[redacted]

Oyster Point Pharma, Inc.

Clinical Protocol: OPP-102:

A Phase 2, Multicenter, Randomized, Controlled, Double-Masked, Clinical Trial to Evaluate the Efficacy and Safety of OC-01 (varenicline) Nasal Spray in Subjects with Neurotrophic Keratopathy (the Olympia Study)

Statistical Analysis Plan
Version 3.0

[redacted]

Date: October 7, 2022

[redacted]

Revision History

[redacted]

Prepared by:

Approval Signatures:

[redacted]

Contents

[redacted]

1 Synopsis

Protocol Title:	A Phase 2, Multicenter, Randomized, Controlled, Double-Masked, Clinical Trial to Evaluate the Efficacy and Safety of OC-01 (varenicline) Nasal Sprayin Subjects with Neurotrophic Keratopathy (the Olympia Study)
Protocol Number:	OPP-102
Investigational Product:	OC-01 (varenicline) Nasal Spray: • 1.2 mg/mL
Study Objective:	The objective of this study is to evaluate the safety and effectiveness of OC- 01 (varenicline) nasal spray as compared to placebo nasal spray for mean change from baseline in corneal fluorescein staining in subjects with Stage 1 (corneal epithelial hyperplasia/punctate keratopathy) neurotrophic keratopathy (NK) in one or both eyes.
Treatment Assignment	100 subjects will be randomized in a 1:1 into one of two treatment groups: • 1.2 mg/mL • Placebo (vehicle)
Sample Size and Power	[redacted]
Randomization and Stratification	The randomization will be stratified by: • Pre-procedure (Baseline) non-anesthetized Schirmer's score (≤ 5, > 5) measured at the screening/randomization visit.
Efficacy Endpoint	Primary Endpoint: • Mean change from baseline in corneal fluorescein staining in subjects with Stage 1 NK at Week 8. Secondary Endpoint • Mean change from baseline in ETDRS visual acuity at Week 8 Exploratory Endpoint • Percent of subjects who achieve ≥ 3 lines (15 letters) of improvement in ETDRS visual acuity at Week 8 • Percent of subjects who achieve complete resolution of corneal staining (defined as complete resolution of corneal staining (0 mm lesion and no residual staining) in subjects with Stage 1 NK at Week 8. • Percentage (%) of subjects that progress to Stage 2 Persistent Epithelial Defect (PED) NK at Week 8. • Mean change from in improvement in corneal sensitivity at Week 8 • Mean change from baseline in corneal fluorescein staining in subjects with Stage 2 NK at Week 8.

	• Schirmer's score with topical anesthes[redacted] • Pain visual analog scale (VAS) • Slit lamp biomicroscopy • NEI-VFQ-25 Survey
Statistical Analysis for Primary Endpoint	The primary efficacy endpoint will be analyzed on the [redacted] controlling for the randomization stratum (Baseline Schirmer's Test Score (≤ 5 and > 5)) and baseline staining as a covariate.
Analysis Populations	[redacted]

[redacted]

Abbreviations

AE	adverse event
BCDVA	best corrected distance visual acuity
BCVA	best corrected visual acuity
CFR	Code of Federal Regulation
CMH	Cochran-Mantel Haenszel
eCRF	Electronic case report form
CI	Confidence interval
CRF	Case report form
ETDRS	Early Treatment Diabetic Retinopathy Study
FDA	Food and Drug Administration
HIPAA	Health Information Portability and Accountability Act
IB	Investigator's Brochure
ICF	informed consent form
ICH	International Conference on Harmonization
IRB	institutional review board
ITT	intent-to-treat
MedDRA	medical dictionary for regulatory activities
NEI-VFQ	National Eye Institute Visual Function Questionnaire
mg	Milligram
NK	Neurotrophic Keratitis
µL	microliter
mL	Milliliter
mm	millimeter
PED	Persistent Epithelial Defect
SAE	serious adverse event
SAP	Statistical Analysis Plan
SD	Standard deviation
STS	Schirmer's Test Score
TEAE	treatment-emergent adverse event
US	United States

2 Introduction

This statistical analysis plan (SAP), which is based on the final protocol (Amendment 6) of the study protocol dated June 15, 2022, defines the methods, and analyses that Oyster Point Pharma, Inc. (henceforth, Oyster Point) plans to use to analyze the data from Protocol OPP-102. This SAP complies with guidance promulgated by the International Conference on Harmonization (ICH) and the US Food and Drug Administration (FDA). If the protocol is subsequently amended, this SAP may be amended as well. Should the SAP and the protocolbe inconsistent with respect to the planned analyses, the language of the SAP prevails.

3 Study objective

The objective of this study is to evaluate the safety and effectiveness of OC-01 (varenicline)nasal spray as compared to placebo for mean change from baseline in corneal fluorescein staining in subjects with Stage 1 (corneal epithelial hyperplasia/punctate keratopathy) NK in one or both eyes.

4 Study Design

This is a Phase 2, multicenter, randomized, controlled, double- masked study designed to evaluate the safety and efficacy of OC-01 (varenicline) nasal spray in subjects with NK. Approximately 100 subjects at least 18 years of age with a physicians' diagnosis of Stage 1 NK, as defined by the Mackie Criteria and meeting all other study eligibility criteria will berandomized 1:1 and will receive OC-01 (varenicline)/ nasal spray or placebo nasal spray for8 weeks (56 days) three times daily (TID).

The two treatments are:

- Placebo (vehicle) [control]
- OC-01 (varenicline) Nasal Spray, 1.2 mg/mL

Subjects who terminate early during the application period will be asked to complete safety and/or efficacy assessments (if the participants agree) prior to study exit. Participants who areterminated early from the study will not be replaced.

Appendix 1 describes the detailed study visits, measurements, and dosing information.

[redacted]

5 Primary, Secondary and Exploratory Endpoints

5.1 Primary Efficacy Endpoint

The primary endpoint will be the mean change from baseline in corneal fluorescein staining at Week 8.

[redacted]

5.2 Secondary Efficacy Endpoint

The secondary efficacy endpoint is the mean change from baseline in ETDRS visual acuity at Week 8.

5.3 Exploratory Efficacy Endpoint

- Percent of subjects who achieve ≥ 3 lines (15 letters) of improvement in ETDRS visual acuity at Week 8.
- Percent of subjects who achieve complete resolution of corneal staining will be the exploratory endpoint. Complete resolution of corneal staining will be the exploratory endpoint is defined as complete resolution of corneal staining (0 mm lesion and no residual staining) in subjects with Stage 1 NK at Week 8.
- Percentage (%) of subjects that progress to Stage 2 Persistent Epithelial Defect (PED) NKat Week 8.
- Improvement in corneal sensitivity at Week 8
- Mean change from baseline in corneal fluorescein staining in subjects with Stage 2 NK at Week 8.
- Schirmer's score with topical anesthesia
- Pain visual analog scale (VAS)
- Slit lamp biomicroscopy
- NEI-VFQ-25 Survey

6 Sample Size Determination and Power Calculation

[redacted]

7 Randomization

Subjects will be randomized 1:1 to receive as a 50 microliter (µL) spray in each nostril:

- OC-01 (varenicline) nasal spray, 1.2 mg/mL
- Placebo (vehicle control) nasal spray

The randomization will be stratified by pre-procedure (Baseline) non-anesthetized Schirmer's score (≤5, >5) measured at thescreening/randomization visit.

8 Statistical Hypothesis Testing

[redacted]

Let μ_h, and μ_p denote the mean change in corneal fluorescein staining from baseline to Week 8 (1.2 mg/mL OC-01 and placebo, respectively) in subjects with Stage 1 NK.

H_0: $\mu_h - \mu_p = 0$
vs.
H_1: $\mu_h - \mu_p \neq 0$

9 Statistical Analysis

9.1 General Consideration

Quantitative variables will be summarized using the number of subjects (n), mean, SD, median, 25th and 75th percentiles, and minimum and maximum. Qualitative variables will besummarized using counts and percentages.

All summaries will be presented by treatment group. Summaries will be provided fordemographics, medical history, concomitant medications, and subject disposition.

For the summaries, medical history, concomitant medications, and AEs will be coded to MedDRA version 24 and World Health Organization Drug dictionaries March 2021 version,as appropriate.

Baseline measures are defined as the last measure prior to the initiation of study treatment,usually at Visit 1 screening.

All summaries for safety data and efficacy data will be presented by treatment group. For thebaseline characteristics, all summaries will be presented by treatment group and overall. All collected data will be presented in listings which will be sorted by treatment, subject ID, andvisit when it is appropriate. Summaries, data listings, and statistical analyses will be generated using SAS® Version 9.4 or higher.

9.2 Analysis Populations

[redacted]

9.2.3 Safety population

The safety population will include all randomized subjects who received at least one dose ofthe study drug. Analysis on the safety population will group subjects according to the treatment received.

9.3 Unit of Analysis

[redacted]

9.4 Definition of Study Day or Dosing Day

Study and dosing days are defined as follows:

Study Day = [Event date – Randomization date + 1] if after randomization[Event date – Randomization date] if before randomization

Dosing Day= [Event date – First dosing date + 1] if after first dosing date[Event date – First dosing date] if before first dosing date.

Note that with the definition above, days of "0" will not be used.

For subjects whose reference date is missing, the study day will also be categorized asmissing.

9.5 Missing and Partial Data

Adverse event onset

If onset date is completely missing, date is set to date of first dose.

If year is present and month and day are missing or year and day are present and month ismissing:

- If year = year of first dose, then set month and day to month and day of first dose.
- If year < year of first dose, then set month and day to December 31.
- If year > year of first dose, then set month and day to January 1.

If month and year are present and day is missing:

- If year = year of first dose and
  - month = month of first dose, then set day to day of first dose date.
  - month < month of first dose, then set day to last day of month.
  - month > month of first dose, then set day to first day of month.
- If year < year of first dose, then set day to last day of month.
- If year > year of first dose, then set day to first day of month.

For all other cases, set date to date of first dose.

Adverse event end date

If year is present and month and day are missing or year and day are present and month ismissing, set end month and day to December 31.

If month and year are present and day is missing, set the day to last day of the month.If fatal event, date is set to minimum of imputed end date and death date.
For all other cases, set date to missing.

For summaries that present distribution of time expressed in weeks and months, weeks willbe defined as days divided by 7 and months as days divided by 30.4375.

9.6 Protocol Deviations

[redacted]

[redacted]

9.7 Subjects Disposition

The number and percentage of subjects randomized and included in each analysis populationwill be summarized by treatment and overall. Reasons for excluding subjects from the analysis populations will be presented in a by-subject listing.

The number of randomized subjects who completed the study, discontinued early from studydrug, and reasons for discontinuation will be summarized by treatment group and overall.
The Case Report Form (CRF) lists the following reasons why subjects may discontinuetreatment before completing of the study:

- Non-Fatal Adverse Event
- Protocol Violation
- Lost to Follow Up
- Pregnancy
- Disease Progression
- Physician Decision
- Subject Non-Compliance
- Death
- Study Terminated by Sponsor
- Withdrawal by Subject
- Other

9.8 Demographics and Baseline Characteristics

Continuous variables will be summarized using the number of subjects (n), mean, SD, median, 25^{th} and 75^{th} percentiles, and minimum and maximum. Categorical variables will besummarized using counts and percentages. Summary data will be presented by treatment group and overall.

The following demographic will be summarized based on ITT population and Safetypopulation:

- Age
- Gender,
- Ethnicity
- Race

The following baseline ocular assessments will be summarized based on Safety population:

- Pain Visual Analog Scale (VAS)
- Best corrected distance visual acuity (BCDVA)
- Corneal Fluorescein Staining (prior to Schirmer's Test) - Modified Oxford GradingScale
- Corneal Sensitivity - Mean Score
- Schirmer's Test without Anesthesia

9.9 Medical, Ocular and Dry Eye History

Medical history terms and ocular history terms will be coded using the Medical Dictionaryfor Regulatory Activities (MedDRA) version 24.0 and the number and percent of subjects with medical history will be summarized by (SOC) and Preferred Term (PT) for each treatment group based on the safety population.

9.10 Treatment Exposure

Each randomized subject will receive an application of OC-01 (varenicline) Nasal Spray or placebo three times daily (TID) for 8 weeks. Duration of exposure to study treatment, in days, will be summarized for all safety subjects. Summary statistics for duration of exposurewill be presented by treatment group.

9.11 Ocular Assessments

Ocular assessments will occur at baseline and different study visits. The results, grade, clinical significance, and relatedness to administration procedure and study drug, will belisted, summarized in tables, and presented in figures as appropriate.

9.11.1 Schirmer's Test with Topical Anesthesia

The Schirmer's Test without topical anesthetic will be performed to assess tear production atthe Screening Visit (Visit 1). Additional Schirmer's Test with topical anesthetic will be assessed after the first treatment at Visit 1. At Week 1 (Visit 2) and Week 8 (Visit 6) and/or at the time of early termination, the Schirmer's Tests will be performed concurrent with treatment.

9.11.2 Pain Visual Analog Scale (VAS)

The Pain Visual Analog Scale (VAS) will be performed at Screening (Visit 1), Week 2 (Visit3), Week 4 (Visit 4), Week 6 (Visit 5), Week 8 (Visit 6). At post-treatment visit, change in VAS from pre- to post-treatment will be collected and summarized by treatment group for both study and fellow eyes.

9.11.3 Early Treatment Diabetic Retinopathy Study (ETDRS) BCDVA

Best corrected distance visual acuity (BCDVA) will be performed and collected at Screening (Visit 1), Week 4 (Visit 4), and Week 8 (Visit 6).

On the BCDVA Assessment CRF Form, the total number of letters read correctly in each rowof letters should be written down. Visual acuity will be measured once for each eye, using Chart 1 for the right eye, Chart 2 for the left eye, and Chart 1 for binocular vision testing.

After each measurement of visual acuity, the visual score for the visit is calculated. Thevisual acuity score is defined as follows:

- If 20 or more letters are read correctly at the 4-meter test distance, the visual acuity score is equal to the numbers of letters read correctly at 4 meters, plus 30;or

- If less than 20 letters are read correctly at the 4-meter test distance, the visualacuity score is equal to the number of letters read correctly at 1 meter plus the number at 4 meters: or

- If no letters are read correctly at either the 4-meter distance or the 1-meterdistance, the visual acuity score is 0.

BCDVA will be summarized by visit and by treatment group for both study and fellow eyes.The change from baseline in BCDVA will be calculated. The descriptive statistics for the treatment difference in change from baseline will be presented. In addition, 95% confidenceinterval in treatment difference will be presented as well.

9.11.4 Corneal Sensitivity

Corneal sensitivity will be performed at Screening (Visit 1, prior to Schirmer's Test), Week 4(Visit 4), and Week 8 (Visit 6).

Corneal sensation is measured in the affected eye of the patient at all applicable visits using a Cochet Bonnet aesthesiometer. The measurements taken from the affected eye are as follows:Sensitivity in each of the 4 quadrants of the cornea:

- Superior nasal (cm)
- Inferior nasal (cm)
- Superior temporal (cm)

- Inferior temporal (cm)

Steps for using the handheld aesthesiometer:
Note: Cochet Bonnet aesthesiometer measurements MUST be performed prior toadministration of Topical Anesthesia.

- Sterilize the filament.
- Extend the filament to full length of 6 cm.
- Perform sensitivity in each of the 4 quadrants of the cornea:
- Superior nasal (cm)
- Inferior nasal (cm)
- Superior temporal (cm)
- Inferior temporal (cm)
- Retract the filament incrementally in 0.5 cm steps until the patient can feel its contact.
- Record the length (NOTE: The shorter the length indicates decreased sensation.)
- Compare the fellow eye cornea.
- Repeat steps 1-4 in each quadrant: superior, temporal, inferior, nasal.
- Sterilize the filament and retract back into the device to protect it from damage.

For Stage 1 subjects, corneal sensitivity is defined as the mean of the 4 quadrants (four measurements).

The superior nasal, inferior nasal, superior nasal, inferior temporal, sensitivity within the areaof PED, and mean score will be calculated at each visit. Corneal sensitivity results will be summarized for each treatment group for the study and fellow eyes by visit using discrete summary statistics.

9.11.5Corneal Fluorescein Staining

Corneal fluorescein staining will be performed, and data will be collected at Screening (Visit1, prior to Schirmer's Test), Week 1 (Visit 2), Week 2 (Visit 3), Week 4 (Visit 4), and Week8 (Visit 6). Corneal fluorescein staining will be assessed for both the study and fellow eyes. The examiner compares the overall appearance of the patient's corneal staining with the Modified Oxford Grading Scale and selects the appropriate grade that best represents the state of corneal staining. The corneal fluorescein staining score will be described by visit, treatment, study eye, and fellow eye with summary statistics.

9.11.6Slit Lamp Biomicroscopy

The slit lamp biomicroscopy will be performed at Screening (Visit 1, prior to Schirmer's Test), Week 1 (Visit 2), Week 2 (Visit 3), Week 4 (Visit 4), and Week 8 (Visit 6). A slit lampwill be used for external examination and biomicroscopy. The cornea, conjunctiva, anterior chamber, iris, eyelid, motility, pupil, and lens will be examined at each visit. Slit lamp biomicroscopy results will be summarized for each treatment group for the study and fellow eyes by visit using discrete summary statistics. Abnormal clinically significant findings will be described. Shifts from baseline including normal to abnormal

(not clinically significant), and normal to abnormal (clinically significant) will be presented using counts and percentages.

10 Intranasal Examination

Intranasal assessments collected at Screening (Visit 1), Week 1 (Visit 2), Week 2 (Visit 3), Week 4 (Visit 4), Week 6 (Visit 5), Week 8 (Visit 6), and Week 24 (Visit 8) will be summarized by treatment group with counts and percentages. Shifts from baseline of normal to abnormal (not clinically significant) and normal to abnormal (clinically significant) will bepresented using counts and percentages.

11 NEI-VFQ-25 Survey

The National Eye Institute (NEI) sponsored the development of the VFQ-25 with the goal of creating a survey that would measure the dimensions of self-reported vision-targeted health status that are most important for patients who have chronic eye diseases. Questions includedin the VFQ25 represent the content identified during a series of condition-specific focus groups with patients who had age-related cataracts, glaucoma, age-related macular degeneration, diabetic retinopathy, or CMV retinitis.

The VFQ-25 consists of a base set of 25 vision-related questions representing 11 vision- targeted constructs, plus an additional single-item general health rating question. Table 1 presents the 11 vision-targeted items and the health-related item and their correspondentquestion numbers.

Table 1 Averaging of Items to Generate VFQ-25 Sub-Scales

Scale	Number of items	Items to be averaged
General Health	1	1
General Vision	1	2
Ocular Pain	2	4, 19
Near Activities	3	5, 6, 7
Distance Activities	3	8, 9, 14
Vision Specific:		
Social Functioning	2	11, 13
Mental Health	4	3, 21, 22, 25
Role Difficulties	2	17, 18
Dependency	3	20, 23, 24
Driving	3	15c, 16, 16a
Color Vision	1	12
Peripheral Vision	1	10

[redacted]

Scoring VFQ-25 with or without optional items is a two-step proces
First, original numeric values from the survey are re-coded following the scoring rules outlined in Table 2. All items are scored so that a high score represents better functioning. Each item is then converted to a 0 to 100 scale so that the lowest and highest possible scores are set at 0 and 100 points, respectively.

Table 2. Scoring Key: Recording of Items

Item Numbers	Change original response category [a]	To recorded value
1, 3, 4, 15c[b]	1	100
	2	75
	3	50
	4	25
	5	0
2	1	100
	2	80
	3	60
	4	40
	5	20
	6	0
5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 16, 16a	1	100
	2	75
	3	50
	4	25
	5	0
	6	*
17, 18, 19, 20, 21, 22, 23, 24, 25	1	0
	2	25
	3	50
	4	75
	5	100

(a) Precoded response choices as printed in the questionnaire.
(b) Item 15c has four-response levels, but is expanded to a five-levels using item 15b.
Note: If 15b=1, then 15c should be recoded to "0"
If 15b=2, then 15c should be recoded to missing.
If 15b=3, then 15c should be recoded to missing.

* Response choice "6" indicates that the person does not perform the activity because of non-vision related problems. If this choice is selected, the item is coded as "missing."

Second, items within each sub-scale are averaged together to create the 12 sub-scale scores. Table indicates which items contribute to each specific sub-scale. Items that are left blank (missing data) are not taken into account when calculating the scale scores. Sub-scales with at least one item answered can be used to generate a sub-scale score. Hence, scores represent the average for all items in the subscale that the respondent

answered.

Table 3. Averaging of Items to Generate VFQ-25 Sub-Scales		
Scale	Number of items	Items to be averaged (after recording per Table 2)
General Health	1	1
General Vision	1	2
Ocular Pain	2	4, 19
Near Activities	3	5, 6, 7
Distance Activities	3	8, 9, 14
Vision Specific:		
Social Functioning	2	11, 13
Mental Health	4	3, 21, 22, 25
Role Difficulties	2	17, 18
Dependency	3	20, 23, 24
Driving	3	15c, 16, 16a
Color Vision	1	12
Peripheral Vision	1	10

Descriptive statistics for the NEI-VFQ-25 Survey collected at Screening (Visit 1), Week 4 (Visit 4), and Week 8 (Visit 6), and their change from baseline will be provided by treatmentgroup and analysis visit based on ITT population.

12 NK Staging per Mackie Criteria

NK Staging per Mackie Criteria collected at Week 1 (Visit 2), Week 2 (Visit 3), Week 4 (Visit 4), Week 6 (Visit 5), and Week 8 (Visit 6) will be summarized by treatment group witheach staging counts and percentages.

13 In-vivo Confocal Microscopy

In-vivo Confocal Microscopy will be listed by subjects ID and visit or visit date.

14 Efficacy Analysis

[redacted]

the primaryefficacy endpoint as well as the secondary endpoints, the significance level of 5% will be used for all the testing hypotheses and no multiple comparison adjustment will be performed.

14.1 Primary Efficacy Endpoints

[redacted]

The primary endpoint will be the mean change from baseline in corn[redacted] staining at Week 8. The primary efficacy endpoint will be analyzed on the PP population using an analysis of covariance model comparing the treatment group to placebo with the randomization strata, baseline Schirmer's Test Score and the baseline corneal fluorescein staining as the covariates.

14.2 Secondary Efficacy Endpoint

The secondary efficacy endpoint is the mean change from baseline in ETDRS visual acuity at Week 8. The secondary efficacy endpoint will be analyzed on the PP population using an analysis of covariance model comparing the treatment group to placebo with the randomization strata, baseline Schirmer's Test Score and the baseline ETDRS visual acuity as the covariates.

14.3 Exploratory endpoints

[redacted]

[redacted]

14.4 Missing Efficacy Data Handling

[redacted]

15 Safety Analysis

The safety population will be used for all safety analyses. All recorded safety parameters willbe listed by treatment, subjects ID and visit or visit date.

15.1 Adverse Events

The investigator will promptly review each Adverse Event (AE) for accuracy and completeness, and classify each AE according to its intensity, its relationship to study drug oradministration procedure, and its seriousness. AEs will be coded using version 24.0 of the MedDRA dictionary. AEs will be monitored throughout the study and documented on the appropriate AE form. AEs will be categorized as ocular and non-

ocular events as well as by system organ class (SOC) and preferred term (PT), seriousness, severity, and relation to study medications.

All treatment-emergent adverse events (TEAEs) will be summarized. TEAE is defined as an AE that is new or worsened in severity compared to the first dose of study drug. All AEs willbe presented in data listing with a flag indicating the event is a TEAE.

TEAEs will be summarized by subject level. In addition, the number of TEAE episodes thatoccurred during the study will be provided in the overall summary of AE table.

The following presentations of TEAEs will be generated:

- Overall adverse events summary (including any TEAEs, ocular TEAEs, non-ocularTEAEs, resolved ocular TEAEs, ocular TEAEs, non-ocular TEAEs, treatment- emergent SAEs, treatment-related treatment emergent SAEs, TEAEs by maximum severity, TEAEs related to study drug, AEs leading to treatment/study discontinuation, TEAEs leading to death);
- All ocular TEAEs by SOC and PT;
- All non-ocular TEAEs by SOC and PT;
- All TEAEs by Severity, SOC, and PT;
- All TEAEs by Relationship to Study Drug, SOC, and PT;
- Serious TEAEs by SOC and PT;
- Serious TEAEs related to Study Drug by SOC and PT;
- TEAEs leading to treatment discontinuation;
- TEAEs leading to study discontinuation;
- TEAEs leading to death.

15.2 Prior and Concomitant Medications

Prior and concomitant medications will be coded using the World Health Organization DrugDictionary (March 2021 version) and summarized for each treatment group in the safety population. A prior medication is defined as any medication taken within 60 days before dosing on Day 1 and stopped prior to the first dose of the study medication in the study. Anymedication taken from the day of first dose of the study treatment up to the day of last date ofthe study will be considered as a concomitant medication for analysis.

Table 4 describes the classification of prior and concomitant medications.

[redacted]

[redacted]

15.3 Urine Pregnancy Test

All urine pregnancy test will be listed by treatment, subjects ID and visit or visit date.

[redacted]