average Movement Count	Total Sleep Time	Total Wake Time	Total Number of Scratching Events	Scratching Events Per Hour	Sleep Efficiency (%)

Rel Day = Relative to first dose of study medication, Day 1.

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Listing 16.2.7.1

Adverse Events by Subject

Treatment Group:

Subject Number	Start Date/ Time (Rel Day)	Stop Date/ Time (Rel Day)	SOC/PT	Description	Severity / Grade	Serious?	Serious Criteria	Outcome [2]	Relation-ship [3]	Action Taken [4]	Discontinued from Study
					Mild / Grade 1	Yes					
						No					
					Mod. / Severe						

Adverse events are coded using MedDRA v20.0.
Rel Day = Relative to first dose of study medication, Day 1.
[1] Severity will be graded based on the NCI CTCAE, Version 4.03.
[2] R = Resolved , NR = Not Resolved.
[3] Treatment-related TEAE is defined as TEAE that was considered by the Investigator to be at least possibly related to the study drug. Relationship decode: Rel = Related, Poss = Possibly Related, Prob = Probably Related, Unl = Unlikely Related, Unr = Definitely Not Related.
[4] Action taken decode: None, Med = Concomitant Medication, Stop = Drug Stopped, Oth = Other.

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Listing 16.2.8.1.1

Hematology – Part 1

Treatment Group:

Subject Number	Visit	Date/ Time of Collection	Rel Day	Subject Fasting?	WBC (10^3/uL)	RBC (10^6/uL)	Hematocrit (%)	Hemoglobin (g/dL)	Platelets (10^3/uL)	Basophil (%)	Basophoil Absolute (10^3/ul)

H = High, L = Low, CS = Clinically Significant, NCS = Abnormal, Not Clinically Significant.
Rel Day = Relative to first dose of study medication, Day 1.

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Programming Note: Concatenate H or L to the lab value, if the lab value is not in the normal range.

Continue for all Hematology parameters in:
Listing 16.2.8.1.2 Hematology – Part 2

Repeat for all Chemistry parameters in:
Listing 16.2.8.2.1 Chemistry – Part 1
Listing 16.2.8.2.2 Chemistry – Part 2

Repeat for all Serology Parameters in:
Listing 16.2.8.3 Serology

Repeat for all Lipid Parameters in:
Listing 16.2.8.4 Lipids

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Listing 16.2.8.5

Urine Pregnancy Test

Treatment Group:

Subject Number	Visit	Date Performed	Rel Day	Pregnancy Test Done?	Reason Not Done	Test Result
					Not Childbearing Potential Female Other	Positive Negative

Rel Day = Relative to first dose of study medication, Day 1.

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PROGRAMMING NOTE: Report for females only.

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Listing 16.2.9.1

Vital Signs

Treatment Group:

Patient Number	Visit	Assessment Date	Rel Day	Height (inch)	Weight (kg)	BMI	Temperature (°C)	Pulse (beats/min)	Systolic Blood Pressure (mmHg)	Diastolic Blood Pressure (mmHg)

Note: Pre-treatment and on-treatment study days are numbered relative to the day of the first dose of study drug, which is designated as Day 1. Events occurring on the last day of study drug are designated with an "L". Post-treatment study days are numbered relative to the last dose and are signed positive.Eg:1P, 2P, etc.
Rel Day = Relative to first dose of study medication, Day 1.

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Listing 16.2.9.2

Physical Exam

Treatment Group:

Subject Number	Visit	Date	Rel Day	Body System	Result	Abnormality Description	Clinically Significant?
							Yes
							No

Rel Day = Relative to first dose of study medication, Day 1.

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PROGRAMMING NOTE: Concetatenate Result + Finding if result is abnormal. Do not present "Not Done" results.

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Listing 16.2.9.3

Concomitant Medications

Treatment Group:

Patient Number	ATC/ Generic Name/ Verbatim Name	Dose per Administration	Dose Units	Frequency	Indication	Route of Administration	Start Date (Rel Day)/ Stop Date (Rel Day)

Rel Day = Relative to first dose of study medication, Day 1.
Concomitant medications are any medications that did not end prior to first dose. If an end date is missing or the medication is ongoing, the medication is included.
Concomitant medications Anatomic Therapeutic Class (ATC) and Preferred Term (PT) are coded using the WHO Drug Dictionary version March 2017.

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Listing 16.2.9.4

Cleanser and Moisturizer

Treatment Group:

Subject Number	Visit	Date of Follow-up	Rel Day	Consistently [1] Using Provided Cleanser and Moisturizer?	If No, Reason	Other Cleanser/ Moisturizer Used	Fre-quency Since Last Visit	Plan to Use Sponsor-Provided Cleanser/ Mositurizer Moving Forward?	Refrain-ing from Makeup Use?	Return Remaining Cleanser/ Moisturizer?
				Yes No			<5 Times 5-10 Times >10 Times			

[1] Consistently meaning they have not used any other cleanser or moisturizer more than once or twice since the last visit.

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