Glenmark A new way for a new world	**STATISTICAL ANALYSIS PLAN**

Statistical Analysis Plan

Protocol No	GPL/CT/2014/018/III (Study No. GSP 301-303)
Protocol Title	A Double-Blind, Randomized, Parallel-Group Study to Evaluate Long-Term Safety, Tolerability, and Efficacy of a Fixed Dose Combination GSP 301 Nasal Spray Compared with Two Placebo Nasal Spray Formulations in Subjects (Aged 12 Years and Older) with Perennial Allergic Rhinitis (PAR)
Protocol version	Version 2.0
Sponsor	Glenmark Specialty S.A. Avenue Léopold-Robert 37 2300 La Chaux-de-Fonds Switzerland

Document Version History

Version Number	Version Date	Description of change
1.0	04-Apr-2017	New Document

Glenmark A new way for a new world	STATISTICAL ANALYSIS PLAN	
Protocol Number: GPL/CT/2014/018/III (Study No. GSP 301-303)	SAP Version Number: Version 1.0	SAP Version Date: 04-Apr-2017

Review and Approval Page

The signatures on this page indicate review and approval of Statistical Analysis Plan.

I have reviewed the above-mentioned version of Statistical Analysis Plan and confirm it to be complete and accurate.		
Prepared by:		
Senior Biostatistician	[redacted]	
	Signature:	**Date** (DD/MMM/YYYY): 04/APR/2017
Approval		
Director of Statistical Science	[redacted]	
	Signature:	**Date** (DD/MMM/YYYY): 05/April/2017

Abbreviations and Specialist Terms

ADaM	Analysis Data Model
AE	Adverse Event
AM	Morning
AESI	Adverse Events of Special Interest
ANCOVA	Analysis of Covariance
AR	Allergic rhinitis
BDRM	Blinded Data Review Meeting
BID	Twice Daily Dosing
CDISC	Clinical Data Interchange Standards Consortium
CI	Confidence Interval
CRF	Case Report Form
CRO	Contract Research Organization
CS	Clinically Significant
CSR	Clinical study report
ECG	Electrocardiogram
ENT	Ears, nose, and throat
°F	Degrees Fahrenheit
FAS	Full Analysis Set
FDA	Food and Drug Administration (of the United States)
FDC	Fixed dose combination
GSP 301 NS	Fixed Dose Combination of olopatadine hydrochloride and mometasone furoate nasal spray
iTNSS	Instantaneous Total Nasal Symptom Score
ICF	Informed consent form
ICH	International Conference on Harmonisation
ITT	Intent To Treat
IP	Investigational product
LOCF	Last Observation Carried Forward
LSM	Least squares mean
µg	Microgram
MedDRA	Medical Dictionary for Regulatory Activities
MMRM	Mixed Model Repeated Measures
NCS	Not Clinically Significant
NS	Nasal Spray
PAR	Perennial Allergic Rhinitis
PK	Pharmacokinetic
PNSS	Physician Assessed Nasal Symptom Score
PPS	Per Protocol Set
PT	Preferred Term
RCAT	Rhinitis Control Assessment Test

RQLQ(S)	Rhinoconjuntivitis Quality of Life Questionnaire Standardized Activities
rTNSS	Reflective Total Nasal Symptom Score
QD	Once Daily Dosing
SAEs	Serious Adverse Events
SAP	Statistical Analysis Plan
SAR	Seasonal Allergic Rhinitis
SAS	Statistical Analysis System
SAS	Safety Analysis Set
SD	Standard Deviation
SDTM	Study Data Tabulation Model
SOC	System Organ Class
SPT	Skin Prick Test
TEAE	Treatment-emergent Adverse Event
TNSS	Total Nasal Symptom Score

1.0 Changes to the Protocol Defined Statistical Analysis Plan

- The protocol states that the efficacy analysis will be conducted using an analysis of covariance (ANCOVA) model (adjusting for study treatment group, site and baseline). The efficacy analysis will now be analyzed using a mixed models repeated measures (MMRM) model. This will be more applicable to the design of the study, and assesses missing data using the Missing at Random (MAR) assumption. More detail is in Section 12.3.
- The protocol states that 'A multiple, imputation-based approach where complete data sets are drawn will be used for handling missing data in the efficacy analysis.' Because assessing efficacy is a secondary objective of the study, the sentence has been modified to state 'A multiple, imputation-based approach *may* be considered for handling missing data for AM reflective Total Nasal Symptom Score (rTNSS) and AM instantaneous Total Nasal Symptom Score (iTNSS) upon review of amount of missing data observed'. More details in Section 12.3.
- The protocol states that the computer-generated randomization scheme will be reviewed and approved by an independent statistician and the randomization will be stratified by site. This was inaccurately stated. The computer-generated randomization scheme will be reviewed and approved by a statistician and the randomization will not be stratified by site. More detail is in Section 7.0.
- The protocol has defined the Full Analysis Set (FAS) as 'The FAS will consist of all subjects who are randomized and received at least 1 dose of Investigational Product (IP) and have at least 1 post-baseline efficacy assessment.' To add more clarity the definition of the FAS is 'The FAS will consist of all subjects who are randomized and received at least 1 dose of IP and have at least 1 post-baseline AM rTNSS assessment.

2.0 Introduction

This Statistical Analysis Plan (SAP) is based on the final Clinical Study Protocol GPL/CT/2014/018/III Version 2.0 (Study No. GSP 301-303) dated 31-Aug-2016. The SAP provides details of the planned statistical methodology for the analysis of the study data. The SAP also outlines the statistical programming specifications for the tables, listings and figures.

This SAP describes the study endpoints, derived variables, anticipated data transformations and manipulations, and other details of the analyses not provided in the study protocol. This SAP therefore outlines in detail all other aspects pertaining to the planned analyses and presentations for this study.

The following documents were reviewed in preparation of this SAP:

- Final Clinical Study Protocol GPL/CT/2014/018/III Version 2.0 (Study No. GSP 301-303) dated 31-Aug-2016

- GSP 301-303 final CRF dated 19-May-2016

The reader of this SAP is encouraged to also read the clinical protocol for details on the conduct of this study, and the operational aspects of clinical assessments and timing for completing a subject in this study.

3.0 Objectives

3.1 Primary Objective

- To compare the long-term safety and tolerability of GSP 301 NS with 2 GSP 301 placebo NS formulations over 52 weeks of study treatment

3.2 Secondary Objective(s)

- To evaluate the long-term efficacy of GSP 301 NS compared with GSP 301 placebo NS p[redacted]n subjects with Perennial Allergic Rhinitis (PAR).

4.0 Study Endpoints

4.1 Primary Endpoints

- Proportion of subjects with treatment-emergent adverse events (TEAEs).
- Proportion of subjects with treatment-related TEAEs.
- Incidence, type, and severity of the TEAEs after 30 weeks of study treatment.
- Incidence, type, and severity of the TEAEs after 52 weeks of study treatment.
- Clinical laboratory assessments (hematology, serum biochemistry, and urinalysis) at baseline, Week 30, and Week 52.
- Vital signs, physical examinations (PE), and focused ears, nose, and throat (ENT) and eye examinations at baseline, Week 30, and Week 52.

4.2 Secondary Endpoints

Efficacy Endpoints:

- Change from baseline in the average AM subject-reported rTNSS over the first 6, 30, and 52 weeks of treatment.
- Change from baseline in the average AM subject-reported instantaneous Total Nasal Symptom Score (iTNSS) over the first 6, 30, and 52 weeks of treatment.
- Change from baseline in the overall Rhinoconjunctivitis Quality of Life Questionnaire – Standardized Activities (RQLQ(S)) score at Weeks 6, 30, and 52 for the Full Analysis Set (FAS).

Other Efficacy Endpoints:

Nasal symptoms:

- Change from baseline in the average AM subject-reported reflective individual nasal symptoms over the first 6, 30, and 52 weeks of treatment.
- Change from baseline in the average AM subject-reported instantaneous individual nasal symptoms over the first 6, 30, and 52 weeks of treatment.
- Change in the average AM subject-reported rTNSS and iTNSS from baseline to the end of each treatment week.
- Change in the average AM subject-reported reflective individual nasal symptoms from baseline to the end of each treatment week.
- Change in the average AM subject-reported instantaneous individual nasal symptoms from baseline to the end of each treatment week.

Physician assessed Nasal Symptom Score (PNSS), Rhinoconjunctivitis Quality of Life Questionnaire – Standardized Activities (RQLQ(S)), and Rhinitis Control Assessment Test (RCAT):

- Change from baseline in PNSS and physician assessed individual nasal symptoms at Weeks 6, 30, and 52.
- Change from baseline in individual domains of the RQLQ(S) at Weeks 6, 30, and 52 for the FAS.
- Change from baseline in overall RQLQ(S) score and individual domains of the RQLQ(S) at Weeks 6, 30, and 52 for the RQLQ(S) Analysis Set.
- Change from baseline in the RCAT at Weeks 6, 30, and 52.
- Change from baseline in individual domains of the RCAT at Weeks 6, 30, and 52.

5.0 Study Design

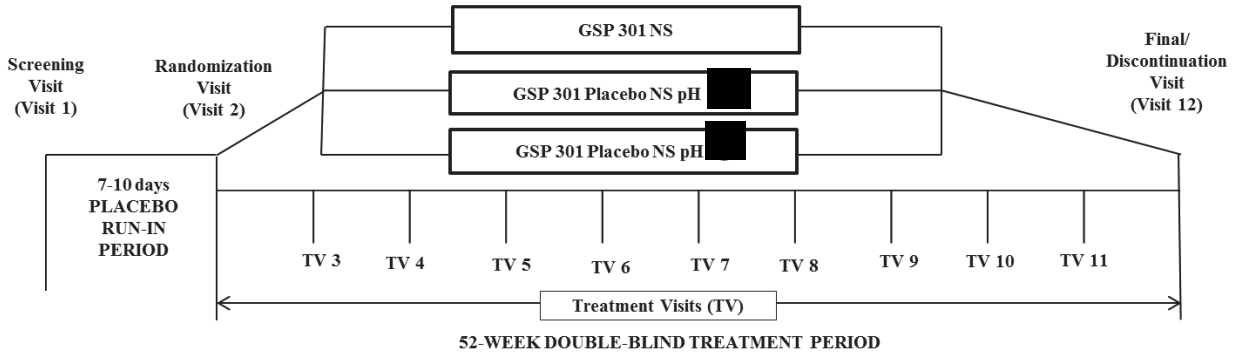
This is a multi-center, double-blind, randomized, parallel-group, 52-week study conducted in subjects with PAR. The subjects will be randomized to the following 3 treatment groups in a ratio of 4:1:1:

- GSP 301 NS (665 µg olopatadine hydrochloride/25 µg mometasone furoate) administered as [redacted]
- GSP 301 placebo NS pH [redacted] administered as [redacted]
- GSP 301 placebo NS pH [redacted] administered as [redacted]

This study consists of 12 visits to the study site (Figure 1). After the initial Screening Visit (Visit 1), subjects who meet all study selection criteria will undergo a single-blind, placebo, run-in period for 7 to 10 days. Following the completion of the run-in period, eligible subjects who meet the randomization criteria will be enrolled and randomized to 1 of the 3 treatment

groups. Randomized subjects will undergo a 52-week treatment period to assess the efficacy and safety of the assigned treatment.

Figure 1: Study Design Schematic



The Screening Visit (Visit 1) will occur 7 to 10 days before the Randomization Visit (Visit 2). The purposes of the Screening Visit (Visit 1) are to obtain informed consent, establish protocol eligibility, and enter eligible subjects into the placebo run-in period. Informed consent will be obtained after the study has been fully explained to each subject and before the conduct of any screening procedures or assessments. The Screening Disposition case report form/electronic case report form (CRF/eCRF) page must be completed to indicate whether the subject is eligible to participate in the study and to provide reasons for screen failure, if applicable. Eligible subjects will be given an AR Assessment Diary to record AR symptoms (morning [AM] rTNSS and iTNSS) during the 7 to 10 day run-in period.

After screening, all eligible subjects will participate in a single-blind, placebo (GSP 301 placebo NS pH [redacted]) run-in period. This is to familiarize the subjects to study procedures (such as study drug administration and symptom assessments) and to identify any potentially non-compliant subjects. The [redacted] of single-blind study medication will be taken immediately after completing the diary. The [redacted] of the single-blind study medication will be taken approximately 12 hours after the [redacted] Subjects must meet the key randomization criteria required for the run-in period (m n mum AM subject-reported rTNSS, AM subject-reported reflective nasal congestion score, adequate AR Assessment Diary compliance, and compliance with avoiding prohibited concomitant medications) to continue in the study.

The treatment period consists of 52 weeks. During this time, subjects will continue to assess their symptoms and complete the AR Assessment Diary every morning. The [redacted] dose of double-blind study medication will be taken immediately after completing the diary. The [redacted] dose of the single-blind study medication will be taken [redacted] The last dose of study medication should be the [redacted] dose on the day before the Final Visit/Discontinuation Visit (Visit 12).

No scheduled post-treatment follow-up visit is planned for this study. However, subjects will be followed up if there is any ongoing AE or for any other reason as per the Investigator's and Sponsor's discretion.

A telephone follow-up will be carried out for this study for any reason as per the Investigator's judgment. If needed, additional unscheduled visits may be conducted to ensure subject safety or to perform other study-related procedures at the discretion of the Investigator or the Sponsor.

No extension phase is planned for this study.

6.0 Statistical Hypotheses

N/A.

7.0 Randomization and Blinding

Subjects will be assigned to 1 of the 3 treatment groups in a 4:1:1 ratio based on a computer-generated randomization scheme that will be reviewed and approved by a statistician.

This study is designed as a double-blind study. The blinding will be maintained by packaging the active products and placebo in identical bottles and outer cartons. Additionally, an unblinded qualified person who is not associated with the study team, will facilitate the randomization process to ensure that the double-blind design of the study is maintained.

8.0 Sample Size Determination

The sample size of 600 subjects for this study (400 subjects on GSP 301 NS and 100 subjects in each of the 2 placebo groups) is based on the ICH E1 Guideline (ICH E1) and the FDA Guidance on Allergic Rhinitis[1] which requires treatment of at least 300 subjects for 6 months and 100 subjects for 1 year. Based on an estimated attrition rate of 25% after 6 months and 50% after 52 weeks, 400 subjects in the GSP 301 NS treatment group are considered sufficient to meet the above requirements.

9.0 Planned Analyses

9.1 Interim Analyses

There is no interim analysis planned in this study.

9.2 Final Analyses

All planned analyses will be carried out once the clinical database lock (DBL) has taken place. Once DBL has been achieved, unblinding will occur and the analyses will be performed.

10.0 Analysis Sets

Full Analysis Set (FAS)

The FAS will consist of all subjects who are randomized and received at least 1 dose of IP and have at least 1 post-baseline AM rTNSS assessment. This will be the primary analysis set for efficacy analyses.

Per Protocol Set (PPS)

The Per Protocol Set (PPS) will consist of the subset of the FAS who do not meet criteria for PPS exclusion. These criteria are to capture relevant non-adherence to the protocol (defined as a 'major deviation', especially those that affect interpretation of the AM rTNSS endpoint). The PPS will be a secondary analysis set for the efficacy analysis (except for RQLQ(S)). The PPS will be used to assess the robustness of the results from the statistical tests based on the FAS.

Major deviations will lead to the exclusion of a subject from the PPS. Major protocol deviations will be identified during the Blinded Data Review Meeting (BDRM) before database lock.

Major protocol deviations *may* include:

- Subjects who had their blinded randomization code broken.
- Subjects with overall treatment compliance <75% or >125%.
- Subjects who used prohibited medications (prior and/or concomitant) that may have significant influence on efficacy.
- Subjects who did not satisfy the inclusion/exclusion that may have significant influence on efficacy.
- Subjects not treated with the treatment assigned at randomization, but wrongly treated in another treatment group.

Safety Analysis Set (SAS)

The Safety Analysis Set (SAS) will consist of all subjects who took at least 1 dose of study medication following randomization and will be used for all safety analyses.

RQLQ(S) Analysis Set

The RQLQ(S) Analysis Set will consist of all English-speaking subjects ≥18 years old with impaired QOL at baseline as defined by a RQLQ(S) score at the Randomization Visit (Visit 2) of 3.0 or greater.

11.0 Efficacy Assessments and Derivation of Endpoints

11.1 Subject-Reported Nasal Symptoms

An efficacy measure in this study is the subject-reported Total Nasal Symptom Score (TNSS). The TNSS is defined as the sum of the subject-reported symptom scores for 4 nasal symptoms: rhinorrhea (runny nose), nasal congestion, nasal itching, and sneezing. The subject will assess and report his/her nasal symptoms in the morning (AM assessment) on each day of the placebo run-in and double-blind treatment periods prior to administering the study treatment. If a nasal symptom score is missing then the TNSS will be set to missing.

The subject will be asked to assess both reflective (i.e., an evaluation of symptom severity over the past 24 hours prior to the recording of the score) and instantaneous (i.e., an evaluation of the symptom severity just before taking study medication [redacted] nasal symptoms. Each of the following symptoms will be assessed.

Each of the following symptoms will be assessed.

Nasal Symptoms	
1. Nasal Congestion	2. Rhinorrhea (Runny Nose)
3. Nasal Itching	4. Sneezing

Each of the above symptoms will be rated on a 4-point scale as follows:

	Grade	Description
0	Absent	No Sign/Symptoms evident
1	Mild	Sign/Symptoms clearly present but minimal awareness; easily tolerated
2	Moderate	Definite awareness of sign/symptoms which is bothersome but tolerable
3	Severe	Sign/symptoms is hard to tolerate; causes interference with activities of daily living and or sleeping

Derivation Method and Baseline

Mixed Model Repeated Measures (MMRM) Approach

Change from baseline in average AM rTNSS to the end of each treatment week will be derived as the average of post-baseline AM rTNSS scores by week (i.e average AM rTNSS score for Week 1 is calculated as the mean rTNSS score in Week 1), where baseline is defined as the average of the last 4 consecutive AM assessments during the last 4 days of the run-in period from the Day -3 AM assessment to the AM assessment on the day of randomization. At least 2 out of 4 assessments (scores) should be available in order to

calculate the baseline scores for the AM rTNSS. In order to calculate the average of post-baseline AM rTNSS scores by week, at least 2 scores need to be present.

The same derivation method will also be applied to all other nasal symptom efficacy endpoints.

11.2 Rhinoconjunctivitis Quality-Of-Life Questionnaire - Standardized Activities (RQLQ(S))

The RQLQ(S) has 28 questions in 7 domains (activities, sleep, non-nose/eye symptoms, practical problems, nasal symptoms, eye symptoms, and emotional). Subjects will be asked to recall their experiences during the previous week and to give their responses on a 7-point scale (0=Not troubled to 6=Extremely troubled) for the domains of activities, sleep, non-nose/eye symptoms, practical problems, nasal symptoms, eye symptoms. The domain "emotional" will utilize a 7-point scale (0=None of the time to 6=All of the time).

RQLQ(S) scores will be summarized by domains. A domain average score is calculated as the sum of the scores in that domain divided by the number of items in that domain; all items in the domain must be valid in order to calculate the corresponding average score. A domain average score will be set to missing if there is a missing item score in that domain.

The overall average RQLQ(S) score is calculated as the sum of the scores in all domains divided by the total number of items in the seven domains; all items in the 7 domains must be valid in order to calculate the corresponding overall average score. If a domain score is missing then the overall average RQLQ(S) score will be set to missing.

Baseline is defined as the RQLQ(S) score at the Randomization Visit (Day 1; Visit 2).

11.3 Physician Assessed Nasal Symptom Score (PNSS)

The Physician-Assessed Total Nasal Symptom Score will be derived from the intensity of the following nasal symptoms associated with AR - rhinorrhea (runny nose), nasal congestion, nasal itching, and sneezing. Physicians will assess severity of the above symptoms for subject-reported nasal symptoms. The PNSS will be based on questioning of the subjects (overall feeling since last visit) and on the ENT examination and other observations by the physician. PNSS is calculated as the sum of the four nasal symptom scores. If a nasal symptom score is missing then the PNSS will be set to missing.

Baseline is defined as the PNSS at the Randomization Visit (Day 1; Visit 2).

11.4 Rhinitis Control Assessment Test (RCAT)

The Rhinitis Control Assessment Test (RCAT) is a brief, subject-completed tool to evaluate rhinitis symptom control. This questionnaire asks the subject about nasal and other allergy symptoms that are not related to a cold or the flu and the control of these symptoms over the past one week. Responses to the questions are scored by the number next to the response box. The total RCAT score will be calculated by adding individual RCAT item or domain scores. The total RCAT score can range from 6 to 30. If a RCAT item or domain score is missing then the total RCAT score will be set to missing.

Baseline is defined as the RCAT score at the Randomization Visit (Day 1; Visit 2).

12.0 Statistical Analysis Methods

In general, all data will be summarized with descriptive statistics (number of subjects, mean, and standard deviation, minimum, median and maximum) for continuous endpoints, and frequency and percentage for categorical endpoints.

All statistical analyses will be conducted using SAS®, Version 9.4 or higher. Datasets will be prepared using headings from Clinical Data Interchange Consortium (CDISC) Study Data Tabulation Model (SDTM, Version 3.2) implementation for human clinical trials and ADaM (Analysis Dataset Model, Version 1.0).

The treatments for all outputs will be labeled as and presented in the order below:

GSP 301 placebo NS pH[redacted]
GSP 301 placebo NS pH[redacted]
GSP 301 NS

The following conventions are applied to all data presentations and summaries:

- Descriptive statistics

  Minimum, Maximum: the same number of decimal places as the raw data Arithmetic mean, Standard Deviation (SD), Median: 1 more decimal place than the raw data.

  Descriptive statistics will be presented aligned by decimal point.

- Categorical Variables

  The number and percentage of the responses are presented in the form xxx (xx.x)

  Percentages: 1 decimal place

  No display of percentage in case that number of subject is zero unless otherwise stated

- P-values

  3 decimal places

  If the p-value is less than 0.001 then it will be presented as <0.001. If the rounded result is a value of 1.000, it will be displayed as >0.999

- Confidence Interval (CI) limits

  The same decimal places as the estimate (in the case of mean, 1 more decimal place than the raw data, and in the case of percentage, 1 decimal place)

A table, figure, listing is to be generated for any required item where no data is available or reported. This will ensure to the health authorities that the tables, figures, listings and narratives are accounted for.

- Generate a table or listing which states “No Data Available” or “No Data Reported”
- Print a one line message indicating there was no report data available: “NO DATA AVAILABLE FOR THIS REPORT”

12.1 Study Population Analyses

12.1.1 Overview of Planned Analyses

The study population analyses will be based on the safety analysis set, unless otherwise specified. **Table 1** provides an overview of the planned study population analyses.

Table 1: Overview of Planned Study Population Analyses

Display Type	Data Displays Generated		
	Table	Figure	Listing
Subject disposition			
Total screened	Y[1]		
Treated with study medication during run-in period	Y[1]		
Randomized	Y[2]		
Study completion/withdrawal	Y[2]		Y
Reason for early termination	Y[2]		Y
Protocol Deviations			
Protocol deviations recorded in the eCRF	Y[2]		Y
Subjects included in /excluded from analysis populations			
Summary of subjects in analysis population	Y[2]		
Subjects excluded from each analysis populations			Y
Subjects who withdrew due to inclusion/exclusion criteria with number			Y
Demographic and Baseline Characteristics			
Demographic Characteristics	Y[3]		Y
Medical History			Y
Exposure and Treatment Compliance			
Exposure	Y[2]		Y
Treatment Compliance	Y[2]		Y
Concomitant Medications			
Prior Medications			Y
Concomitant Medications			Y

NOTES :

- Y = Yes display generated.
- [1]: Data from clinic or database
- [2]: Display will be based on the SAS
- [3]: Display will be based on the SAS population and repeated for the FAS, PPS

12.1.2 Supplementary Information for Study Population Tables and Listings

12.1.2.1 Subject Disposition

The subject accountability and disposition information will be summarized by study treatment group. The number of subjects screened, treated with study medication during the run-in period, randomized, treated with study medication following randomization, and the number of subjects in each analysis set will be tabulated. In addition, completion status and primary reason for withdrawal will be summarized by study treatment group.

12.1.2.2 Demographic and Other Baseline Characteristics

Demographics and other baseline characteristics will be summarized by treatment group separately for the SAS, FAS, PPS, and RQLQ(S) analysis set.

Continuous variables such as age will be summarized using descriptive statistics (number of subjects, mean, standard deviation, median, minimum and maximum). Categorical variables such as sex and race will be summarized using frequencies and percentage.

All data will be listed by treatment and subject.

12.1.2.3 Medical History

All relevant medical and surgical history and current medical conditions will be recorded at the Screening Visit (Visit 1).

Medical history data will be listed by treatment and subject.

12.1.2.4 Extent of Exposure

The number of subjects exposed to each study treatment will be summarized.

The number of days on treatment and the number of days on study will be summarized by study treatment.

Treatment compliance will be calculated as follows:

> Compliance = (the total number of doses actually taken) / (total number of doses scheduled)*100 where:

For subjects who have completed the study, the total number of doses scheduled is 728 (2*7*52=728, [redacted] for 52 weeks).

For subjects whose participation is terminated early, compliance will be determined from their duration in the study, up to the time they are considered early terminated. The total number of doses scheduled = the minimum between 728 and [(Date of Discontinuation – Date of First Application +1)*2].

Subjects taking fewer than 75% or more than 125% of the required doses will be considered non-compliant with dosing.

In addition, treatment compliance will be classified into four categories (less than 75%, 75% to 100%, greater than 100% to125%, and greater than 125%). Treatment compliance will be summarized by categories and study treatment.

12.1.2.5 Concomitant Medications

At Visit 1 subjects will be questioned about current and prior concomitant medication use. At other visits subjects will be questioned about ongoing or new concomitant medication use.

Medications will be grouped and presented as follows:

- Prior medications: defined as medications that started and ended before the first administration of the study medication.
- Concomitant medications: defined as medications either ongoing or ended on or after the first dose of study medication.

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

- If the end date and 'ongoing' are missing then the medication will be considered as concomitant medication.
- In cases of partial end dates, the following conventions will be applied:
  - If the end day is missing, and the end month and year are not missing, the end day will be imputed using the last day of the month.
  - If the end day and month is missing, and the end year is not missing, the end day and month will be imputed using '31DEC'. If this leads to a date after the last visit date, then the last visit date will be used instead.
  - If the end date is completely missing, the end date will be imputed using the last visit date.
- The partial dates will be provided as such in the subject data listings (with the imputed dates).

12.2 Safety Analyses

12.2.1 Overview of Planned Safety Analyses

The safety analyses will be based on the SAS, unless otherwise specified.

Table 2 provides an overview of the planned analyses.

Table 2: Overview of Planned Safety Analyses

Display Type	Data Displays Generated		
	Table	Figure	Listing
Adverse Events			
Overview	Y[2]		
Treatment Emergent AEs	Y[1][2]		Y
Treatment Emergent AEs Severity	Y[2]		Y
Drug-Related AEs	Y[2]		Y
Placebo Run-In Period AEs	Y[2]		Y
AEs Leading to Withdrawal			Y
SAEs	Y[2]		Y
Treatment Emergent SAEs	Y[2]		Y
Laboratory			
Biochemistry	Y[3] [2]		Y
Haematology	Y[3] [2]		Y
Urinalysis	Y[3] [2]		Y
Pregnancy Test Results			Y
Other			
Vital Signs	Y[4] [2]		Y
ECGs	Y [5] [2]		Y
Physical Examination	Y[6] [2]		Y
Focused ENT Examination	Y[7] [2]		Y

NOTES :

- Y = Yes display generated.
- [1]: Display will also be produced by SOC, severity, and by relationship to study medication
- [2]: Display will be based on safety analysis set
- [3]: Display will be produced separately for overall laboratory assessments (inc. change from baseline), change from baseline in laboratory results, and potentially clinically significant laboratory results, and shift tables
- [4]: Display will be produced separately for overall summary (inc. change from baseline), for potentially clinically significant results, and shift tables
- [5]: Display will be produced separately for overall summary (inc. change from baseline), change from baseline in ECG interpretation, and potentially clinical significant ECGs, and shift tables
- [6]:Display will be produced separately for overall summary, and for potentially clinically significant results
- [7]:Display will be produced separately for overall summary, and for

Display Type	Data Displays Generated		
	Table	Figure	Listing
potentially clinically significant results			

12.2.2 Adverse Events

All AEs will be coded according to the current version of MedDRA (version 18.1 or later). Adverse events occurring between the subjects signing informed consent and administration of the first dose of the randomized study medication will be regarded as pre-treatment AEs and will be included in the subject listings but not in the summary tables. Adverse events occurring after the first dose of the randomized study medication will be defined as treatment-emergent adverse events (TEAEs) and will be listed and summarized by System Organ Class (SOC) and Preferred Term (PT).

The safety endpoints related to AEs are:

- Proportion of subjects with TEAEs.
- Proportion of subjects with treatment-related TEAEs.
- Incidence, type, and severity of the TEAEs after 30 weeks of study treatment.
- Incidence, type, and severity of the TEAEs after 52 weeks of study treatment.

Summaries of the number and percentage of subjects with TEAEs and the number of TEAEs experienced will be presented by treatment group. The number of subjects and the number of TEAEs will be presented using frequency counts and percentages, overall and by SOC and PT. The percentages will be calculated as the number of subjects with TEAEs divided by the number of subjects in the safety analysis set. Tables of the number and percentage of subjects and the number of TEAEs by intensity and by relationship to study medication will also be presented. Similar tables will be created for treatment related AEs. Events will be assigned to the study treatment administered prior to the start of the TEAE. Events that occurred during discharge and final follow-up will be assigned to the final treatment.

The number and percentage of subjects with a TEAE that has a start date within 30 weeks of the start of treatment (≤182 days) will be summarized by severity and study treatment group, overall, and by SOC and PT using frequency counts and percentages. A similar summary will be produced including all TEAEs during the study (i.e., after 52 weeks of treatment).

The overall p-value of the comparison among three treatment groups by SOC and PT will be produced using Fisher's exact test for each SOC and PT as well as overall subjects with at least one TEAEs. .

Additionally, the number and percentage of AEs, SAEs, TEAEs leading to discontinuation, and TEAEs related to the IP will be summarized by SOC, PT, and study treatment group.

12.2.3 Adverse Events of Special Interest (AESI)

The following SOC terms will be grouped into a Special Interest AE Group.

Special Interest AE Group	SOCs	PTs
Nasal toxicities	Respiratory, thoracic and mediastinal disorders	Nasal septum perforation
	Respiratory, thoracic and mediastinal disorders	Nasal mucosal ulcer
	Respiratory, thoracic and mediastinal disorders(Primary)	Epistaxis
Opthalmic toxicities	Eye disorders	-Open angle glaucoma -Glaucoma
	Investigations	Intraocular pressure increased
	Eye disorders	Cataract
Somnolence	Nervous system disorders(Primary)	Somnolence
Others	Nervous system disorders (Primary)	Dysgeusia
	Nervous system disorders	Headaches

The following tables will be produced for AESI:

- Summary of Treatment Emergent Adverse Events of Special Interest (Safety Analysis Set)
- Summary of Treatment Related Emergent Adverse Events of Special Interest (Safety Analysis Set)
- Summary of Treatment Emergent Adverse Events of Special Interest by Severity (Safety Analysis Set)
- Summary of Treatment Emergent Adverse Events of Special Interest by Relationship to Study Treatment (Safety Analysis Set)

12.2.4 Laboratory Data

Clinical laboratory test data (hematology, biochemistry, and urinalysis), will be summarized for each visit at which laboratory assessments are done (Screening Visit [Visit 1], Week 30 [Visit 8], and Week 52 [Visit 12]).

Descriptive statistics (number of subjects, mean, standard deviation, median, minimum and maximum) will be presented for laboratory data as well as change from baseline by treatment and visit.

Baseline is defined as the last available lab values at Screening Visit [Visit 1].

In addition, values outside the normal range and values deemed as clinically significant by the Investigator will be listed. The number of subjects with values of potentially clinical significance determined by the investigator will be tabulated by treatment group and visit.

Shift tables will present changes from baseline in laboratory data (categorized as normal; abnormal, not clinically significant; and abnormal, clinically significant) to end of treatment.

All laboratory data will be listed by treatment and subject.

12.2.5 Pregnancy Test

All females of child bearing potential will have a urine pregnancy test at each visit.

Pregnancy test results will be listed by treatment and subject.

12.2.6 Vital Signs

Descriptive statistics (number of subjects, mean, standard deviation, median, minimum and maximum) will be used to summarize vital sign results and changes from baseline by treatment group and time point (Week 1 [Visit 2], Week 30 [Visit 8] and Week 52 [Visit 12]).

Baseline is defined as the last available vital signs at Randomization Visit [Visit 2].

Values outside the respective normal range and values deemed as clinically significant by the Investigator will be listed.

The number of subjects with values of potential clinical significance determined by the investigator will be tabulated by treatment group and visit.

Shift tables will present changes from baseline in vital signs (categorized as normal; abnormal, not clinically significant; and abnormal, clinically significant) to end of treatment.

All vital sign data will be listed by treatment and subject.

12.2.7 ECGs

Descriptive statistics (number of subjects, mean, standard deviation, median, minimum and maximum) for ECG parameters and changes from baseline will be presented by treatment group.

Baseline is defined as the last available ECG values at Screening Visit [Visit 1].

Shift tables will present changes from baseline in ECG interpretation (categorized as normal; abnormal, not clinically significant; and abnormal, clinically significant) to end of treatment.

The number of subjects with values of potential clinical significance determined by the investigator will be tabulated by treatment group and visit.

All ECG data will be listed by treatment and subject.

12.2.8 Physical Examinations

Descriptive statistics (frequency and percentage) will be used to summarize physical examination results by treatment group and time point (Screening Visit, Week 30 and Week 52).

In addition, the number of subjects with values of potential clinical significance determined by the investigator will be tabulated.

All physical examination data will be listed by treatment and subject.

12.2.9 ENT examination

Descriptive statistics (frequency and percentage) will be used to summarize ENT examination results by treatment group and time point (Screening Visit, Week 30 and Week 52).

In addition, the number of subjects with values of potential clinical significance determined by the investigator will be tabulated.

All ENT examination data will be listed by treatment and subject.

12.2.10 Rescue Medication

Descriptive statistics will be used to summarize the number and percentage of subjects who used rescue medication by treatment and rescue medication categories.

Rescue medication along with the type, dose, and duration of rescue medication will be listed by treatment and subject.

12.3 Efficacy Analyses of Efficacy Endpoints

For all efficacy statistical analysis of efficacy endpoints, the comparison of interest will be GSP 301 NS vs. placebo NS pH[redacted] The statistical analysis will only include up to week 52 data in the analysis.

12.3.1 Overview of Efficacy Analysis of the Efficacy Endpoints (rTNSS, iTNSS, RQLQ(S) over the first 6, 30, and 52 weeks of treatment)

The efficacy analysis of the efficacy endpoints will be performed on the FAS (primary) and the PPS (supportive) for rTNSS and iTNSS. For RQLQ(S) outputs will be performed on the FAS.

Table 3 provides an overview of the planned efficacy analyses.

Table 3: Overview of Planned Efficacy Analyses

	Stats Analysis		Summary		Individual
	T	F	T	F	L
Change from baseline in the average AM rTNSS over the first 6, 30, and 52 weeks of treatment					
rTNSS – MMRM – FAS	Y	Y			
rTNSS – MMRM – PPS	Y	Y			
rTNSS Raw Data					
By Day (including post-baseline and change from baseline) - SAS					Y
Change from baseline in the average AM iTNSS over the first 6, 30, and 52 weeks of treatment					
iTNSS – MMRM – FAS	Y	Y			
iTNSS – MMRM – PPS	Y	Y			
iTNSS Raw Data					
By Day (including post-baseline and change from baseline) - SAS					Y
Change from baseline in the overall RQLQ(S) score at Weeks 6, 30, and 52					
RQLQ(S) – MMRM – FAS	Y	Y	Y		
RQLQ(S) Raw Data					
Visit (including post-baseline and change from baseline) - SAS					Y

NOTES :

- T = Table, F = Figure, L = Listing, Y = Yes display generated.
- Stats Analysis = Represents TF related to any formal statistical analyses (i.e. modeling) conducted.
- Summary = Represents TF related to summaries (i.e. descriptive statistics) of the baseline, post-treatment and change from baseline for the primary efficacy analyses method.
- Individual = Represents L related to any displays of individual subject observed raw data.

12.3.2 Analysis Method of the Efficacy Endpoints (rTNSS, iTNSS, RQLQ(S)): Mixed Model Repeated Measures Approach

12.3.2.1 Change from baseline in the average AM rTNSS over the first 6, 30 and 52 weeks of treatment

The efficacy endpoints rTNSS will be analyzed using a mixed model repeated measures model, adjusting for covariates that include treatment, site, baseline and week as the within-subject effect (for both the FAS and the PPS). The interactions of

site-by-treatment and baseline-by-treatment will be investigated separately in the model and will only be included in final model if they are statistically significant at the alpha=5% level. An unstructured (UN) covariance will be assumed. If the model does not converge using the unstructured covariance structure, the autoregressive (order 1) AR(1) structure will be used. If this also does not converge other covariance structures deemed appropriate to fit the data will be used. This method will assume that any missing data is Missing at Random (MAR). The statements of a SAS PROC MIXED analysis would be (if the interactions of treatment*baseline and treatment*site is not statistically significant):

```
proc mixed;
class subject treatment site week;
model change = treatment site baseline week;
repeated week / subject = subject type=UN;
lsmeans treatment / cl diff e ;
ods output lsmeans=lsmeans ;
ods output diffs=diffs ;
run ; quit ;
```

The adjusted means for each treatment and the estimated treatment differences for the treatment comparisons will be presented together with 95% confidence intervals for the differences and p-values for the treatment comparisons. The adjusted means and estimated treatment differences for the treatment comparisons will also be plotted, with corresponding 95% confidence intervals.

The responses for the first 6, 30 and 52 weeks of treatment will all be analysed in separate statistical models.

A multiple, imputation-based approach may be considered for handling missing data for AM rTNSS upon review of amount of missing data observed.

12.3.2.2 Change from baseline in the average AM iTNSS over the first 6, 30 and 52 weeks of treatment

AM iTNSS will be analyzed using same methods as described in Section 12.3.2.1.

The efficacy endpoints iTNSS will be analyzed using a mixed model repeated measures model, adjusting for covariates that include treatment, site, baseline and week as the within-subject effect (for both the FAS and the PPS). The interactions of site-by-treatment and baseline-by-treatment will be investigated separately in the model and will only be included in final model if they are statistically significant at the alpha=5% level. An unstructured (UN) covariance will be assumed. If the model does not converge using the unstructured covariance structure, the autoregressive (order 1) AR(1) structure will be used. If this also does not converge other covariance structures deemed appropriate to fit the data will be used. This method will assume that any missing data is Missing at Random (MAR). The statements of a

SAS PROC MIXED analysis would be (if the interactions of treatment*baseline and treatment*site is not statistically significant):

```
proc mixed;
class subject treatment site week;
model change = treatment site baseline week;
repeated week / subject = subject type=UN;
lsmeans treatment / cl diff e ;
ods output lsmeans=lsmeans ;
ods output diffs=diffs ;
run ; quit ;
```

The adjusted means for each treatment and the estimated treatment differences for the treatment comparisons will be presented together with 95% confidence intervals for the differences and p-values for the treatment comparisons. The adjusted means and estimated treatment differences for the treatment comparisons will also be plotted, with corresponding 95% confidence intervals.

The responses for the first 6, 30 and 52 weeks of treatment will all be analysed in separate statistical models.

A multiple, imputation-based approach may be considered for handling missing data for AM iTNSS upon review of amount of missing data observed.

12.3.2.3 Change from baseline in the overall RQLQ(S) score at Weeks 6, 30, and 52

RQLQ(S) (for the FAS) will be analyzed using similar methods as described in Section 12.3.2.1, with the following differences:

- Interaction of week-by-treatment will be included in the statistical model
  - Addition of week*treatment interaction in SAS model statement
  - Week*treatment interaction stated in SAS lsmeans statement
- The responses at 6, 30 and 52 weeks of treatment will all be analysed in the same statistical model.

The interactions of site-by-treatment and baseline-by-treatment will be investigated separately in the model and will only be included in final model if they are statistically significant at the alpha=5% level. An unstructured (UN) covariance will be assumed. If the model does not converge using the unstructured covariance structure, the autoregressive (order 1) AR(1) structure will be used. If this also does not converge other covariance structures deemed appropriate to fit the data will be used.

For each visit, the adjusted means for each treatment and the estimated treatment differences for the treatment comparisons will be presented together with 95% confidence intervals for the differences and p-values for the treatment comparisons.

The adjusted means and estimated treatment differences for the treatment comparisons will also be plotted, with corresponding 95% confidence intervals.

12.3.6 Examination of Subgroups

As well as producing summary tables for the efficacy endpoints rTNSS and iTNSS, the following subgroups of clinical interest will also be summarized for the FAS only by treatment group and week: age group (12-17, 18-65, 65 and above), sex (female/male), race (American Indian or Alaska Native, Asian, Black/African American, Other and White) and ethnicity (Hispanic or Latino and Not Hispanic or Latino).

12.4 Efficacy Analyses of Other Efficacy Endpoints

12.4.1 Overview of Analysis of the Other Efficacy Endpoints

The efficacy analysis of the other efficacy endpoints will be performed on the FAS only, unless otherwise specified. For RQLQ(S) certain outputs will also be performed on the RQLQ(S) analysis set. The interaction of site-by-treatment and baseline-by-treatment will not be investigated for the other efficacy endpoints.

Efficacy analyses of other efficacy endpoints include the following:

Nasal symptoms:

- Change from baseline in the average AM subject-reported reflective individual nasal symptoms over the first 6, 30, and 52 weeks of treatment.
- Change from baseline in the average AM subject-reported instantaneous individual nasal symptoms over the first 6, 30, and 52 weeks of treatment.
- Change in the average AM subject-reported rTNSS and iTNSS from baseline to the end of each treatment week.
- Change in the average AM subject-reported reflective individual nasal symptoms from baseline to the end of each treatment week.
- Change in the average AM subject-reported instantaneous individual nasal symptoms from baseline to the end of each treatment week.

Physician assessed Nasal Symptom Score (PNSS), Rhinoconjunctivitis Quality of Life Questionnaire – Standardized Activities (RQLQ(S)), and Rhinitis Control Assessment Test (RCAT):

- Change from baseline in PNSS and physician assessed individual nasal symptoms at Weeks 6, 30, and 52.
- Change from baseline in individual domains of the RQLQ(S) at Weeks 6, 30, and 52 for the FAS.

- Change from baseline in overall RQLQ(S) score and individual domains of the RQLQ(S) at Weeks 6, 30, and 52 for the RQLQ(S) Analysis Set.
- Change from baseline in the RCAT at Weeks 6, 30, and 52.
- Change from baseline in individual domains of the RCAT at Weeks 6, 30, and 52.

Table **4** provides an overview of the planned efficacy analyses.

Table 4: Overview of Planned Efficacy Analyses for Other Efficacy Endpoints

	Stats Analysis		Summary		Individual
	T	F	T	F	L
Change from baseline in the average AM reflective individual nasal symptoms over the first 6, 30, and 52 weeks of treatment					
MMRM – FAS	Y				Y
Change from baseline in the average AM instantaneous individual nasal symptoms over the first 6, 30, and 52 weeks of treatment					
MMRM – FAS	Y				Y
Change in the average AM subject-reported rTNSS and iTNSS from baseline to the end of each treatment week					
rTNSS – MMRM – FAS	Y		Y		Y
rTNSS - PPS			Y		
iTNSS – MMRM – FAS	Y		Y		Y
iTNSS - PPS			Y		
Change in the average AM reflective individual nasal symptoms from baseline to the end of each treatment week					
MMRM – FAS	Y		Y		Y
Change in the average AM instantaneous individual nasal symptoms from baseline to the end of each treatment week					
MMRM – FAS	Y		Y		Y
Change from baseline in PNSS and physician assessed individual nasal symptoms at Weeks 6, 30, and 52					
MMRM – FAS	Y		Y		Y
Change from baseline in individual domains of the RQLQ(S) at Weeks 6, 30, and 52 for the FAS					
MMRM – FAS	Y		Y		Y
Change from baseline in overall RQLQ(S) score and individual domains of the RQLQ(S) at Weeks 6, 30, and 52 for the RQLQ(S) Analysis Set					
MMRM – RQLQ analysis set	Y		Y		
Change from baseline in the RCAT at Weeks 6, 30, and 52					
MMRM – FAS	Y		Y		Y
Change from baseline in individual domains of the RCAT at Weeks 6, 30, and 52					
MMRM – FAS	Y		Y		Y

NOTES :

- T = Table, F = Figure, L = Listing, Y = Yes display generated.
- Stats Analysis = Represents TF related to any formal statistical analyses (i.e. modeling) conducted.
- Summary = Represents TF related to summaries (i.e. descriptive statistics) of the baseline, post-treatment and change from baseline for the primary efficacy analyses method.
- Individual = Represents L related to any displays of individual subject observed raw data.

12.4.2 Analysis of Change from Baseline in Other Efficacy Endpoints

12.4.2.1 Change from baseline in the average AM reflective and AM instantaneous individual nasal symptoms over the first 6, 30, and 52 weeks of treatment

Similar to the analysis mentioned in section 12.3.2.1, the endpoints will be analyzed separately using a mixed model repeated measures model (by each individual nasal symptom), adjusting for covariates that include treatment, site, baseline and week as the within-subject effect (for the FAS). An unstructured (UN) covariance will be assumed. If the model does not converge using the unstructured covariance structure, the autoregressive (order 1) AR(1) structure will be used. If this also does not converge other covariance structures deemed appropriate to fit the data will be used. The statements of a SAS PROC MIXED analysis would be:

```
proc mixed;

by individual nasal symptom;
class subject treatment site week;
model change = treatment site baseline week;
repeated week / subject = subject type=UN;
lsmeans treatment / cl diff e ;
ods output lsmeans=lsmeans ;
ods output diffs=diffs ;
run ; quit ;
```

For each individual nasal symptom, the adjusted means for each treatment and the estimated treatment differences for the treatment comparisons will be presented together with 95% confidence intervals for the differences and p-values for the treatment comparisons. The adjusted means and estimated treatment differences for the treatment comparisons will also be plotted, with corresponding 95% confidence intervals.

The responses for the first 6, 30 and 52 weeks of treatment will all be analysed in separate statistical models.

12.4.2.2 Change in the average AM subject-reported rTNSS and iTNSS from baseline to the end of each treatment week

The efficacy endpoints rTNSS and iTNSS will be analyzed separately using a mixed model repeated measures model, adjusting for covariates that include treatment, site, baseline and week as the within-subject effect, and the model will include treatment*week interaction term (for the FAS). The statements of a SAS PROC MIXED analysis would be:

```
proc mixed;
```

```
class subject treatment site week;
model change = treatment site baseline week treatment*week;
repeated week / subject = subject type=UN;
lsmeans treatment treatment*week / cl diff e ;
ods output lsmeans=lsmeans ;
ods output diffs=diffs ;
run ; quit ;
```

For each week, the adjusted means for each treatment and the estimated treatment differences for the treatment comparisons will be presented together with 95% confidence intervals for the differences and p-values for the treatment comparisons. The adjusted means and estimated treatment differences for the treatment comparisons will also be plotted, with corresponding 95% confidence intervals.

Descriptive statistics (number of subjects, mean, standard deviation, median, minimum and maximum) will be provided for baseline, post treatment and change from baseline by treatment group and week (for both the FAS and the PPS).

12.4.2.3 Change in the average AM reflective and AM instantaneous individual nasal symptoms from baseline to the end of each treatment week

Similar to Section 12.4.2.2, the efficacy endpoints will be analyzed separately using a mixed model repeated measures model, adjusting for covariates that include treatment, site, baseline and week as the within-subject effect, and the model will include treatment*week interaction term (for the FAS). The statements of a SAS PROC MIXED analysis would be:

```
proc mixed;

by individual nasal symptom;
class subject treatment site week;
model change = treatment site baseline week treatment*week;
repeated week / subject = subject type=UN;
lsmeans treatment treatment*week / cl diff e ;
ods output lsmeans=lsmeans ;
ods output diffs=diffs ;
run ; quit ;
```

For each individual symptom and each week, the adjusted means for each treatment and the estimated treatment differences for the treatment comparisons will be presented together with 95% confidence intervals for the differences and p-values for the treatment comparisons. The adjusted means and estimated treatment differences for the treatment comparisons will also be plotted, with corresponding 95% confidence intervals.

12.4.2.4 Change from baseline in PNSS, Overall RQLQ(S) score and RCAT at Weeks 6, 30, and 52

RQLQ(S) (for RQLQ(S) Analysis Set), PNSS (for FAS) and RCAT (for FAS) will be analyzed separately using the same methods as described in Section 12.3.2.2 with the exeption that the interaction of site-by-treatment and baseline-by-treatment will not be investigated separately in the model.

12.4.2.5 Change from baseline in physician assessed individual nasal symptoms, individual domains of the RQLQ(S) and individual domains of the RCAT at Weeks 6, 30, and 52

RQLQ(S) (for both the FAS and RQLQ(S) Analysis Set), PNSS (for FAS) and RCAT (for FAS) will be analyzed separately using the same methods as described in Section 12.4.2.4, with the addition of a by statement (for the individual symptoms/domains) in the SAS PROC MIXED model.

Appendix 1

The following shells are provided in order to provide a framework for the display of data from this study. These shells may not be reflective of every aspect of this study but are intended to show the general layout of the Tables, Listings and Figures that will be included in the final clinical study report. Tables, Listings and Figures are numbered following the ICH structure. Table headers, variables names and footnotes will be modified as needed following data analyses. Additional Tables, Listings and Figures will be generated, as needed, following the data analysis (post-hoc). All descriptive and inferential statistical analyses will be performed using SAS® statistical software Version 9.4 or later, unless otherwise noted. In general, Listings will be sorted and presented by treatment and subject number. Subject number when broken down consists of the Site Number and Subject Number.

Tables:

Listings:

Figures:

T14.1.9.1 Summary of Subject Disposition

Subjects	GSP 301 placebo NS pH[redacted] (N=xxx) n (%)	GSP 301 placebo NS pH[redacted] (N=xxx) n (%)	GSP 301 NS (N=xxx) n (%)	Total (N=xxx) n (%)
Total Screened				xxx
Screen failures				xxx
Treated in run-in period				xxx
Randomized	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Randomized failures				xxx
Terminated early	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Completed study	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Early Termination Reason				
Adverse Event	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Death	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Lack of efficacy	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Lost to follow-up	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Non-compliance with study drug	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Physician Decision	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Protocol Deviation	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Pregnancy	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Study terminated by sponsor	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Withdrawal by subject	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Withdrawal by parent/guardian	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Withdrawal of consent	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Others	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Data source: xx
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T14.1.9.2.1 Summary of Protocol Deviations During Randomized Treatment Period (Safety Analysis Set)

	GSP 301 placebo NS pH[redacted] (N=xxx) n (%)	GSP 301 placebo NS pH[redacted] (N=xxx) n (%)	GSP 301 NS (N=xxx) n (%)
Total Subjects with Protocol Deviations	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Total Deviations	xxx	xxx	xxx
Restricted medication/procedure used for the treatment of seasonal allergic rhinitis	xxx	xxx	xxx
Restricted medication/procedure used for reasons other than the treatment of seasonal allergic rhinitis	xxx	xxx	xxx
Lost to follow up	xxx	xxx	xxx
Enrolled in error	xxx	xxx	xxx
Randomized in error	xxx	xxx	xxx
Non-compliance with study drug	xxx	xxx	xxx
Non-compliance with study procedure	xxx	xxx	xxx
Outside visit window	xxx	xxx	xxx
Visit procedure not completed per protocol	xxx	xxx	xxx
Dosing procedure non-compliance	xxx	xxx	xxx
Lost to follow up	xxx	xxx	xxx
rTNSS ratings non-compliance	xxx	xxx	xxx
Other	xxx	xxx	xxx

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T14.1.9.2.2 Summary of Protocol Deviations during Placebo Run-In Period
Repeat of T14.1.9.2.1 for placebo Run-in period

T14.1.9.2.3 Summary of Major Protocol Deviations during Randomized Treatment Period
Repeat of T14.1.9.2.1 for major protocol deviations in treatment period

T14.1.9.3 Summary of Subjects in Each Analysis Set

Number of Subjects	GSP 301 placebo NS pH[redacted] (N=xxx n (%)	GSP 301 placebo NS pH[redacted] (N=xxx n (%)	GSP 301 NS (N=xxx) n (%)	Overall (N=xxx) n (%)
Randomized	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Safety analysis set	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Did not take any study medication	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Full analysis set	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Did not have at least one post-baseline primary AM rTNSS assessment	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Per protocol set	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Subjects with Major protocol violation	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
RQLQ(S) Analysis Set	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

Data source: xx

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T14.1.9.4.1 Summary of Demographic Data
(Safety Analysis Set)

		GSP 301 placebo NS pH[redacted] (N=xxx)	GSP 301 placebo NS pH[redacted] (N=xxx)	GSP 301 NS (N=xxx)	Overall (N=xxx)
Age	n	xxx	xxx	xxx	xxx
	Mean (SD)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)	xx.x (xx.x)
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Race n (%)	White	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Asian	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	American Indian or Alaska Native	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Black/African American	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Native Hawaiian or other Pacific Islander	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Other	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Ethnicity n (%)	Hispanic or Latino	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Not Hispanic or Latino	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Sex n (%)	Male	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Female	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

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

Data source: xx
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T14.1.9.4.2 Summary of Demographic Data (Full Analysis Set)

Repeat of T14.1.9.4.1 for FAS

T14.1.9.4.3 Summary of Demographic Data (Per Protocol Set)

Repeat of T14.1.9.4.1 for PPS

T14.1.9.4.4 Summary of Demographic Data (RQLQ(S) Analysis Set)

Repeat of T14.1.9.4.1 for RQLQ(S) analysis set

T14.1.9.5.1 Overall Summary of Treatment Emergent Adverse Events after 52 Weeks of Study Treatment (Safety Analysis Set)

	GSP 301 placebo NS pH[redacted] (N=xxx)	GSP 301 placebo NS pH[redacted] (N=xxx)	GSP 301 NS (N=xxx)
Subjects in Safety Analysis Set (N1)	xxx	xxx	xxx
Subjects with at least one TEAE (n1(%))	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Discontinued study drug due to above AE (n1(%))	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
TEAEs reported (N2)	xxx	xxx	xxx
Mild (n2(%))	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Moderate (n2(%))	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Severe (n2(%))	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Not Related (n2(%))	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Related (n2(%))	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Death (n2(%))	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Serious AE (n2(%))	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

N1: number of subjects in safety analysis sets in treatment group; n1(%): percentage based on N1

N2: number of adverse events in treatment group; n2(%): percentage based on N2

Data source: xx

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T14.1.9.5.2 Overall Summary of Treatment Emergent Adverse Events after 30 Weeks of Study Treatment (Safety Analysis Set)

Repeat of T14.1.9.5.1 for after 30 weeks of study treatment

T14.1.9.5.3 Summary of Treatment Emergent Adverse Events after 52 Weeks of Study Treatment (Safety Analysis Set)

Body System	MedDRA Term	GSP 301 placebo NS pH[redacted] (N=xxx) Events	GSP 301 placebo NS pH[redacted] (N=xxx Subjects n(%)	GSP 301 NS (N=xxx) Events	Subjects n(%)	Events	Subjects n(%)	Fisher's P-value
Subjects with at least one AEs	Total	xxx	xxx (xx.x)	xxx	xxx (xx.x)	xxx	xxx (xx.x)	x.xxxx
Ear and labyrinth disorders	Ear pain	xxx	xxx (xx.x)	xxx	xxx (xx.x)	xxx	xxx (xx.x)	x.xxxx
	etc.							
etc.								

N = Total number of subjects in each treatment group in the safety set; n = number of subjects with adverse events in each MedDRA term; Percentages are based on total number of subjects in the safety set within each treatment group.

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.5.4 Summary of Treatment Emergent Adverse Events after 30 Weeks of Study Treatment (Safety Analysis Set)

Repeat of T14.1.9.5.3 for after 30 weeks of study treatment

T14.1.9.5.5 Summary of Treatment-Related Emergent Adverse Events after 52 Weeks of Study Treatment (Safety Analysis Set)

Repeat of T14.1.9.5.3 for related TEAEs after 52 weeks of study treatment

T14.1.9.5.6 Summary of Treatment-Related Emergent Adverse Events after 30 Weeks of Study Treatment (Safety Analysis Set)

Repeat of T14.1.9.5.3 for related TEAEs after 30 weeks of study treatment

T14.1.9.5.7 Summary of Treatment Emergent Adverse Events of Special Interest (Safety Analysis Set)

Repeat of T14.1.9.5.3 for AESI

T14.1.9.5.8 Summary of Treatment Related Emergent Adverse Events of Special Interest (Safety Analysis Set)

Repeat of T14.1.9.5.3 for related TEAEs of AESI

T14.1.9.5.9 Summary of Treatment Emergent Adverse Events after 52 Weeks of Study Treatment by Severity (Safety Analysis Set)

		GSP 301 placebo NS pH[redacted] # of Events (N=xx)			GSP 301 placebo NS pH[redacted] # of Events (N=xx)			GSP 301 NS # of Events (N=xx)		
Body System	MedDRA Term	Mild n(%)	Moderate n(%)	Severe n(%)	Mild n(%)	Moderate n(%)	Severe n(%)	Mild n(%)	Moderate n(%)	Severe n(%)
Total AEs	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)	xx (xx.x)
Ear and labyrinth disorders	Ear pain	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

N = Total number of subjects in each treatment group in the safety set; n = number of subjects with adverse events in each MedDRA term;
Percentages are based on total number of subjects in the safety set within each treatment group

Data source: xx
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T14.1.9.5.10 Summary of Treatment Emergent Adverse Events after 30 Weeks of Study Treatment by Severity (Safety Analysis Set)

Repeat of T14.1.9.5.9 for after 30 weeks of study treatment

T14.1.9.5.11 Summary of Treatment Emergent Adverse Events of Special Interest by Severity (Safety Analysis Set)

Repeat of T14.1.9.5.9 for AESI

T14.1.9.5.12 Summary of Treatment Emergent Adverse Events after 52 Weeks of Study Treatment by Relationship to Study Treatment (Safety Analysis Set)

		GSP 301 placebo NS pH[redacted] # of Events (N=xx)		GSP 301 placebo NS pH[redacted] # of Events (N=xx)		GSP 301 NS # of Events (N=xx)	
Body System	MedDRA Term	Related n(%)	Not Related n(%)	Related n(%)	Not Related n(%)	Related n(%)	Not Related n(%)
Total AEs	Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
Ear and labyrinth disorders	Ear pain	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

N = Total number of subjects in each treatment group in the safety set; n = number of subjects with adverse events in each MedDRA term;
Percentages are based on total number of subjects in the safety set within each treatment group

Data source: xx
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T14.1.9.5.13 Summary of Treatment Emergent Adverse Events after 30 Weeks of Study Treatment by Relationship to Study Treatment (Safety Analysis Set)

Repeat of T14.1.9.5.12 for after 30 weeks of study treatment

T14.1.9.5.14 Summary of Treatment Emergent Adverse Events of Special Interest by Relationship to Study Treatment (Safety Analysis Set)

Repeat of T14.1.9.5.12 for AESI

T14.1.9.5.15 Summary of Treatment Emergent Serious Adverse Events after 52 Weeks of Study Treatment (Safety Analysis Set)

Body System	MedDRA Term	GSP 301 placebo NS pH[redacted] (N=xxx) n(%)	GSP 301 placebo NS pH[redacted] (N=xxx) n(%)	GSP 301 NS (N=xxx) n(%)
Subject with at least one SAE	Subject with at least one SAE	xxx (xx.x)	xxx(xx.x)	xxx(xx.x)
Gastrointestinal disorders	Dry mouth	xxx (xx.x)	xxx (xx.x)	xxx(xx.x)
etc.	etc.			

N = Total number of subjects in each treatment group in the safety set;
n = number of subjects with adverse events in each MedDRA term;
Percentages are based on total number of subjects in the safety set within each treatment group

Data source: xx
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T14.1.9.5.16 Summary of Treatment Emergent Serious Adverse Events after 30 Weeks of Study Treatment (Safety Analysis Set)

Repeat of T14.1.9.5.15 for after 30 weeks of study treatment

T14.1.9.5.17 Summary of Treatment Related Emergent Serious Adverse Events after 52 Weeks of Study Treatment (Safety Analysis Set)

Repeat of T14.1.9.5.15 for treatment emergent SAE after 52 weeks of study treatment

T14.1.9.5.18 Summary of Treatment Related Emergent Serious Adverse Events after 30 Weeks of Study Treatment (Safety Analysis Set)

Repeat of T14.1.9.5.15 for treatment emergent SAE after 30 weeks of study treatment

T14.1.9.5.19.1 Overall Summary of Adverse Events During Placebo Run-In Period (Safety Analysis Set)

	GSP 301 placebo NS pH[redacted]	GSP 301 placebo NS pH[redacted]	GSP 301 NS
Subjects in Safety Analysis Set (N1)	xxx	xxx	xxx
Subjects with at least one AE n1(%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Discontinued study drug due to above AE n1(%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
AEs reported (N2)	xxx	xxx	xxx
Mild n2(%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Moderate n2(%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Severe n2(%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Not Related n2(%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Related n2(%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Death n2(%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
Serious AE n2(%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

N1: number of subjects in safety analysis sets in treatment group; n1(%): percentage based on N1

N2: number of adverse events in treatment group; n2(%): percentage based on N2

Data source: xx

Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.5.19.2 Overall Summary of Adverse Events Pre-Randomization

Repeat of T14.1.9.5.19.1 for pre-randomization

T14.1.9.6.1 Summary of Clinical laboratory Assessment (Biochemistry)
(Safety Analysis Set)
Lab Test: xxxxx

			Observed Data				Change from Baseline		
Treatment Group	Visit	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH[redacted](N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	Visit 8	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	Visit 12	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH[redacted](N=xxx)									
GSP 301 NS (N=xxx)									

Baseline is defined as the last available lab values at Screening Visit [Visit 1].

Table will continue for other lab tests.

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.6.2 Summary of Clinical laboratory Assessment (Hematology)
(Safety Analysis Set)

Repeat of T14.1.9.6.1 for hematology

T14.1.9.6.3 Summary of Clinical laboratory Assessment (Urinalysis)
(Safety Analysis Set)

Repeat of T14.1.9.6.1 for urinalysis

T14.1.9.6.4 Summary of Potentially Clinical Significant Laboratory Results (Biochemistry)
(Safety Analysis Set)
Lab Test: xxxxx

Treatment Group	Visit	Normal n(%)	Abnormal n(%)	Abnormal (NCS) n(%)	Abnormal(CS) n(%)
GSP 301 placebo NS pH[redacted](N=xxx)	Baseline	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 8	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 12	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted](N=xxx)					
GSP 301 NS (N=xxx)					

. Baseline is defined as the last available lab values at Screening Visit [Visit 1].
CS= Clinically Significant, NCS= Not Clinically Significant

Table will continue for other lab tests.

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.6.5 Summary of Potentially Clinical Significant Laboratory Results (Hematology) (Safety Analysis Set)

Repeat of T14.1.9.6.4 for hematology

T14.1.9.6.6 Summary of Potentially Clinical Significant Laboratory Results (Urinalysis) (Safety Analysis Set)

Repeat of T14.1.9.6.4 for urinalysis

T14.1.9.6.7 Shift Tables for Changes from Baseline in Laboratory Results (Biochemistry) to End of Treatment (Safety Analysis Set)

Lab Test: xxxxx

		End of Treatment			
Treatment Group	Baseline	Normal n (%)	Abnormal n (%)	Abnormal (NCS) n (%)	Abnormal (CS) n (%)
GSP 301 placebo NS pH[redacted]N=xxx)	Normal	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Abnormal	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Abnormal (NCS)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Abnormal (CS)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted]N=xxx)					
GSP 301 NS (N=xxx)					

. Baseline is defined as the last available lab values at Screening Visit [Visit 1].
CS= Clinically Significant, NCS= Not Clinically Significant

Table will continue for other lab tests.

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.6.8 Shift Tables for Changes from Baseline in Laboratory Results (Hematology) to End of Treatment (Safety Analysis Set)

Repeat of T14.1.9.6.7 for hematology

T14.1.9.6.9 Shift Tables for Changes from Baseline in Laboratory Results (Urinalysis) to End of Treatment (Safety Analysis Set)

Repeat of T14.1.9.6.7 for urinalysis

T14.1.9.7.1 Summary of Vital Signs
(Safety Analysis Set)

Systolic Blood Pressure (mmHg)

		Observed Data				Change from Baseline			
Treatment Group	Visit	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH[redacted](N=xxx)	Visit 2	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	Visit 8	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	Visit 12	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH[redacted](N=xxx)									

Baseline is defined as the last available vital signs at Randomization Visit [Visit 2].
Table will continue for Diastolic Blood Pressure (mmHg) and Pulse Rate (bpm).

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.7.2 Summary of Potentially Clinical Significant Vital Signs
(Safety Analysis Set)

Systolic Blood Pressure (mmHg)

Treatment Group	Visit	Normal n (%)	Abnormal n (%)	Abnormal (NCS) n (%)	Abnormal (CS) n (%)
GSP 301 placebo NS pH[redacted] (N=xxx)	Visit 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 2	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 8	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 12	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted] (N=xxx)					
GSP 301 NS (N=xxx)					

Baseline is defined as the last available vital signs at Randomization Visit [Visit 2].
CS= Clinically Significant, NCS= Not Clinically Significant

Table will continue for Diastolic Blood Pressure (mmHg) and Pulse Rate (bpm).

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.7.3 Shift Tables for Changes from Baseline in Vital Signs to End of Treatment
(Safety Analysis Set)

Systolic Blood Pressure (mmHg)

		End of Treatment			
Treatment Group	Baseline	Normal n (%)	Abnormal n (%)	Abnormal (NCS) n (%)	Abnormal (CS) n (%)
GSP 301 placebo NS pH[redacted](N=xxx)	Normal	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Abnormal	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Abnormal (NCS)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Abnormal (CS)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted](N=xxx)					
GSP 301 NS (N=xxx)					

. Baseline is defined as the last available vital signs at Randomization Visit [Visit 2].
CS= Clinically Significant, NCS= Not Clinically Significant

Table will continue for Diastolic Blood Pressure (mmHg) and Pulse Rate (bpm).

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.8.1 Summary of ECGs
(Safety Analysis Set)

PR Interval

		Observed Data				Change from Baseline			
Treatment Group	Visit	N	Mean (SD)	Median	Min, Max	N	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH[redacted](N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	Visit 12	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH[redacted](N=xxx)									
GSP 301 NS (N=xxx)									

Baseline is defined as the last available ECG values at Screening Visit [Visit 1].
Table will continue for other ECG parameters.

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.8.2 Summary of Potentially Clinical Significant ECGs
(Safety Analysis Set)

Treatment Group	Visit	Normal n (%)	Abnormal n (%)	Abnormal (NCS) n (%)	Abnormal (CS) n (%)
GSP 301 placebo NS pH[redacted] N=xxx)	Baseline	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 12	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted] (N=xxx)					
GSP 301 NS (N=xxx)					

. Baseline is defined as the last available ECG values at Screening Visit [Visit 1].
CS= Clinically Significant, NCS= Not Clinically Significant

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.8.3 Shift Tables for Changes from Baseline in ECG Interpretation to End of Treatment (Safety Analysis Set)

		End of Treatment			
Treatment Group	Baseline	Normal n (%)	Abnormal n (%)	Abnormal (NCS) n (%)	Abnormal (CS) n (%)
GSP 301 placebo NS pH[redacted](N=xxx)	Normal	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Abnormal	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Abnormal (NCS)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Abnormal (CS)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted](N=xxx)					
GSP 301 NS (N=xxx)					

. Baseline is defined as the last available ECG values at Screening Visit [Visit 1].
CS= Clinically Significant, NCS= Not Clinically Significant

Data source: xx
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T14.1.9.9 Summary of Physical Examinations (Safety Analysis Set)

General Appearance

Treatment Group	Visit	Normal n (%)	Abnormal n (%)	Abnormal (NCS) n (%)	Abnormal (CS) n (%)
GSP 301 placebo NS pH[redacted]N=xxx)	Visit 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 8	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 12	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted](N=xxx)					
GSP 301 NS (N=xxx)					

. CS= Clinically Significant, NCS= Not Clinically Significant

Table will continue for other body systems.

Data source: xx

Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.10.1 Summary of Focused ENT Examination (Safety Analysis Set)

ENT Examination: Nasal Irritation

Treatment Group	Visit	ENT Grading					
		0 n (%)	1A n (%)	1B n (%)	2 n (%)	3 n (%)	4 n (%)
GSP 301 placebo NS pH[redacted] (N=xxx)	Visit 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 2	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 3	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 4	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 5	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 6	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 7	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 8	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 9	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 10	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 11	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 12	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted] N=xxx)							
GSP 301 NS (N=xxx)							

Data source: xx

Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.10.1 Summary of Focused ENT Examination (Safety Analysis Set) (continued)

ENT Examination: Epistaxis

Treatment Group	Visit	ENT Grading 0 (None) n (%)	1 (Mild) n (%)	2 (Moderate) n (%)	3 (Severe) n (%)
GSP 301 placebo NS pH[redacted]N=xxx)	Visit 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 2	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 3	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 4	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 5	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 6	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 7	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 8	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 9	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 10	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 11	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 12	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted](N=xxx)					
GSP 301 NS (N=xxx)					

Programming notes: table will continue for Mucosal Edema , Nasal Discharge , Mucosal Erythema , and Crusting of Mucosa

Data source: xx

Created on: ddmmmyy hh:mm Page 1 of N

T14.1.9.10.1 Summary of Focused ENT Examination (Safety Analysis Set) (continued)

ENT Examination: Throat irritation

Treatment Group	Visit	ENT Grading	
		Absent n (%)	Present n (%)
GSP 301 placebo NS pH[redacted](N=xxx)	Visit 1	xxx (xx.x)	xxx (xx.x)
	Visit 2	xxx (xx.x)	xxx (xx.x)
	Visit 3	xxx (xx.x)	xxx (xx.x)
	Visit 4	xxx (xx.x)	xxx (xx.x)
	Visit 5	xxx (xx.x)	xxx (xx.x)
	Visit 6	xxx (xx.x)	xxx (xx.x)
	Visit 7	xxx (xx.x)	xxx (xx.x)
	Visit 8	xxx (xx.x)	xxx (xx.x)
	Visit 9	xxx (xx.x)	xxx (xx.x)
	Visit 10	xxx (xx.x)	xxx (xx.x)
	Visit 11	xxx (xx.x)	xxx (xx.x)
	Visit 12	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted](N=xxx)			
GSP 301 NS (N=xxx)			

Programming notes: table will continue for candidiasis, post nasal drip.

Data source: xx

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T14.1.9.10.2 Summary of Potentially Clinical Significant Focused ENT Examination (Safety Analysis Set)

Nasal Irritation

Treatment Group	Visit	Normal n(%)	Abnormal n(%)	Abnormal (NCS) n(%)	Abnormal (CS) n(%)
GSP 301 placebo NS pH[redacted](N=xxx)	Visit 1	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 2	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 3	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 4	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 5	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 6	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 7	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 8	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 9	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 10	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 11	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	Visit 12	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
GSP 301 placebo NS pH[redacted](N=xxx)					
GSP 301 NS (N=xxx)					

. CS= Clinically Significant, NCS= Not Clinically Significant

Table will continue for other evaluations.

T14.1.9.11.1 Summary of Extent of Exposure during the Post Randomization Treatment Period (Safety Analysis Set)

		GSP 301 placebo NS pH[redacted] (N=xxx)	GSP 301 placebo NS pH[redacted] (N=xxx)	GSP 301 NS (N=xxx)
Number of days on treatment	n	xxx	xxx	xxx
	Mean ± SD	xx.x ± x.x	xx.x ± x.x	xx.x ± x.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Number of days on study	n	xxx	xxx	xxx
	Mean ± SD	xx.x ± x.x	xx.x ± x.x	xx.x ± x.x
	Median	xx.x	xx.x	xx.x
	Min, Max	xx.x, xx.x	xx.x, xx.x	xx.x, xx.x
Treatment Compliance n (%)	<75%	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	>=75% - <=100%	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	>100% - =<125%	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
	>125%	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

N= number of subjects in the treatment group; n= number of subject with data available;

Number of days on study = End of Study Date - Enrollment Date (Screening Visit) +1

Data source: xx

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T14.1.9.11.2 Summary of Rescue Medication
(Safety Analysis Set)

Rescue medication	GSP 301 placebo NS pH[redacted] (N=xxx)	GSP 301 placebo NS pH[redacted] (N=xxx)	GSP 301 NS (N=xxx)
Loratadine n (%)	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
etc	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)
etc	xxx (xx.x)	xxx (xx.x)	xxx (xx.x)

N= number of subjects in the treatment group; n= number of subject with data available;

Data source: xx
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T14.1.9.12.1 Summary of Average AM rTNSS
(Full Analysis Set)

			Observed Data				Change from Baseline		
Treatment Group	Week	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH[redacted](N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	1	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	2	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	etc	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	52	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x

GSP 301 placebo NS pH[redacted]N=xxx)
GSP 301 NS (N=xxx)

Baseline is defined as the mean of the last 4 AM reading scores including the AM on the day of randomization
Max=maximum; Min=minimum; N= number of subjects in the treatment group; n= number of subjects with data available;

Data source: xx
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T14.1.9.12.2 Summary of Repeated Measures Analysis Results in Average AM rTNSS over the First 6, 30, and 52 Weeks of Treatment (Full Analysis Set)

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH[redacted] LSMean Difference	Std Err Difference	95% CI	P-value
6 Weeks	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
30 Weeks	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
52 Weeks	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the mean of the last 4 AM reading scores including the AM on the day of randomization

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on separate mixed model repeated measures models for each week assessment, with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, and week as the within-subject effect.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model

Data source: xx

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T14.1.9.12.3 Summary of Average AM rTNSS
(Per Protocol Set)
Repeat of Table T14.1.9.12.1 for Per Protocol Set

T14.1.9.12.4 Summary of Repeated Measures Analysis Results in Average AM rTNSS over the First 6, 30, and 52 Weeks of Treatment
(Per Protocol Set)
Repeat of Table T14.1.9.12.2 for Per Protocol Set

T14.1.9.12.5 Subgroup Analyses (Age Group): Summary of Average AM rTNSS
(Full Analysis Set)
Repeat of Table T14.1.9.12.1 for age group

T14.1.9.12.6 Subgroup Analyses (Sex): Summary of Average AM rTNSS
(Full Analysis Set)
Repeat of Table T14.1.9.12.1 for sex

T14.1.9.12.7 Subgroup Analyses (Race): Summary of Average AM rTNSS
(Full Analysis Set)
Repeat of Table T14.1.9.12.1 for race

T14.1.9.12.8 Subgroup Analyses (Ethnicity): Summary of Average AM rTNSS
(Full Analysis Set)
Repeat of Table T14.1.9.12.1 for ethnicity

T14.1.9.13.1 Summary of Average AM iTNSS
(Full Analysis Set)

			Observed Data				Change from Baseline		
Treatment Group	Week	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH [redacted] (N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	1	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	2	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	etc	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	52	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH [redacted] (N=xxx)									
GSP 301 NS (N=xxx)									

Baseline is defined as the mean of the last 4 AM reading scores including the AM on the day of randomization

Max=maximum; Min=minimum; N= number of subjects in the treatment group; n= number of subjects with data available;

Data source: xx

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T14.1.9.13.2 Summary of Repeated Measures Analysis Results in Average AM iTNSS over the First 6, 30, and 52 Weeks of Treatment (Full Analysis Set)

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH[redacted] LSMean Difference	Std Err Difference	95% CI	P-value
6 Weeks	GSP 301 placebo NS pH[redacted] N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
30 Weeks	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
52 Weeks	GSP 301 placebo NS pH[redacted] N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the mean of the last 4 AM reading scores including the AM on the day of randomization

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on separate mixed model repeated measures models for each week assessment, with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, and week as the within-subject effect.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model

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T14.1.9.13.3 Summary of Average AM iTNSS
(Per Protocol Set)
Repeat of Table T14.1.9.13.1 for Per Protocol Set

T14.1.9.13.4 Summary of Repeated Measures Analysis Results in Average AM iTNSS over the First 6, 30, and 52 Weeks of Treatment
(Per Protocol Set)
Repeat of Table T14.1.9.13.2 for Per Protocol Set

T14.1.9.13.5 Subgroup Analyses (Age Group): Summary of Average AM iTNSS
(Full Analysis Set)
Repeat of Table T14.1.9.13.1 for age group

T14.1.9.13.6 Subgroup Analyses (Sex): Summary of Average AM iTNSS
(Full Analysis Set)
Repeat of Table T14.1.9.13.1 for sex

T14.1.9.13.7 Subgroup Analyses (Race): Summary of Average AM iTNSS
(Full Analysis Set)
Repeat of Table T14.1.9.13.1 for race

T14.1.9.13.8 Subgroup Analyses (Ethnicity): Summary of Average AM iTNSS
(Full Analysis Set)
Repeat of Table T14.1.9.13.1 for ethnicity

T14.1.9.14.1 Summary of the Overall RQLQ(S)
(Full Analysis Set)

			Observed Data				Change from Baseline		
Treatment Group	Week	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH [redacted] N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	6	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	30	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	52	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH [redacted] N=xxx)									
GSP 301 NS (N=xxx)									

Baseline is defined as the RQLQ(S) score at the randomization visit.
Max=maximum; Min=minimum; N= number of subjects in the treatment group; n= number of subjects with data available;

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T14.1.9.14.2 Summary of Repeated Measures Analysis Results in Overall RQLQ(S) at Weeks 6, 30, and 52
(Full Analysis Set)

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH[redacted] LSMean Difference	Std Err Difference	95% CI	P-value
Week 6	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 30	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 52	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the RQLQ(S) score at the randomization visit.

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on mixed model repeated measures model with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, week as the within-subject effect and week-by-treatment interaction.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model

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T14.1.9.14.3 Summary of Overall RQLQ(S)
(RQLQ(S) Analysis Set)
Repeat of Table T14.1.9.14.1 for RQLQ(S) Analysis Set

T14.1.9.14.4 Summary of Repeated Measures Analysis Results in Overall RQLQ(S) at Weeks 6, 30, and 52
(RQLQ(S) Analysis Set)
Repeat of Table T14.1.9.14.2 for RQLQ(S) Analysis Set

T14.1.9.15.1 Summary of Average AM Reflective Individual Nasal Symptoms
(Full Analysis Set)
Rhinorrhea

		Observed Data				Change from Baseline			
Treatment Group	Week	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH[redacted] (N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	1	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	2	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	etc	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	52	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH[redacted] (N=xxx)									
GSP 301 NS (N=xxx)									

Baseline is defined as the mean of the last 4 AM reading scores including the AM on the day of randomization
Max=maximum; Min=minimum; N= number of subjects in the treatment group; n= number of subjects with data available;

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Programming notes: table will continue for other nasal symptom scores (nasal congestion, nasal itching, and sneezing).

T14.1.9.15.2 Summary of Repeated Measures Analysis Results in Average AM Reflective Individual Nasal Symptoms over the First 6, 30, and 52 Weeks of Treatment
(Full Analysis Set)
Rhinorrhea

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH[redacted] LSMean Difference	Std Err Difference	95% CI	P-value
6 Weeks	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
30 Weeks	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
52 Weeks	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the mean of the last 4 AM reading scores including the AM on the day of randomization

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on separate mixed model repeated measures models for each week assessment, with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, and week as the within-subject effect.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model
Programming notes: table will continue for other nasal symptom scores (nasal congestion, nasal itching, and sneezing).

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T14.1.9.16.1 Summary of Average AM Instantaneous Individual Nasal Symptoms
(Full Analysis Set)

Repeat of Table T14.1.9.15.1 for Instantaneous Individual Nasal Symptoms

T14.1.9.16.2 Summary of Repeated Measures Analysis Results in Average AM Instantaneous Individual Nasal Symptoms over the First 6, 30, and 52 Weeks of Treatment
(Full Analysis Set)

Repeat of Table T14.1.9.15.2 for Instantaneous Individual Nasal Symptoms

T14.1.9.17.1 Summary of Repeated Measures Analysis Results in Average AM rTNSS over Each Treatment Week (Full Analysis Set)

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH[redacted] LSMean Difference	Std Err Difference	95% CI	P-value
Week 1	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
etc	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 52	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the mean of the last 4 AM reading scores including the AM on the day of randomization

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on mixed model repeated measures model with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, week as the within-subject effect and week-by-treatment interaction.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model

Data source: xx

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T14.1.9.17.2 Summary of Repeated Measures Analysis Results in Average AM iTNSS over Each Treatment Week (Full Analysis Set)

Repeat of Table T14.1.9.17.1 for iTNSS

T14.1.9.18.1 Summary of Repeated Measures Analysis Results in Average AM Subject-reported Reflective Individual Nasal Symptoms over Each Treatment Week
(Full Analysis Set)
Rhinorrhea

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH[redacted] LSMean Difference	Std Err Difference	95% CI	P-value
Week 1	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
etc	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 52	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the mean of the last 4 AM reading scores including the AM on the day of randomization

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on mixed model repeated measures model with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, week as the within-subject effect and week-by-treatment interaction.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model
Programming notes: table will continue for other nasal symptom scores (nasal congestion, nasal itching, and sneezing).

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T14.1.9.18.2 Summary of Repeated Measures Analysis Results in Average AM Subject-reported Instantaneous Individual Nasal Symptoms over Each Treatment Week
(Full Analysis Set)

Repeat of Table T14.1.9.18.1 for instantaneous individual nasal symptoms

T14.1.9.19.1 Summary of the Physician Assessed Nasal Symptom Score (PNSS)
(Full Analysis Set)

			Observed Data				Change from Baseline		
Treatment Group	Week	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH [redacted] (N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	3	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	etc	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	52	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH [redacted] (N=xxx)									
GSP 301 NS (N=xxx)									

Baseline is defined as the PNSS score at the randomization visit.
Max=maximum; Min=minimum; N= number of subjects in the treatment group; n= number of subjects with data available;

Data source: xx
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T14.1.9.19.2 Summary of Repeated Measures Analysis Results in Physician Assessed Nasal Symptom Score (PNSS) at Weeks 6, 30, and 52 (Full Analysis Set)

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH [redacted]			
					LSMean Difference	Std Err Difference	95% CI	P-value
Week 6	GSP 301 placebo NS pH [redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 30	GSP 301 placebo NS pH [redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 52	GSP 301 placebo NS pH [redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the PNSS score at the randomization visit.

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on mixed model repeated measures model with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, week as the within-subject effect and week-by-treatment interaction.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model

Data source: xx

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T14.1.9.20.1 Summary of the Physician Assessed Individual Nasal Symptom Score
(Full Analysis Set)

Runny Nose

			Observed Data				Change from Baseline		
Treatment Group	Week	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH [redacted] (N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	3	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	etc	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	52	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH [redacted] (N=xxx)									
GSP 301 NS (N=xxx)									

Baseline is defined as the nasal symptom score at the randomization visit.
Max=maximum; Min=minimum; N= number of subjects in the treatment group; n= number of subjects with data available;

Data source: xx
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Programming notes: table will continue for other nasal symptom scores (nasal congestion, nasal itching, and sneezing).

T14.1.9.20.2 Summary of Repeated Measures Analysis Results in Physician Assessed Individual Nasal Symptom Score at Weeks 6, 30, and 52 (Full Analysis Set) Running Nose

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH[redacted] LSMean Difference	Std Err Difference	95% CI	P-value
Week 6	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 30	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 52	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the nasal symptom score at the randomization visit.

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on mixed model repeated measures model with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, week as the within-subject effect and week-by-treatment interaction.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model

Programming notes: table will continue for other nasal symptom scores (nasal congestion, nasal itching, and sneezing).

Data source: xx

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T14.1.9.21.1 Summary of the Individual Domains of the RQLQ(S)
(Full Analysis Set)

Emotional

			Observed Data				Change from Baseline		
Treatment Group	Week	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH [redacted] N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	3	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	etc	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	52	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH [redacted] N=xxx)									
GSP 301 NS (N=xxx)									

Baseline is defined as the domain score at the randomization visit.
Max=maximum; Min=minimum; N= number of subjects in the treatment group; n= number of subjects with data available;

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Programming notes: table will continue for other domains.

T14.1.9.21.2 Summary of Repeated Measures Analysis Results in the Individual Domains of the RQLQ(S) at Weeks 6, 30, and 52 (Full Analysis Set)
Emotional

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH[redacted] LSMean Difference	Std Err Difference	95% CI	P-value
Week 6	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 30	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 52	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the domain score at the randomization visit.

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on mixed model repeated measures model with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, week as the within-subject effect and week-by-treatment interaction.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model

Programming notes: table will continue for other domains

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T14.1.9.21.3 Summary of the Individual Domains of the RQLQ(S)
(RQLQ(S) Analysis Set)
Repeat of Table T14.1.9.21.1 for RQLQ(S) Analysis Set

T14.1.9.21.4 Summary of Repeated Measures Analysis Results in the Individual Domains of the RQLQ(S) at Weeks 6, 30, and 52
(RQLQ(S) Analysis Set)
Repeat of Table T14.1.9.21.2 for RQLQ(S) Analysis Set

T14.1.9.22.1 Summary of RCAT
(Full Analysis Set)

			Observed Data				Change from Baseline		
Treatment Group	Week	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH[redacted](N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	3	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	etc	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	52	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH[redacted](N=xxx)									
GSP 301 NS (N=xxx)									

Baseline is defined as the RCAT score at the randomization visit.
Max=maximum; Min=minimum; N= number of subjects in the treatment group; n= number of subjects with data available;

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Programming notes: table will continue for other domains.

T14.1.9.22.2 Summary of Repeated Measures Analysis Results in RCAT at Weeks 6, 30, and 52
(Full Analysis Set)
Domain 1

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH[redacted] LSMean Difference	Std Err Difference	95% CI	P-value
Week 6	GSP 301 placebo NS pH[redacted] N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 30	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 52	GSP 301 placebo NS pH[redacted] N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the RCAT score at the randomization visit.

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on mixed model repeated measures model with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, week as the within-subject effect and week-by-treatment interaction.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model

Programming notes: table will continue for other domains

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T14.1.9.23.1 Summary of the Individual Domains of the RCAT
(Full Analysis Set)

Domain 1

			Observed Data				Change from Baseline		
Treatment Group	Week	n	Mean (SD)	Median	Min, Max	n	Mean (SD)	Median	Min, Max
GSP 301 placebo NS pH[redacted] (N=xxx)	Baseline	xx	xx.x (xx.x)	xx.x	xx.x, xx.x				
	3	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	etc	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
	52	xx	xx.x (xx.x)	xx.x	xx.x, xx.x	xx	xx.x (xx.x)	xx.x	xx.x, xx.x
GSP 301 placebo NS pH[redacted] (N=xxx)									
GSP 301 NS (N=xxx)									

Baseline is defined as the domain score at the randomization visit.
Max=maximum; Min=minimum; N= number of subjects in the treatment group; n= number of subjects with data available;

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Programming notes: table will continue for other domains.

T14.1.9.23.2 Summary of Repeated Measures Analysis Results in the Individual Domains of the RCAT at Weeks 6, 30, and 52
(Full Analysis Set)
Domain 1

Week	Treatment Group	Number of Subjects (n)	LSMean	Std Err LSMean	Treatment vs. Placebo NS pH[redacted] LSMean Difference	Std Err Difference	95% CI	P-value
Week 6	GSP 301 placebo NS pH[redacted] N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 30	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.xx – xx.xx	x.xxxx
Week 52	GSP 301 placebo NS pH[redacted] (N=xxx)	xxx	xxx.xx	xxx.xx				
	GSP 301 NS (N=xxx)	xxx	xxx.xx	xxx.xx	xxx.xx	xxx.xx	xx.x – xx.x	x.xxxx

Baseline is defined as the domain score at the randomization visit.

n: Number of subjects with data available in the specific treatment group

LSMeans: Least square means; Std Err LSMeans: Standard error of the LSMeans

LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on mixed model repeated measures model with change from baseline as dependent variable, treatment group and site as fixed effect, baseline as covariate, week as the within-subject effect and week-by-treatment interaction.

Programming note: the interaction terms treatment*baseline and treatment*site will only be included in the footnote if significant in the model

Programming notes: table will continue for other domains

Data source: xx

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L16.2.1 Listing of Subject Disposition
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Date of Last Dose Taken	Date of Completion/ Early Termination/ Withdrawal	Reason for Early Termination/ Withdrawal
GSP 301 placebo NS pH [redacted]	xx-xxx/xxxxx	ddmmmyyyy	ddmmmyyyy	Adverse Event
GSP 301 placebo NS pH [redacted] GSP 301 NS				

Data source: xx
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L16.2.2 Listing of Protocol Deviations
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Deviation Occurred During	Event Description
GSP 301 placebo NS pH [redacted]	xx-xxx/xxxxx	Randomized Treatment	Outside Visit Window (Visit # 4)
GSP 301 placebo NS pH [redacted]			
GSP 301 NS			

Data source: xx
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L16.2.3.1 Listing of Subject Excluded from the Per Protocol Set

Treatment Group	Subject / Randomization Number	Exclusion Reason
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Subject did not meet IE criterion
GSP 301 placebo NS pH[redacted] GSP 301 NS		

Data source: xx

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L16.2.3.2 Listing of Subject Excluded from the Full Analysis Set

Treatment Group	Subject / Randomization Number	Exclusion Reason
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Subject did not have at least one post- randomization evaluation
GSP 301 placebo NS pH[redacted]		
GSP 301 NS		

Data source: xx

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L16.2.3.3 Listing of Subjects Who Withdrew Due to Inclusion/Exclusion Criteria (Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Inclusion/Exclusion Criteria
GSP 301 placebo NS pH [redacted]	xx-xxx/xxxxx	Exclusion Criteria #1: xxxxxxxxxxxxxxxxxxxx
GSP 301 placebo NS pH [redacted] GSP 301 NS		

Data source: xx

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L16.2.4.1 Listing of Demographic Data
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Age	Sex	Ethnicity	Race	Weight (kg)
GSP 301 placebo NS pH [redacted]	xx-xxx/xxxxx	42	Male	Hispanic or Latino	Black/ African American	xx.x
	xx-xxx/xxxxx	35	Female	Hispanic or Latino	White	
GSP 301 placebo NS pH [redacted]						
GSP 301 NS						

Data source: xx
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L16.2.4.2 Listing of Medical History
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Body System	Condition/Procedure	Start Date/ End Date	Ongoing	Severity Grade	Any Nasal Structural Abnormalities?
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Respiratory System	xxxxxxxxxxxxx	ddmmmyyyy/ ddmmmyyyy	No	Mild	No
	xx-xxx/xxxxx	Cardiovascular System	xxxxxxxxxxxxx	ddmmmyyyy/	Yes		Yes (xxxx)

GSP 301 placebo NS pH[redacted]
GSP 301 NS

Data source: xx
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L16.2.4.3 Listing of Concomitant Medication
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Type of Medication	Medication Name	Dose	Frequency	Route	Start Date/ End Date	Indication
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Prior	xxxxxxxxxxxx	20mg	QD	PO	ddmmmyyyy/ ddmmmyyyy	xxxxxxxxxx
	xx-xxx/xxxxx	Concomitant	xxxxxxxxxxxx	10mg	QD	PO	ddmmmyyyy/	xxxxxxxxxx

GSP 301 placebo NS pH[redacted]
GSP 301 NS

Data source: xx
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L16.2.4.4 Listing of Rescue Medication
(Safety Analysis Set)

Repeat of Listing L16.2.4.3 for rescue medication

L16.2.4.5 Listing of Skin Test and Wheal Measurements
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Test Date	Allergen	Wheal Diameter (mm)	PAR-inducing allergen 3 mm greater than the negative control?	Expected to be exposed to the above specified PAR allergen?
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	ddmmmyyyy	xxx	xxx	xxx	Yes
GSP 301 placebo NS pH[redacted] GSP 301 NS						

Data source: xx
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L16.2.5.1 Listing of Visit Date Information
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Informed Consent Date	Visit 1/ Visit 2	Visit 3/ Visit 4	Visit 5/ Visit 6	Visit 7/ Visit 8	Visit 9/ Visit 10	Visit 11/ Visit 12/ Early termination
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	ddmmmyyyy	ddmmmyyyy/ ddmmmyyyy	ddmmmyyyy/ ddmmmyyyy	ddmmmyyyy/ ddmmmyyyy	ddmmmyyyy/ ddmmmyyyy	ddmmmyyyy/ ddmmmyyyy	ddmmmyyyy/ ddmmmyyyy
GSP 301 placebo NS pH[redacted] GSP 301 NS								

Data source: xx
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L16.2.5.2 Listing of Study Compliance
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Was the used study medication collected?	Was Diary 2 collected and reviewed?	Date of last entry in Diary 2	Total number of confirmed doses applied in Diary 2	Wa the subject retrained on proper use of the nasal spray?	Was the study medication primed and dispensed?	Was the AR assessment Diary 3 distributed?
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 3	Yes	Yes	ddmmmyyyy	xx	Yes	Yes	Yes
		Visit 8	Yes	Yes	ddmmmyyyy	xx	Yes	Yes	Yes
		Visit 12	Yes	Yes	ddmmmyyyy	xx	Yes	Yes	Yes
GSP 301 placebo NS pH[redacted] GSP 301 NS									

Data source: xx
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L16.2.5.3 Listing of Extent of Exposure
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Date of First Dose Taken	Date of Last Dose Taken	Number of Days on Treatment	Date of Inform Consent Date	Date of Completion/ Early Termination/ Withdrawal	Number of Days on Study
GSP 301 placebo NS pH [redacted]	xx-xxx/xxxxx	ddmmmyyyy	ddmmmyyyy	xxx	ddmmmyyyy	ddmmmyyyy	xxx
GSP 301 placebo NS pH [redacted]							
GSP 301 NS							

Data source: xx
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L16.2.6.1 Listing of AM Reflective Nasal Symptom Scores
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Day/Week	Date	Dosing Time	Assessment Time	Rhinorrhea	Nasal Congestion	Nasal Itching	Sneezing	rTNSS
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Day -7	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Day -6	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Day -5	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		etc	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Day -1	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Day 1/Week 1	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Week 3	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		etc	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Week 52	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
GSP 301 placebo NS pH[redacted]										
GSP 301 NS										

rTNSS = sum of four nasal symptom scores (Rhinorrhea, Nasal Congestion, Nasal Itching, Sneezing)

Data source: xx
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L16.2.6.2 Listing of AM Instantaneous Nasal Symptom Scores
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Day/Week	Date	Dosing Time	Assessment Time	Rhinorrhea	Nasal Congestion	Nasal Itching	Sneezing	rTNSS
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Day -7	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Day -6	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Day -5	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		etc	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Day -1	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Day 1/Week 1	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Week 3	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		etc	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
		Week 52	ddmmmyyy	hh:mm	hh:mm	0	0	1	0	1
GSP 301 placebo NS pH[redacted]										
GSP 301 NS										

iTNSS = sum of four nasal symptom scores (Rhinorrhea, Nasal Congestion, Nasal Itching, Sneezing)

Data source: xx
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L16.2.6.3 Listing of the Average AM Reflective Nasal Symptom Scores (Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Week	Rhinorrhea	Nasal Congestion	Nasal Itching	Sneezing	rTNSS
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Baseline	xx	xx	xx	xx	xx
		Week 1	xx	xx	xx	xx	xx
		Week 2	xx	xx	xx	xx	xx
		Week 3	xx	xx	xx	xx	xx
		Week 4	xx	xx	xx	xx	xx
		Week 5	xx	xx	xx	xx	xx
		Week 6	xx	xx	xx	xx	xx
		etc	xx	xx	xx	xx	xx
		Week 30	xx	xx	xx	xx	xx
		etc	xx	xx	xx	xx	xx
		Week 52	xx	xx	xx	xx	xx
GSP 301 placebo NS pH[redacted]							
GSP 301 NS							

rTNSS = sum of four nasal symptom scores (Rhinorrhea, Nasal Congestion, Nasal Itching, Sneezing)
Baseline is defined as the average of the last 4 consecutive AM assessments during the last 4 days of the run-in period from the Day -3 AM assessment to the AM assessment on the day of randomization.

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L16.2.6.4 Listing of the Average AM Instantaneous Nasal Symptom Scores (Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Week	Rhinorrhea	Nasal Congestion	Nasal Itching	Sneezing	iTNSS
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Baseline	xx	xx	xx	xx	xx
		Week 1	xx	xx	xx	xx	xx
		Week 2	xx	xx	xx	xx	xx
		Week 3	xx	xx	xx	xx	xx
		Week 4	xx	xx	xx	xx	xx
		Week 5	xx	xx	xx	xx	xx
		Week 6	xx	xx	xx	xx	xx
		etc	xx	xx	xx	xx	xx
		Week 30	xx	xx	xx	xx	xx
		etc	xx	xx	xx	xx	xx
		Week 52	xx	xx	xx	xx	xx
GSP 301 placebo NS pH[redacted] GSP 301 NS							

iTNSS = sum of four nasal symptom scores (Rhinorrhea, Nasal Congestion, Nasal Itching, Sneezing)
Baseline is defined as the average of the last 4 consecutive AM assessments during the last 4 days of the run-in period from the Day -3 AM assessment to the AM assessment on the day of randomization.

Data source: xx
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L16.2.6.5 Listing of Change from Baseline of the Average AM Reflective Nasal Symptom Scores (Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Week	Rhinorrhea	Nasal Congestion	Nasal Itching	Sneezing	rTNSS
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Week 1	xx	xx	xx	xx	xx
		Week 2	xx	xx	xx	xx	xx
		Week 3	xx	xx	xx	xx	xx
		Week 4	xx	xx	xx	xx	xx
		Week 5	xx	xx	xx	xx	xx
		Week 6	xx	xx	xx	xx	xx
		etc	xx	xx	xx	xx	xx
		Week 30	xx	xx	xx	xx	xx
		etc	xx	xx	xx	xx	xx
GSP 301 placebo NS pH[redacted]							
GSP 301 NS							

rTNSS = sum of four nasal symptom scores (Rhinorrhea, Nasal Congestion, Nasal Itching, Sneezing)
Baseline is defined as the average of the last 4 consecutive AM assessments during the last 4 days of the run-in period from the Day -3 AM assessment to the AM assessment on the day of randomization.

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L16.2.6.6 Listing of Change from Baseline of the Average AM Instantaneous Nasal Symptom Scores (Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Week	Rhinorrhea	Nasal Congestion	Nasal Itching	Sneezing	iTNSS
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Week 1	xx	xx	xx	xx	xx
		Week 2	xx	xx	xx	xx	xx
		Week 3	xx	xx	xx	xx	xx
		Week 4	xx	xx	xx	xx	xx
		Week 5	xx	xx	xx	xx	xx
		Week 6	xx	xx	xx	xx	xx
		etc	xx	xx	xx	xx	xx
		Week 30	xx	xx	xx	xx	xx
		etc	xx	xx	xx	xx	xx
GSP 301 placebo NS pH[redacted]							
GSP 301 NS							

iTNSS = sum of four nasal symptom scores (Rhinorrhea, Nasal Congestion, Nasal Itching, Sneezing)
Baseline is defined as the average of the last 4 consecutive AM assessments during the last 4 days of the run-in period from the Day -3 AM assessment to the AM assessment on the day of randomization.

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L16.2.6.7 Listing of Rhinoconjunctivitis Quality of Life (RQLQ(S)) (Part I)
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Activities			Sleep			Non-Nose/Eye Symptom						Practical Problem		
			Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12	Q13	Q14	Q15	Q16
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 2	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		Visit 4	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		Visit 8	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
		Visit 12	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x
GSP 301 placebo NS pH[redacted] GSP 301 NS																		

Data source: xx
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L16.2.6.7 Listing of Rhinoconjunctivitis Quality of Life (RQLQ(S)) (Part II)
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Nasal ____ Symptom ___				Eye _____Symptom_____				_____ Emotional _____			
			Q17	Q18	Q19	Q20	Q21	Q22	Q23	Q24	Q25	Q26	Q27	Q28
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 2	x	x	x	x	x	x	x	x	x	x	x	x
		Visit 4	x	x	x	x	x	x	x	x	x	x	x	x
		Visit 8	x	x	x	x	x	x	x	x	x	x	x	x
		Visit 12	x	x	x	x	x	x	x	x	x	x	x	x
GSP 301 placebo NS pH[redacted] GSP 301 NS														

Data source: xx
Created on: ddmmmyy hh:mm

L16.2.6.8 Listing of Rhinoconjunctivitis Quality of Life (RQLQ(S)) by Domain
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Activities	Sleep	Non-Nose/Eye Symptom	Practical Problem	Nasal Symptom	Eye Symptom	Emotional	Overall Average RQLQ
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 2	xx	xx	xx	xx	xx	xx	xx	xx
		Visit 4	xx	xx	xx	xx	xx	xx	xx	xx
		Visit 8	xx	xx	xx	xx	xx	xx	xx	xx
		Visit 12	xx	xx	xx	xx	xx	xx	xx	xx

GSP 301 placebo NS pH[redacted]
GSP 301 NS

A domain average score is calculated as the sum of the scores in that domain divided by the number of items in that domain.
The overall average RQLQ(S) score is calculated as the sum of the scores in all domains divided by the total number of items in the seven domains.

Data source: xx
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L16.2.6.9 Listing of Change from Baseline in Rhinoconjunctivitis Quality of Life (RQLQ(S)) by Domain (Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Activities	Sleep	Non-Nose/Eye Symptom	Practical Problem	Nasal Symptom	Eye Symptom	Emotional	Overall Average RQLQ
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 4	xx	xx	xx	xx	xx	xx	xx	xx
		Visit 8	xx	xx	xx	xx	xx	xx	xx	xx
		Visit 12	xx	xx	xx	xx	xx	xx	xx	xx

GSP 301 placebo NS pH[redacted]
GSP 301 NS

Baseline is defined as the RQLQ(S) score at the Randomization Visit (Visit 2).
A domain average score is calculated as the sum of the scores in that domain divided by the number of items in that domain.
The overall average RQLQ(S) score is calculated as the sum of the scores in all domains divided by the total number of items in the seven domains.

Data source: xx
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L16.2.6.10 Listing of Physician Assessed Nasal Symptom Scores (PNSS)
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Rhinorrhea	Nasal Congestion	Nasal Itching	Sneezing	PNSS
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 2	0	1	1	0	2
		Visit 3	0	0	1	0	1
		Visit 4	0	1	0	0	1
		etc	0	0	0	0	0
GSP 301 placebo NS pH[redacted]							
GSP 301 NS							

PNSS = sum of four nasal symptom scores (Rhinorrhea, Nasal Congestion, Nasal Itching, Sneezing)

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.6.11 Listing of Change from Baseline in Physician Assessed Nasal Symptom Scores (PNSS)
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Rhinorrhea	Nasal Congestion	Nasal Itching	Sneezing	PNSS
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 3	xx	xx	xx	xx	xx
		etc	xx	xx	xx	xx	xx
GSP 301 placebo NS pH[redacted]							
GSP 301 NS							

PNSS = sum of four nasal symptom scores (Rhinorrhea, Nasal Congestion, Nasal Itching, Sneezing)
Baseline is defined as the symptom score at the Randomization Visit (Visit 2).

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.6.12 Listing of Rhinitis Control Assessment Test (RCAT)
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Domain 6	Total RCAT
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 2	0	1	1	0	2	2	6
		Visit 4	0	0	1	0	1	2	4
		Visit 8	0	1	0	0	0	0	1
		Visit 12	0	0	0	0	2	0	2
GSP 301 placebo NS pH[redacted]									
GSP 301 NS									

Total RCAT score is calculated by adding individual scores for each RCAT item. The total RCAT score can range from 6 to 30.

Data source: xx

Created on: ddmmmyy hh:mm Page 1 of N

L16.2.6.13 Listing of Change from Baseline in Rhinitis Control Assessment Test (RCAT)
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Domain 1	Domain 2	Domain 3	Domain 4	Domain 5	Domain 6	Total RCAT
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 4	0	-1	0	0	-1	0	-2
		Visit 8	0	0	-1	0	-2	-2	-5
		Visit 12	0	-1	-1	0	0	-2	-4
GSP 301 placebo NS pH[redacted] GSP 301 NS									

Total RCAT score is calculated by adding individual scores for each RCAT item. The total RCAT score can range from 6 to 30.
Baseline is defined as the domain score at the Randomization Visit (Visit 2).

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.7.1 Listing of Treatment Emergent Adverse Events by Treatment During Randomized Treatment Period (Safety Analysis Set)

GSP 301 placebo NS pH[redacted]

Subject / Randomization Number	AE No.	Body System/ MedDRA Term/ AE Term	Start /End Date	Severity	Relationship to Study Medication	Outcome	Action Taken with IP	Other Action Taken	Serious AE?
xx-xxx/xxxxx	xx	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	2012-10-12/ 2012-10-15	Mild	Not Related	Improved	None	None	No

Programming note: table will continure for GSP 301 placebo NS pH[redacted] and GSP 301 NS

Data source: xx

Created on: ddmmmyy hh:mm Page 1 of N

L16.2.7.2 Listing of Adverse Events During Placebo Run-in Period

Subject / Randomization Number	AE No.	Body System/ MedDRA Term/ AE Term	Start /End Date	Severity	Relationship to Study Medication	Outcome	Action Taken with IP	Other Action Taken	Serious AE?
xx-xxx/xxxxx	xx	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	2012-10-12/ 2012-10-15	Mild	Not Related	Recovered/Resolved	None	None	No

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.7.3 Listing of Pre-Treatment Adverse Events
(Safety Analysis Set)

Subject / Randomization Number	AE No.	Body System/ MedDRA Term/ AE Term	Start /End Date	Severity	Relationship to Study Medication	Outcome	Action Taken with IP	Other Action Taken	Serious AE?
xx-xxx/xxxxx	xx	NERVOUS SYSTEM DISORDERS/ HEADACHE/ HEADACHE	2012-10-12/ 2012-10-15	Mild	Not Related	Improved	None	None	No

Data source: xx
Created on: ddmmmyy hh:mm

L16.2.8.1 Listing of Clinical Laboratory Test Results (Biochemistry)
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Date /Time	Lab Test	Results	Unit	Normal Range	Flag/ Significance (CS/NCS)
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 1	ddmmmyyy h:mm	ALBUMIN	46	g/L	30 - 50	Normal
				BILIRUBIN	1.6	mg/dL	0.2 - 1.2	High (NCS)
				etc				
		Visit 8						
		Visit 12						
GSP 301 placebo NS pH[redacted] GSP 301 NS								

CS= Clinically Significant; NCS= Not Clinically Significant;

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.8.2 Listing of Clinical Laboratory Test Results (Hematology)
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Date /Time	Lab Test	Results	Unit	Normal Range	Flag/ Significance (CS/NCS)
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 1	ddmmmyyy h:mm	RBC	xxx	xxx	xx - xxx	Normal
				WBC	xxx	xxx	xx - xxx	Normal
				etc				
		Visit 8						
		Visit 12						
GSP 301 placebo NS pH[redacted]								
GSP 301 NS								

CS= Clinically Significant; NCS= Not Clinically Significant;

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.8.3 Listing of Clinical Laboratory Test Results (Urinalysis)
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Date /Time	Lab Test	Results	Unit	Normal Range	Flag/ Significance (CS/NCS)
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 1	ddmmmyyy h:mm	xxx	xxx	xxx	xx - xxx	Normal
				xxx etc	xxx	xxx	xx - xxx	Normal
		Visit 8						
		Visit 12						
GSP 301 placebo NS pH[redacted]								
GSP 301 NS								

CS= Clinically Significant; NCS= Not Clinically Significant;

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.8.4 Listing of Pregnancy Test Results
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Date	Result	Reason Not done
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 1	ddmmmyyyy	Negative	
		Visit 2			xxxxxxxxxxxxxxx
		Visit 3	ddmmmyyyy	Negative	
		Visit 4			
		etc			
		Visit 12			
GSP 301 placebo NS pH[redacted]					
GSP 301 NS					

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.8.5 Listing of Vital Signs
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Test	Result	Unit	Normal/ Abnormal (CS/NCS)
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit1	Blood Pressure (Sitting)	126/70	mmHg	Normal
			Pulse Rate	118	bpm	Abnormal (NCS)
			Body Weight	62.5	kg	
			Height	168	cm	
		Visit 2	Blood Pressure (Sitting)	xxx/xxx	mmHg	
			Pulse Rate	xxx	bpm	
		Visit 8				
		Visit 12				
GSP 301 placebo NS pH[redacted]						
GSP 301 NS						

CS= Clinically Significant; NCS= Not Clinically Significant;

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.8.6 Listing of 12-Lead ECGs
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Date	Heart Rate (bpm)	PR Interval (ms)	RR Interval (ms)	QRS Duration (ms)	QT Interval (ms)	QTc Interval (ms)	Normal/ Abnormal (CS/NCS)
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 1	ddmmmyyy	xxx	xxx	xxx	xxx	xxx	xxx	Normal
		Visit 12	ddmmmyyy	xxx	xxx	xxx	xxx	xxx	xxx	Abnormal (NCS)

GSP 301 placebo NS pH[redacted]
GSP 301 NS

CS= Clinically Significant; NCS= Not Clinically Significant;

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.8.7 Listing of Physical Examination
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Body System	Normal/ Abnormal (CS/NCS)	Comments
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 1	General Appearance	Normal	
			Neck	Normal	
			Head and Eyes	Abnormal (NCS)	
			Cardiovascular	Normal	
			Lungs and Thorax	Normal	
			Abdominal and Gastro-Enteric	Normal	
			Neurological	Normal	
			Dermatological		
			Musculoskeletal and Extremities		
		Visit 8			
		Visit 12			
GSP 301 placebo NS pH[redacted]					
GSP 301 NS					

CS= Clinically Significant; NCS= Not Clinically Significant;

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.8.8 Listing of Focused ENT Examination
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Evaluation	Grading (Scale) or Results	Clinical Significance (CS/NCS)
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 1	Nasal Irritation	1B (Superficial mucosal erosion)	
			Epistaxis	1 (Mild)	
			Mucosal Edema	1 (Mild)	
			Mucosal Erythema	0 (None)	
			Crusting Of Mucosa	0 (None)	
			Nasal Discharge	0 (None)	
			Throat Irritation	0 (Absent)	
			Candidiasis	0 (Absent)	
			Post Nasal Drip	0 (Absent)	
		Visit 2			
		etc			
		Visit 12			
GSP 301 placebo NS pH[redacted]					
GSP 301 NS					

CS= Clinically Significant; NCS= Not Clinically Significant;

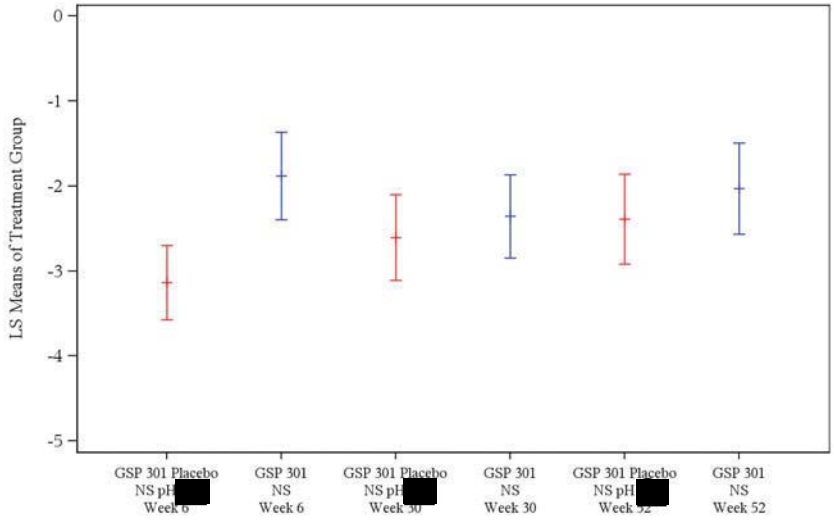
Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

L16.2.8.9 Listing of Eye Examination
(Safety Analysis Set)

Treatment Group	Subject / Randomization Number	Visit	Eye Examination Date	Results Right Eye	Results Left Eye
GSP 301 placebo NS pH[redacted]	xx-xxx/xxxxx	Visit 1 Visit 2 Visit 3 Visit 4 etc Visit 12	ddmmmyyyy	Normal	Normal
GSP 301 placebo NS pH[redacted] GSP 301 NS					

Data source: xx
Created on: ddmmmyy hh:mm Page 1 of N

F15.1.1 LS Means with 95% CIs of of AM Average rTNSS over the First 6, 30, and 52 Weeks of Treatment (Full Analysis Set)



Programming note: For the LS means plots, please maintain consistency over y-axis range for endpoints.
For example for TNSS outputs, ensure the y-axis range is the same in case various outputs need comparing.

F15.1.2 LS Means with 95% CIs of of AM Average rTNSS over the First 6, 30, and 52 Weeks of Treatment (Per Protocol Set)

Repeat of F15.1.1 for Per Protocol Set

F15.1.3 LS Means with 95% CIs of of AM Average iTNSS over the First 6, 30, and 52 Weeks of Treatment (Full Analysis Set)

Repeat of F15.1.1 for iTNSS Full Analysis Set

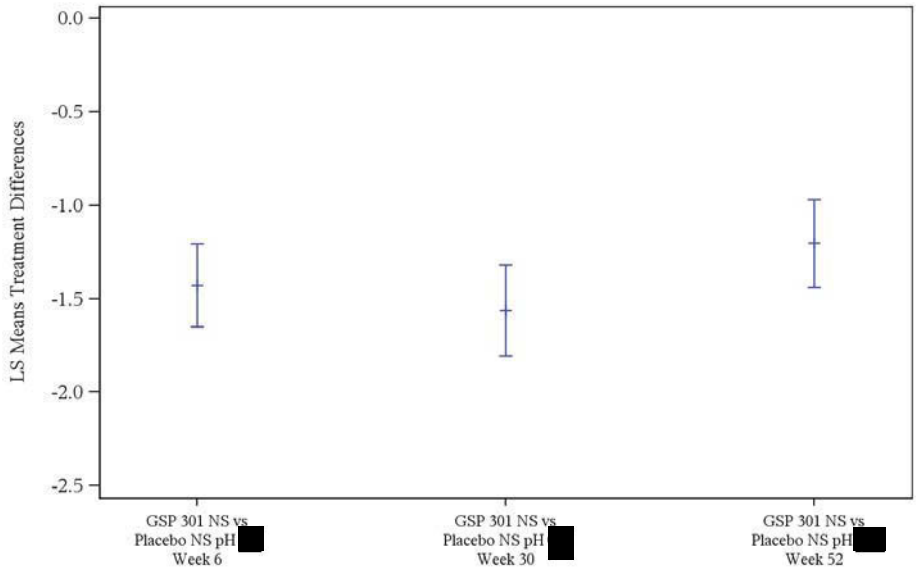
F15.1.4 LS Means with 95% CIs of of AM Average iTNSS over the First 6, 30, and 52 Weeks of Treatment (Per Protocol Set)

Repeat of F15.1.1 for iTNSS Per Protocol Set

F15.1.5 LS Means with 95% CIs of of Overall RQLQ(S) at Weeks 6, 30, and 52 (Full Analysis Set)

Repeat of F15.1.1 for RQLQ(S) Full Analysis Set

F15.2.1 Treatment Differences of LS Means with 95% CIs of AM Average rTNSS over the First 6, 30, and 52 Weeks of Treatment (Full Analysis Set)



Programming note: For the treatment differences of LS means plots, please maintain consistency over y-axis range for endpoints. For example for TNSS outputs, ensure the y-axis range is the same in case various outputs need comparing.

F15.2.2 Treatment Differences of LS Means with 95% CIs of AM Average rTNSS over the First 6, 30, and 52 Weeks of Treatment (Per Protocol Set)

Repeat of F15.2.1 for Per Protocol Set

F15.2.3 Treatment Differences of LS Means with 95% CIs of AM Average iTNSS over the First 6, 30, and 52 Weeks of Treatment (Full Analysis Set)

Repeat of F15.2.1 for iTNSS Full Analysis Set

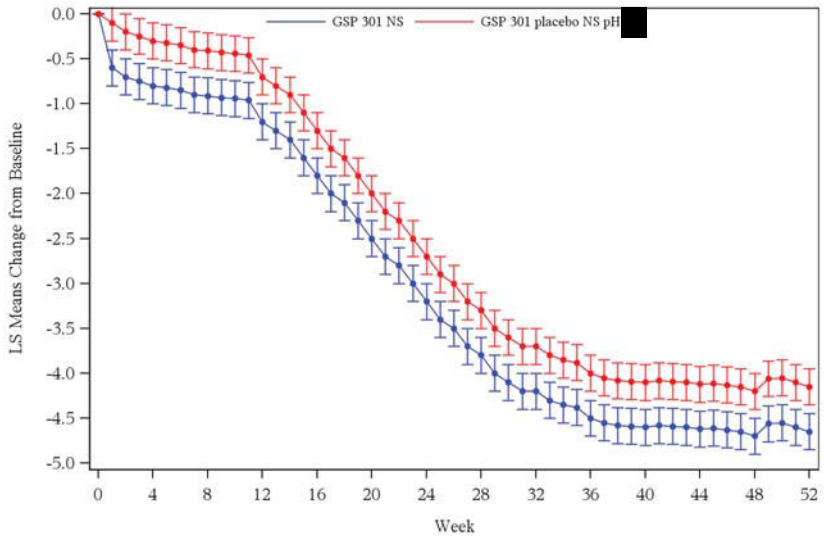
F15.2.4 Treatment Differences of LS Means with 95% CIs of AM Average iTNSS over the First 6, 30, and 52 Weeks of Treatment (Per Protocol Set)

Repeat of F15.2.1 for iTNSS Per Protocol Set

F15.2.5 Treatment Differences of LS Means with 95% CIs of Overall RQLQ(S) at Weeks 6, 30, and 52 (Full Analysis Set)

Repeat of F15.2.1 for RQLQ(S) Full Analysis Set

F15.3.1 LS Means with 95% CIs of Average AM rTNSS over each Treatment Week (Full Analysis Set)

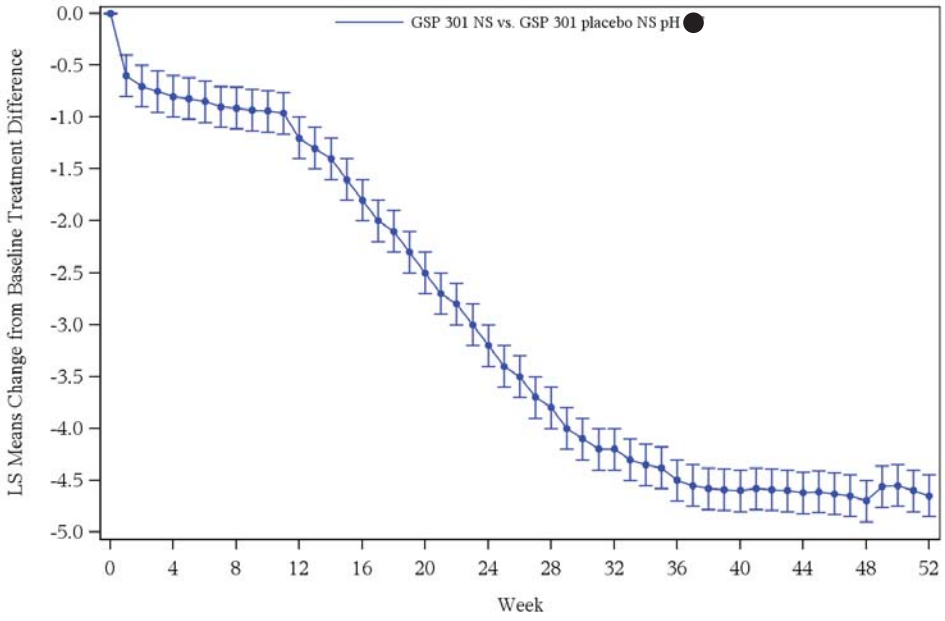


Programming note: An offset will be applied to the treatments to prevent an overlap of treatment information. Offset values TBD during programming'. An example at the time of programming could be the following: GSP 301 could have an offset of -0.1 and placebo of +0.1, so to plot the treatment information at week 28, the x-value for GSP 301 will be 27.9 and placebo will be 28.1, but again a visual check needs to be applied to see how practical/appropriate the plot looks.

F15.3.2 LS Means with 95% CIs of Average AM iTNSS over each Treatment Week (Full Analysis Set)

Repeat of F15.3.1 for iTNSS

F15.4.1 Treatment Differences of LS Means with 95% CIs of AM Average rTNSS over each Treatment Week (Full Analysis Set)



F15.4.2 Treatment Differences of LS Means with 95% CIs of AM Average iTNSS over each Treatment Week (Full Analysis Set)

Repeat of F15.4.1 for iTNSS

Reference:

1. Center for Drug Evaluation and Research. Guidance for Industry. Allergic Rhinitis: Clinical Development Programs for Drug Products. Apr 2000.

Appendix 2

Schedule of Procedures and Assessments

Visits	Screening Visit (SV) Visit 1	Randomization Visit (RV) Visit 2	Treatment Visits (TV)									Final Visit / Discontinuation Visit (FV/DV) Visit 12
			TV 3	TV 4	TV 5	TV 6	TV 7	TV 8	TV 9	TV 10	TV 11	
Week	**-1**	**1**	**3**	**6**	**12**	**18**	**24**	**30**	**36**	**42**	**48**	**52**
Day ± Window	**(-7 to -10)**	**1**	**22± 3**	**43± 3**	**85± 5**	**127 ±7**	**169 ±7**	**211 ±7**	**253 ±7**	**295 ±7**	**337 ±7**	**365+10**
Activity / Observation												
Written informed consent (assent, if applicable) and HIPAA authorization	X											
Inclusion/exclusion criteria review	X											
Demographic data	X											
Medical & treatment history	X											
Concomitant medication evaluation	X	X	X	X	X	X	X	X	X	X	X	X
Physical examination	X							X				X
Vital signs	X	X						X				X
Height and weight measurements	X							X				X
Clinical laboratory investigations (hematology, biochemistry, urinalysis)[a]	X							X				X
Focused ENT and eye examination[b]	X	X	X	X	X	X	X	X	X	X	X	X
Allergen testing (skin prick test for relevant allergen, if required)[c]	X											
12-lead ECG	X											X
Urine pregnancy test (if applicable)	X	X	X	X	X	X	X	X	X	X	X	X

Visits	Screening Visit (SV) Visit 1	Randomization Visit (RV) Visit 2	Treatment Visits (TV)									Final Visit / Discontinuation Visit (FV/DV) Visit 12
			TV 3	TV 4	TV 5	TV 6	TV 7	TV 8	TV 9	TV 10	TV 11	
Week	**-1**	**1**	**3**	**6**	**12**	**18**	**24**	**30**	**36**	**42**	**48**	**52**
Day ± Window	**(-7 to -10)**	**1**	**22± 3**	**43± 3**	**85± 5**	**127 ±7**	**169 ±7**	**211 ±7**	**253 ±7**	**295 ±7**	**337 ±7**	**365+10**
Review instructions and train on the proper use of the nasal spray using the GSP 301 placebo NS pH [redacted] bottle	X											
Review instructions and train on the proper use of the nasal spray		X	X	X	X	X	X	X	X	X	X	
Prime and dispensation and administration of single-blind GSP 301 placebo NS pH [redacted] at the clinic[d]	X											
Return single-blind GSP 301 placebo NS pH [redacted] to the clinic[e]		X										
Distribution of the AR Assessment Diary	X	X	X	X	X	X	X	X	X	X	X	
Collection/Review of the AR Assessment Diary		X	X	X	X	X	X	X	X	X	X	X
Subject assessment of AR symptoms and recording and self-administration of placebo run-in medication[d]	X[d] →											
Subject assessment of AR symptoms and recording and self-administration of double-blind study medication[d]		X →										
Physician assessment of nasal symptom severity		X	X	X	X	X	X	X	X	X	X	X
Review randomization criteria		X										

Visits	**Screening Visit (SV) Visit 1**	**Randomization Visit (RV) Visit 2**	**Treatment Visits (TV)**									**Final Visit / Discontinuation Visit (FV/DV) Visit 12**
			TV 3	**TV 4**	**TV 5**	**TV 6**	**TV 7**	**TV 8**	**TV 9**	**TV 10**	**TV 11**	
Week	**-1**	**1**	**3**	**6**	**12**	**18**	**24**	**30**	**36**	**42**	**48**	**52**
Day ± Window	**(-7 to -10)**	**1**	**22± 3**	**43± 3**	**85± 5**	**127 ±7**	**169 ±7**	**211 ±7**	**253 ±7**	**295 ±7**	**337 ±7**	**365+10**
Randomization/treatment assignment		X										
Prime and dispensation of double-blind study medication		X	X	X	X	X	X	X	X	X	X	
Administration of double-blind study medication at the clinic[d]		X										
Return double-blind study medication to the clinic[e]			X	X	X	X	X	X	X	X	X	X
Distribution of the RQLQ(S), review instructions with the subject, and subject completion of the RQLQ(S)[f]		X		X				X				X
RCAT		X		X				X				X
Adverse events monitoring	X	X	X	X	X	X	X	X	X	X	X	X
Subject compliance check		X	X	X	X	X	X	X	X	X	X	X

Abbreviations: AM = morning; AR = allergic rhinitis; ECG = electrocardiogram; ENT = ears, nose, and throat; HIPAA = Health Insurance Portability and Accountability Act; NS = nasal spray; RQLQ(S) = Rhinoconjunctivitis Quality of Life Questionnaire - Standardized Activities; RCAT = Rhinitis Control Assessment Test.

a: Refer to Appendix 3 for the list of clinical laboratory tests.

b: A focused ENT and eye examination will be done at all visits. Focused nasal examinations will be performed to assess signs of AR as well as known complications of intranasal corticosteroid or antihistamine use (i.e., bleeding, perforation, and ulceration). Throat examinations will be conducted to evaluate evidence of throat irritation and candidiasis. . If at any visit, clinically significant nasal ulceration, nasal mucosal erosion, and nasal septal perforation are observed, or a finding at a previous visit has worsened (as judged by the Investigator), the subject should be referred to a qualified ENT specialist or other medically qualified specialist (qualified to evaluate and record these conditions, as judged by the Investigator) for further evaluation. A record from the specialist should be maintained, including the photographic evidence (imaging of nasal mucosa) of the assessment to allow pre- and post-treatment comparisons for AEs. The Sponsor will collect the de-identified information as part of the study data collection. Eligibility of the subject for participation/continued participation in the study will be at the Investigator's discretion based on whether or not the protocol-defined selection criteria are met. These subjects may need to be re-screened due to delay in scheduling an ENT visit to obtain the necessary evaluation, as applicable, upon consultation with

the Sponsor's study team and approval. A thorough eye examination will also be performed by the Investigator or medically qualified designee to assess signs of AR as well as any known complications of intranasal corticosteroid or antihistamine use. If needed, the subject should be referred to a qualified ophthalmologist for further evaluation as soon as possible.
c: Documentation of a positive result within the last year (12 months) before the Screening Visit (Visit 1) is acceptable to meet the eligibility criteria. Intradermal and/or RAST testing will not be accepted.
d: Generally, subjects will assess/record AR symptoms and take study medication at home. Subjects will assess their symptoms at specified clinic visits, as directed by the site personnel. The subject assessment and recording of AR symptoms will be done at the clinic at the Screening Visit (Visit 1) and study medication will be self-administered in the clinic at the Screening Visit (Visit 1) and the Randomization Visit (Visit 2) [redacted] doses of study medication during the run-in and treatment periods should be taken immediately following completion of the AR Assessment Diary (as applicable) except on the morning of the Screening Visit (Visit 1) and Randomization Visit (Visit 2) when the first dose of the placebo run-in medication and the double-blind study medication, respectively, will be self-administered in the clinic under the supervision of site personnel. [redacted] doses of study medication should be taken approximately [redacted] At the Screening Visit (Visit 1), subjects should be told not to take study medication before com ng to the clinic for the Randomization Visit (Visit 2). The last dose of the double-blind study medication should be the [redacted] dose on the day before the Final Visit/Discontinuation Visit (Visit 12). Subjects should be reminded not to take study medication on the morning of the Final Visit/Discontinuation Visit (Visit 12).
e: Subjects should be instructed to bring their study medication kit to each visit after the Screening Visit (Visit 1). Site personnel will collect the kit, take the used study medication, and return the rest of the kit to the subject, as applicable.
f: The RQLQ(S) must be the first procedure conducted at these visits.