Statistical Analysis Plan

Cetero Research Protocol No. CTJK09001
Theracos, Inc. Protocol No. THR-1442-C-402

A Phase II, four-week, multi-center, double-blind, placebo-controlled parallel group study to evaluate the safety and efficacy of EGT0001442 in subjects with type 2 Diabetes Mellitus with an ascending dose safety and pharmacokinetic evaluation period

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17-May-2010
Final Version 1.0

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LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

AE	adverse event
ANOVA	analysis of variance
ATC	the anatomic therapeutic chemical classification
AUC	area under the curve
AUC_{0-t}	area under the plasma concentration-time curve from time 0 to time t (time of last quantifiable plasma concentration)
AUC_{0-inf}	area under the plasma concentration-time curve from time 0 to infinity
AUC_{0-24}	area under the plasma concentration-time curve from time 0 to 24 h
BMI	body mass index
CI	confidence interval
CL/F	the apparent total body clearance
C_{max}	maximum observed plasma concentration
CRF	case report form
CV	coefficient of variation
DSMB	data and safety monitoring board
ECG	electrocardiogram
FDA	food and drug administration
FPG	fasting plasma glucose
GCP	good clinical practice
HbA1c	glycated hemoglobin
ICH	international conference on harmonisation
ITT	intent-to-treat
Kel	terminal phase rate constant
MedDRA	medical dictionary for regulatory activities
PK	pharmacokinetics
PP	per protocol
SAE	serious adverse event
SAP	statistical analysis plan

SD	standard deviation
SMBG	self monitored blood glucose
TEAE	treatment emergent adverse event
Thalf	apparent terminal half life
T_{max}	time of observed maximum plasma concentration
UGE0-24	urinary glucose excretion from 0 to 24 h post dose
V_z/F	the apparent total volume of distribution

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Statistical Analysis Plan

1. INTRODUCTION

This SAP is based on the final Protocol THR-1442-C-402 Amendment 2 dated 23 February 2010. The SAP provides details on the planned statistical methodology for 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:

- Clinical Research Protocol final Protocol THR-1442-C-402 Amendment 1 dated 23 February 2010
- Case report forms (CRFs) issued on 22 March 2010: R09-0980 (THR-1442-C-402) eCRF Template - Insubject V1.2.pdf and R09-0980 (THR-1442-C-402) eCRF Template - Outsubject V1.2.pdf
- ICH Guidance on Statistical Principles for Clinical Trials.

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.

2. OBJECTIVES

Primary Objectives:

The primary objectives of this study are:

- To determine the effect of EGT0001442 on fasting plasma glucose (FPG) at the end of 4 weeks of treatment.
- To assess the pharmacokinetics and safety and tolerability of EGT0001442 at four dose levels in diabetic subjects given the drug daily for 4 weeks.

Secondary Objectives:

- To determine changes in body weight at week 4 from baseline.
- To determine changes in HbA1c at week 4 compared to baseline.
- To determine changes in FPG following cessation of treatment
- To determine the pharmacodynamics of EGT0001442 by urinary glucose excretion (UGE) in diabetic subjects on day 0, day 1 and day 28.

PK Objective:

- To determine the pharmacokinetics of EGT0001442 in diabetic subjects

Exploratory Objective:

- To measure changes in post-prandial blood glucose from baseline to day 2 in the 20 subjects in the dose escalation segment of the trial while they remain supervised in the clinic.

3. OVERALL STUDY DESIGN AND PLAN

EGT0001442 is an experimental agent being developed by Theracos Inc. for the treatment of type 2 diabetes. EGT0001442 is a selective inhibitor of human sodium glucose cotransporter 2 (SGLT2). A first-in-human study and a subsequent phase I study in diabetic subjects have previously evaluated the safety and tolerability of EGT0001442 (as proline cocrystal) up to a dose of 100 mg/d for 14 days (150 mg/d of cocrystal) in healthy volunteers or as a single dose of 100 mg (150 mg of cocrystal) in diabetic subjects. This trial is the first to expose human subjects to EGT0001442 as a single agent (i.e., not as proline cocrystal) and is conducted at dose levels of 5, 10, 20 and 50 mg per day, or placebo, in two segments.

The first segment is a single center, open labeled pharmacokinetic 3 day insubject study with a 25 day outsubject continuation, intended to assess any significant changes in the exposure to EGT0001442 when delivered by single agent crystal compared to proline cocrystal. The similar solubility and dissolution rate of the two formulations of EGT0001442 suggest that significant differences in exposure compared to those observed following proline cocrystal administration are unlikely. However a drug and safety monitoring board will review the outcomes and pharmacokinetic data to determine if the pharmacokinetic profile will result in the mean C_{max} or AUC_{0-24} exceeding the NOAEL in male rats (the limiting sex and species derived from 28 day repeat dosing studies).

The second segment of the proposed clinical evaluation is a multicenter, placebo-controlled, five-arm parallel group, double-blind, randomized clinical trial of 28 day duration conducted in an outsubject population. EGT0001442 delivered at dose levels of 5, 10, 20 and 50 mg per day, or placebo, is administered to approximately 25 subjects per dose for a period of 28 days followed by a 14 day follow-up period.

The primary objective of the second segment is to evaluate the efficacy of EGT0001442 in the treatment of type 2 diabetes mellitus. Approximately 125 subjects will be randomly assigned to receive EGT0001442 at 5, 10, 20, or 50 mg/day or placebo with an equal number of subjects per group.

The primary efficacy end point is the assessment of the effect of EGT0001442 on fasting plasma glucose (FPG) after 4 weeks on treatment compared to baseline FPG values. The secondary efficacy end points include:

- Changes in body weight at week 4 from baseline
- Changes in HbA1c at week 4 compared to baseline
- Change in FPG following cessation of treatment
- Pharmacodynamic effects of EGT0001442 on urinary glucose excretion (UGE) in

diabetic subjects on day 0 (baseline), day 1 and day 28.

Safety of EGT0001442 will be evaluated by assessment of adverse events and concomitant medication records, hematology and blood chemistry laboratory results, cardiovascular events, electrocardiograms (ECG), urine electrolytes and urinalysis.

PK parameters will be evaluated in the 20 subjects in the dose escalation segment. An exploratory analysis of changes in post-prandial blood glucose on day 0 and day 2 while in-clinic from subjects in the dose escalation segment will also be conducted.

4. TREATMENT ADMINISTERED

In the open labeled, dose escalation segment, subjects will take one of the 5 mg, one of the 10 mg, two of the 10 mg, or two of the 25 mg EGT0001442 capsules daily in the 5, 10, 20, or 50 mg cohort.

In the outsubject randomization segment, the following treatments will be administered:

Table 1. EGT0001442 or placebo treatments

Treatment group	Placebo capsule /day	EGT0001442 capsules /day 5	10	25	Total # capsules/day
5 mg EGT0001442	1	1	--	--	2
10 mg EGT0001442	1	--	1	--	2
20 mg EGT0001442	--	--	2	--	2
50 mg EGT0001442	--	--	--	2	2
Placebo	2	--	--	--	2

During the dose escalation segment of the study, the study drug will be administered orally to subjects in the upright position with approximately 200 mL of water between 07:00 h and 10:00 h, following a minimum of a 10 h overnight fast. During fasting, no fluids will be taken in the two hours prior to drug administration. The capsules will be swallowed without chewing. Breakfast will be given 0.5 h after dosing. Administration of all study medications will be supervised. After drug administration, a hand and mouth inspection will take place.

In the outsubject setting, subjects will be instructed to self administer one capsule from each of the two bottles prior to breakfast once daily for 25 or 28 days, respectively, and complete the dosing log. Taking the study medication with a glass of water is recommended.

5. BLINDING

The dose escalation segment of the study will be open labeled. In the randomization segment, the study drug will be blinded to the sponsor, investigators, the study coordinator, study subjects, and pharmacist. Upon randomization, each subject will receive a subject randomization number and a drug kit number assigned to the subject.

The dosing information will remain blinded to all of the study team until the last subject has completed the last follow up visit and the database has been locked. A designated statistician that will provide safety data upon request from the DSMB will be allowed to receive unblinded data.

To manage the safety monitoring and maintain blinding of the treatment, there will be an unblinded study staff who will review the FPG data and alert the investigator and essential study staff if glucose is below 2.8 mmol/L (50 mg/dL), 3.9 mmol/L (70 mg/dL), or above 12 mmol/L (216 mg/dL), 15 mmol/L (270 mg/dL) or 16.7 mmol/L (300 mg/dL). The actual numerical values of the FPG will remain blinded to all study personnel and subjects unless clinically indicated, as outlined in section 5.4.

The investigator will also receive a sealed envelope for each subject containing a description of the dispensed medication. The envelope can be opened only if knowledge of the test substance is needed to manage the subject's condition. If opened, the date of opening and the reason for opening must be written on the envelope. At the conclusion of the study, all envelopes must be returned to the Sponsor. These will be checked to ensure that the seals had not been broken, unless warranted by the occurrence of the events mentioned above. If unblinding occurs, the time and reason for unblinding will be recorded on the CRF and the sponsor must be notified within 24 h.

6. METHOD OF ASSIGNING SUBJECTS TO TREATMENT GROUPS

The dose escalation segment of the study will be open labeled. Study drug will be provided to the site pharmacist in bottles of 30 capsules. The pharmacist will dispense the study drug to the subjects.

In the randomization segment, eligible subjects who complete the 15 ± 2 day washout period to verify eligibility for the study and stability of their diabetes will be randomized to receive EGT0001442 or placebo according to a randomization code generated by the Pharmacometric Department of the contract research organization (CRO). Approximately 125 subjects will be randomly assigned to a treatment group within each treatment center to control for any potential bias due to center. Subjects are assigned to placebo or EGT0001442 at doses of 5, 10, 20, or 50 mg/day in a 1:1:1:1:1 ratio. Randomization will be stratified by study center. Completion of a block of 5 will initiate the assignment of a new random block and the process will continue until all subjects are enrolled. This randomization protocol is designed to balance experimental treatments within each center.

The Outsubject Segment of this study will be conducted at multiple investigative sites and will likely involve variable numbers of subjects at each site. Enrollment will be on a competitive basis but will be capped at 40% of the total randomized subjects (50 subjects) from one center.

7. SAMPLE SIZE

The efficacy pairwise null and alternative hypotheses to be assessed are as follows:

$$H_{0i}: \mu_i = \mu_P$$
vs.
$$H_{1i}: \mu_i \neq \mu_P$$

where μ_i = the mean change in FPG from baseline to week 4 for dose i (i = 5, 10, 20 or 50 mg/day of EGT0001442) and μ_P = the mean change in FPG from baseline to week 4 for placebo. The test of each pairwise null hypothesis will be carried out at the two-sided 0.05 level of significance; no adjustment for multiple comparisons will be made.

The sample size of 25 subjects per group was calculated based on the following assumptions:

1. Baseline mean (± standard deviation) FPG is 190 (± 40) mg/dL for each dose group;
2. The active doses will decrease FPG on average by 25 (± 25) mg/dL from baseline to day 28
3. The placebo will not experience a substantive average decrease in mean FPG from baseline to day 28; the standard deviation of the change in mean FPG from baseline to day 28 is assumed conservatively to be 25 (same standard deviation as for active doses).
4. The two-sided significance level for each pairwise hypothesis is 0.05.

Under the above assumptions, an evaluable sample size of 22 evaluable subjects per treatment arm yields approximately 90% power that at least one dose will be found to be significantly different from placebo. A sample size of 25 subjects per treatment arm will be enrolled to account for any subject lost-to-follow-up.

8. ANALYSIS POPULATIONS

Intent-to-Treat Analysis Set:

All randomized subjects in segment 2 of the study. This is the analysis set on which efficacy endpoints will be evaluated. All subjects will be analyzed according to the treatment to which they were randomized. The Intent-to-Treat Analysis Set will be used to perform the efficacy analysis for the double-blind segment only.

Per-Protocol Analysis Set:

The subset of subjects from the Intent-to-Treat analysis set that received at least 24 doses of study drug to which they were randomized, did not miss more than one dose in the last week of study medication, did not have any major protocol deviations and were measured for FPG visit with confirmed ≥10 hour fast at the day 27 and day 29 visits within the specified visit window. Subjects who stopped treatment due to rescue medication are also included in the analysis set. All subjects will be analyzed according to the treatment received.

The Per-Protocol Analysis Set will be evaluated only for primary efficacy to confirm results from the Intent-to-Treat Analysis Set. The final subject evaluability will be performed prior to breaking treatment codes and locking the database.

Double-blind Safety Analysis Set:

All randomized subjects who receive at least one dose of treatment during the randomization segment. Subjects will be analyzed according to the treatment received. The Double-blind Safety Analysis Set will be used to perform safety assessments for the double-blind segment.

Dose-Escalation Safety Analysis Set:

All subjects who receive at least one dose of treatment during the dose escalation segment of the study. Subjects will be analyzed according to the treatment received.

The Dose-Escalation Safety Analysis Set will be used to perform safety assessments for the open-label dose escalation segment.

9. STUDY ENDPOINTS

Primary Efficacy Endpoint

The primary efficacy endpoint is change in FPG.

Secondary Efficacy Endpoints

- Change in body weight from baseline to day 29
- Change in HbA1c from baseline to day 29.
- Change in FPG from cessation of treatment (days 27/29 to days 41/43).
- 24 h UGE on day 0, day 1 and day 28

Primary Safety Endpoints

- Adverse events
- Clinical and laboratory variables
- Concomitant medication
- FPG, Vital signs, SMBG record, and ECG parameters

10. STATISTICAL METHODS

Data will be summarized with respect to demographic and baseline characteristics, efficacy variables and safety variables.

Summary statistics will include the mean, N, standard deviation, median, minimum, and maximum values for continuous variables, and frequencies and percentages for categorical variables.

If not otherwise specified, all statistical analyses will be two-sided and the Type I (alpha) error is fixed at the 5% level.

10.1 Baseline Characteristics

10.1.1 Demographics and Baseline Characteristics

Baseline characteristics will be descriptively summarized for all subjects by treatment group for the ITT population in the Double-blind Segment, and for all subjects in the dose escalation segment by dose. Continuous measures will be summarized with sample size, mean, median, standard deviation, minimum and maximum; categorical measures will be presented with the counts and percents of subjects in each category. No statistical tests comparing treatments at baseline will be performed.

Age is calculated in years after rounding down as follows:

Year of age = (Date informed consent signed - Date of birth) / 365.25

All data will be listed by study segment, treatment group and subject in the double-blind segment and by study segment, dose and subject in the dose escalation segment.

10.1.2 Medical History

Medical history data recorded at screening will be listed by study segment, treatment group and subject in the double-blind segment and by study segment, dose and subject in the dose escalation segment.

10.1.3 Inclusion/Exclusion Criteria and Exceptions

Subject inclusion/exclusion criteria and exceptions will be listed by study segment, treatment group and subject in the double-blind segment and by study segment, dose and subject in the dose escalation segment.

10.1.4 Urine Drug Screen

Urine drug screen will be listed by study segment, treatment group and subject in the double-blind segment and by study segment, dose and subject in the dose escalation segment.

10.1.5 Study Drug Administration

Visit, date and time for study drug administration will be listed by study segment, treatment group and subject in the double-blind segment and by study segment, dose and subject in the dose escalation segment.

10.2 Primary Analysis

Efficacy analysis will only be performed for the double-blind randomization segment. FPG from subjects in segment 1 will be presented in by-subject listings.

Response Variable and Baseline:

The primary efficacy endpoint of change in FPG will be treated as the response variable. FPG will be determined from the blood samples drawn at baseline, defined as the mean of FPG values on day -2 and day 1 and after 4 weeks of treatment, defined

as the mean of FPG values on day 27 and day 29. If one of the two FPG values at baseline or at 4-week treatment is missing, the single value available will be used. If both values are missing (either baseline or at the 4-week treatment), this data will not be used.

Descriptive Summary:

Descriptive statistics (sample size, mean, median, standard deviation, minimum and maximum) of the primary endpoint will be presented for each treatment group. In addition, descriptive statistics of the baseline and after 4 weeks of treatment values will be presented.

ANCOVA Model:

Pairwise comparisons of each active dose versus placebo on mean change in FPG from baseline will be carried out at the two-sided 0.05 alpha level of significance using analysis of covariance adjusting for study center and baseline FPG. Baseline FPG and center will be treated as covariate. The pairwise differences in mean change in FPG means between each dose and placebo, and its associated two-sided 95% confidence interval, adjusted for study center and baseline FPG will be presented.

Assessment of Interactions:

The interactions of treatment-by-baseline and treatment-by-center will be assessed in two separate models using 2 two-way analysis of covariance models with the effects of treatment, center and baseline FPG common to both.

A non-significant interaction effect at the 0.10 level of significance or a significant interaction that is only quantitative and not qualitative in nature (i.e. where the treatment effect differs only in magnitude but not direction across study centers) will support the pooling of subjects across study centers for purposes of the primary analysis pairwise comparisons. Centers with less than 5 subjects randomized will be pooled into one or more centers based on the geographic regions.

Missing Data:

No imputation will be carried out for missing data with the exception of subjects who ended treatment due to rescue medication. For such subjects, the last FPG value measured prior to the subject receiving rescue medication will be carried forward to day 29.

10.3 Secondary Analyses

Analysis for the secondary endpoints will be carried out in a similar manner as for the primary efficacy endpoint of FPG. The change in FPG following cessation of treatment will be determined from the blood samples drawn at week 4 of treatment, defined as the mean of FPG values on day 27 and day 29 to week 6, defined as the mean of FPG values on day 41 and day 43. No imputation will be carried out for missing data. Due to the secondary nature of these outcomes, no assessments of the treatment-by-center interaction will be carried out, unless a significant qualitative treatment-by-center interaction is found for FPG. The interaction of treatment-by-baseline, however, will be carried out on all secondary analyses where baseline is measured.

Baseline for weight is defined as the pre-dose weight value on Day 1 at Visit 5. Baseline for HbA1c is defined as the pre-dose HbA1c value on Day 1 at Visit 5. Baseline for 24h UGE is defined as the pre-dose UGE value on Day 0 at Visit 4.

If the safety and ITT analysis sets differ by more than 10%, the analysis on UGE will also be conducted on the safety analysis set.

10.4 Safety Analysis

Safety endpoints will be summarized using descriptive statistics and by-subject listings included in the clinical study report. Safety analysis will be performed separately for subjects in the double-blind study and subjects in the dose escalation study where applicable. Results will be presented by treatment group/dose group.

For repeat safety assessments (clinical laboratory tests, vital signs and ECGs), the following will apply for the summary tables.

- Repeat safety assessments prior to dosing, the repeated values will be used for calculations but all values will be included in the listings.
- Repeat safety assessments after dosing, the original values will be used but all values will be included in the listings.

10.4.1 Adverse Event Analysis

Adverse events will be mapped using the Medical Dictionary for Regulatory Activities (MedDRA) central coding dictionary (version 12.1). Each adverse event is to be evaluated for date/time of onset, duration, severity and causal relationship with the study drug or other factors.

<u>Treatment Emergent Adverse Events</u>

Treatment Emergent Adverse Events (TEAEs) are any AEs that start or worsen at or after administration of the first dose of study medication.

Adverse Event listings will be provided for all TEAEs, all drug-related TEAEs, serious TEAEs, and any TEAEs leading to study discontinuation.

The number and percentage of subjects experiencing TEAEs will be summarized by treatment group overall and for each System Organ Class and Preferred Term. Each subject will be counted only once within each preferred term. If the same AE occurs in a subject on multiple occasions, the highest severity and least complementary relationship will be assumed. If two or more AEs are reported as a single event, the individual terms will be reported as separate AEs.

This analysis will be repeated for drug-related and serious TEAEs and for TEAEs leading to study discontinuation.

TEAEs will also be tabulated by maximum severity experienced.

No formal statistical tests comparing treatment groups will be performed.

<u>Adverse Events during Washout Period</u>

Adverse events reported during the washout period will be presented by subject-listings.

Serious Adverse Events

Serious adverse events will be listed by-subject listings.

Cardiovascular Risk Assessment

Cardiovascular adverse events will be presented in by-subject listings.

10.4.2 Clinical Laboratory Tests

Clinical laboratory tests include clinical chemistries, CBC with differential, urinalysis, and urinary electrolytes. These variables will be presented in by-subject listings by study segment, treatment/dose group and subject.

Descriptive statistics (sample size, mean, median standard deviation, minimum, and maximum) of the continuous variables at each visit will be summarized for both double-blind segment and dose escalation segment by treatment/dose group.

Change from baseline to each visit will be presented for double-blind segment. Baseline is defined as the laboratory value prior to dosing. A paired t-test assessing the significance of the change from baseline will be presented for each variable within each treatment group.

Shift tables displaying the change in normality status from baseline to post-baseline visits will be presented for the double-blind segment.

10.4.3 Concomitant Medication

Concomitant medications will be coded using the World Health Organization Dictionary (WHODrug Version 101E). A table of concomitant medications based on the anatomic therapeutic chemical classification (ATC) and preferred name will be produced by treatment/dose group.

A listing of concomitant medications will include all medications taken during the course of the study.

Any medications taken prior to the start of the study medication will be listed and summarized in a similar manner.

No formal statistical tests comparing treatment groups will be performed.

10.4.4 FPG, Vital Signs, SMBG record, and ECG Parameters

Vitals signs including pulse, systolic and diastolic blood pressure at sitting position, respiration rate, and temperature will be measured at screening, prior to dosing, and at each follow up visit.

A 12-lead electrocardiogram (ECG) will be conducted at screening, prior to dosing, and at each follow up visit.

Fasting plasma glucose, vital signs and ECG parameters will be listed and presented in a similar manner as for clinical laboratory tests above.

The SMBG record will be summarized in by-subject listings.

10.4.5 Physical Exam

A complete physical examination will be performed at screening and at the termination visit. A complete physical examination will include measurement of body weight and height (height will be measured only at screening), general assessment of all body systems (except genitals) including the skin, head, eyes, ears, nose, throat, neck, thyroid, lungs, heart, abdomen, lymph nodes, and extremities. A partial physical examination will include body weight and general assessment of the skin, heart, lungs and abdomen.

Physical exam will be listed by study segment, treatment group and subject in the double-blind segment and by study segment, dose and subject in the dose escalation segment.

10.5 PK Assessments

Pharmacokinetic analyses will be performed for EGT0001442 plasma data. All subjects who received EGT0001442 and have sufficient plasma concentration data will be included in the analysis to characterize the PK of EGT0001442. This determination will be made by the study pharmacokineticist.

Subjects who experience emesis will be treated according to Cetero Research SOP entitled “Handling Subjects Experiencing Emesis Episode(s) in BA/BE Studies.” Although the SOP's scope is specified as for BA/BE studies, it will be adopted for the analysis of this study, where applicable. Subjects vomiting within 6.6 hours after drug administration will be dropped from the study (based on 2 times the a priori mean population Tmax of 3.3 hours). Their samples will be analyzed by the bioanalytical laboratory and presented in the report but will be excluded from the pharmacokinetic analyses.

Concentration values below the lower limit of quantification (BLQ) will be treated according to Cetero Research SOP entitled “Handling BLQ data in PK/PD studies”. Subjects with BLQ values between two non-BLQ concentrations will be set to missing. BLQ values that occur at the beginning on the profile will be set to zero.

Data from subjects with missing concentration values (missed blood draws, lost samples, samples unable to be quantitated) may be used if pharmacokinetic parameters can be estimated using the remaining data points. Otherwise, concentration data from these subjects will be excluded from the final analysis.

A non-compartmental pharmacokinetic analysis (SAS, Cary, NC or WinNonlin 5.0.1, Pharsight Corp., Mountain View, CA, USA) will be used to calculate the PK parameters for each subject. The actual time of sample collection will be used in the PK parameters calculations.

- C_{max} Maximum observed plasma concentration
- T_{max} Time of observed maximum plasma concentration
- Kel Terminal phase rate constant
- Thalf Apparent terminal half life
- CL/F The apparent total body clearance

- V_z/F The apparent total volume of distribution
- AUC_{0-t} Area under the plasma concentration-time curve from Time 0 to Time t (time of last quantifiable plasma concentration)
- AUC_{0-inf} Area under the plasma concentration-time curve from Time 0 to infinity
- AUC_{0-24} Area under the plasma concentration-time curve from Time 0 to 24 h

Descriptive statistics (arithmetic mean, standard deviation [sd], median, minimum, maximum, coefficient of variation) will be summarized by dose group for the parameters listed above and for ln-AUC_{0-t}, ln-AUC_{0-24}, ln-AUC_{0-inf} and ln-C_{max}. Additionally, geometric means will be calculated for AUC_{0-t}, AUC_{0-24}, AUC_{0-inf} and C_{max}.

No value of Kel, AUC_{0-inf}, Thalf, CL/F, or V_z/F will be reported for cases that do not exhibit a terminal log-linear phase in the concentration versus time profile.

Other pharmacokinetic parameters may be calculated if deemed necessary.

10.6 Exploratory Analysis of the Post-prandial Blood Glucose

The impact of EGT0001442 on 2-h post-prandial glucose levels will be determined by measuring fingerstick blood glucose values at 7 points on day 0 and then again on day 2 of drug administration for the 20 subjects in the dose escalation phase of the trial. Measurements will be taken before each meal (breakfast, lunch, and dinner) and then 2 hour after meal completion. A seventh measurement will be taken at 10 pm (± 30 mins) at night.

The difference between the post-meal measurement and the measurement before the same meal will be identified as the post-prandial glucose change for that meal. For each meal, the difference in day 0 to day 2 post-prandial glucose changes will be descriptively summarized for all subjects in the dose escalation segment, categorized by dose. The data will be summarized with sample size, mean, median, standard deviation, minimum and maximum. No statistical tests comparing doses will be performed

For each subject, AUC of the glucose levels across the 7 points will be calculated at each of day 0 and day 2. The difference in day 0 to day 2 AUC will be descriptively summarized for all subjects in the dose escalation segment, categorized by dose. The data will be summarized with sample size, mean, median, standard deviation, minimum and maximum. No statistical tests comparing doses will be performed.

10.7 Interim Analysis

There will be no formal interim efficacy analysis for this study. An independent data and safety monitoring board (DSMB) will inspect the safety data from the dose escalation segment, review SAE reports, and will periodically inspect unblinded safety data from the double-blind study. A DSMB charter will be written outlining the safety data to be inspected periodically by the DSMB.

10.8 Missing Data

No imputation will be carried out for missing data with the exception of subjects who ended treatment due to rescue medication. For such subjects, the last FPG value measured prior to the subject receiving rescue medication will be carried forward to Day 28.

10.9 Multiple Comparisons

Given the Phase II nature of this study, no adjustment of the significance level for multiple comparisons will be made.

11. TABLE, LISTING AND FIGURE SHELLS

The following shells are provided in order to provide a framework for the display of data from this study. The shells may change due to unforeseen circumstances. 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 report. Tables and listings are numbered following the ICH structure. Table headers, variables names and footnotes will be modified as needed following data analyses. Please note that all summary tables and listings will be generated using SAS® Version 9.1.3. Figures will be generated using SigmaPlot Version 10 and/or SAS® Version 9.1.3.

Summary Tables

Table 14.1.1 Disposition of Subjects (Double-blind Segment)

	Treatment Group					
	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)	Overall (N=xx)
Number of subjects randomized (N)	xx	xx	xx	xx	xx	xx
Included in Double-blind Safety Analysis Set [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Included in Intent-to-Treat Analysis Set [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Included in Per-Protocol Analysis Set [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Included in Completed study [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Discontinued from study [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Reason for Discontinuation						
Discontinued due to Adverse Event [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Subject elected to withdraw from study [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Death [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Study terminated by sponsor [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Investigator decision [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Lost to follow-up [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Poor Glycemic Control [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Other [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)

N: Number of subjects randomized in the specified treatment group
n: Number of subjects
%: Percentage based on N

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.1.2 Disposition of Subjects (Dose Escalation Segment)

	Dose Group				
	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)	Overall (N=xx)
Number of subjects enrolled (N)	xx	xx	xx	xx	xx
Included in Dose-Escalation Safety Analysis Set [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Included in Completed study [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Discontinued from study [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Reason for Discontinuation					
Discontinued due to Adverse Event [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Subject elected to withdraw from study [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Death [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Study terminated by sponsor [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Investigator decision [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Lost to follow-up [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Other [n (%)]	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)

N: Number of subjects enrolled in the specified dose group
n: Number of subjects
%: Percentage based on N

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.1.3 Summary of Demographics (Double-blind Segment)

		Treatment Group					
Parameter	Statistic	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)	Overall (N=xx)
Age (years)	n	xx	xx	xx	xx	xx	xx
	Mean ± SD	xx ± x.x	xx ± x.x	xx ± x.x	xx ± x.x	xx ± x.x	xx ± x.x
	Median	xx	xx	xx	xx	xx	xx
	Min , Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Height (cm)	n	xx	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	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	xx.x , xx.x	xx.x , xx.x
Weight (kg)	n	xx	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	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	xx.x , xx.x	xx.x , xx.x
BMI (kg/m^2)	n	xx	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	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	xx.x , xx.x	xx.x , xx.x

N: Number of subjects randomized in the specified treatment group
n: Number of subjects
SD: Standard Deviation

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.1.3 Summary of Demographics (Double-blind Segment) (continued)

		Treatment Group					
Parameter	Statistic	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)	Overall (N=xx)
Race	[n (%)]						
American Indian / Alaska Native		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Asian		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Black / African American		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Native Hawaiian / Other Pacific Islander		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
White		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Gender	[n (%)]						
Male		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Female		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Ethnicity	[n (%)]						
Hispanic or Latino		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Not Hispanic or Latino		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)

N: Number of subjects randomized in the specified treatment group
n: Number of subjects
%: Percentage based on N

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.1.4 Summary of Demographics (Dose Escalation Segment)

		Treatment Group				
Parameter	Statistic	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)	Overall (N=xx)
Age (years)	n	xx	xx	xx	xx	xx
	Mean ± SD	xx ± x.x	xx ± x.x	xx ± x.x	xx ± x.x	xx ± x.x
	Median	xx	xx	xx	xx	xx
	Min , Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Height (cm)	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	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	xx.x , xx.x
Weight (kg)	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	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	xx.x , xx.x
BMI (kg/m^2)	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	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	xx.x , xx.x

N: Number of subjects enrolled in the specified dose group
n: Number of subjects
SD: Standard Deviation

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.1.4 Summary of Demographics (Dose Escalation Segment) (continued)

		Treatment Group				
Parameter	Statistic	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)	Overall (N=xx)
Race	[n (%)]					
American Indian / Alaska Native		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Asian		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Black / African American		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Native Hawaiian / Other Pacific Islander		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
White		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Gender	[n (%)]					
Male		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Female		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Ethnicity	[n (%)]					
Hispanic or Latino		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)
Not Hispanic or Latino		xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)	xx(xx.x%)

N: Number of subjects randomized in the specified treatment group
n: Number of subjects
%: Percentage based on N

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.1 Primary Efficacy Analysis: Descriptive Summary of Fasting Plasma Glucose from Baseline to End of Treatment
Double-blind Segment
Intent-to-Treat Analysis Set

		Treatment Group				
	Statistic	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Baseline*	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
End of Treatment#	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Change from Baseline to End of Treatment	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx

Note: * Baseline is defined as the mean of FPG values on day -2 and day 1.
End of Treatment is defined as the mean of FPG values on day 27 and day 29.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.2 Primary Efficacy Analysis: ANCOVA Results on Mean Change in FPG from Baseline to End of Treatment
Double-blind Segment
Intent-to-Treat Analysis Set

Treatment	n	LSMeans	Std Err LSMeans	Difference between Treatments					
				LSMeans	Std Err LSMeans	95%-confidence Interval	P-value Treatment	P-value Baseline	P-value Center
Overall	xxx						x.xxxx	x.xxxx	x.xxxx
Placebo	xxx	x.xxx	x.xxx						
5 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
10 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
20 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
50 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		

n: Number of subjects with data available in the specific treatment group
LSMeans: Least square means
Std Err LSMeans: Standard error of the LSMeans
Note: LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on an ANCOVA with change from baseline as dependent variable and treatment as fixed effect and baseline and center as covariates. P-values are from two-sided test at 5%-level.
Note: Baseline is defined as the mean of FPG values on day -2 and day 1.
End of Treatment is defined as the mean of FPG values on day 27 and day 29.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Similar tables:

Table 14.2.3 Descriptive Summary of Fasting Plasma Glucose from Baseline to End of Treatment
Double-blind Segment
Per-Protocol Analysis Set

Table 14.2.4 ANCOVA Results on Mean Change in FPG from Baseline to End of Treatment
Double-blind Segment
Per-Protocol Analysis Set

Table 14.2.5 Descriptive Summary of Fasting Plasma Glucose from End of Treatment to Post Treatment
Double-blind Segment
Intent-to-Treat Analysis Set

		Treatment Group				
	Statistic	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
End of Treatment#	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Post Treatment+	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Change from End of Treatment to Post Treatment	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx

Note: # End of Treatment is defined as the mean of FPG values on day 27 and day 29.
+ Post Treatment is determined from the blood samples drawn at week 4 of treatment, defined as the mean of FPG values on day 27 and day 29 to week 6, defined as the mean of FPG values on day 41 and day 43.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.6 ANCOVA Results on Mean Change in FPG from End of Treatment to Post Treatment
Double-blind Segment
Intent-to-Treat Analysis Set

Treatment	n	LSMeans	Std Err LSMeans	Difference between Treatments					
				LSMeans	Std Err LSMeans	95%-confidence Interval	P-value Treatment	P-value Baseline	P-value Center
Overall	xxx						x.xxxx	x.xxxx	x.xxxx
Placebo	xxx	x.xxx	x.xxx						
5 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
10 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
20 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
50 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		

n: Number of subjects with data available in the specific treatment group
LSMeans: Least square means
Std Err LSMeans: Standard error of the LSMeans
Note: LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on an ANCOVA with change from baseline as dependent variable and treatment as fixed effect and baseline and center as covariates. P-values are from two-sided test at 5%-level.
Note: End of Treatment is defined as the mean of FPG values on day 27 and day 29.
Post Treatment is determined from the blood samples drawn at week 4 of treatment, defined as the mean of FPG values on day 27 and day 29 to week 6, defined as the mean of FPG values on day 41 and day 43.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.7 Descriptive Summary of Change in Body Weight from Baseline to Day 29
Double-blind Segment
Intent-to-Treat Analysis Set

		Treatment Group				
	Statistic	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Baseline	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Day 29	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Change from baseline	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx

Note: Baseline is defined as the pre-dose body weight value on Day 1.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.8 ANCOVA Results on Mean Change in Body Weight from Baseline to Day 29
Double-blind Segment
Intent-to-Treat Analysis Set

				Difference between Treatments					
Treatment	n	LSMeans	Std Err LSMeans	LSMeans	Std Err LSMeans	95%-confidence Interval	P-value Treatment	P-value Baseline	P-value Center
Overall	xxx						x.xxxx	x.xxxx	x.xxxx
Placebo	xxx	x.xxx	x.xxx						
5 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
10 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
20 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
50 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		

n: Number of subjects with data available in the specific treatment group
LSMeans: Least square means
Std Err LSMeans: Standard error of the LSMeans
Note: LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on an ANCOVA with change from baseline as dependent variable and treatment as fixed effect and baseline and center as covariates. P-values are from two-sided test at 5%-level.
Note: Baseline is defined as the pre-dose body weight value on Day 1.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.9 Descriptive Summary of Change in HbA1c from Baseline to Day 29
Double-blind Segment
Intent-to-Treat Analysis Set

		Treatment Group				
	Statistic	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Baseline	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Day 29	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Change from baseline	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx

Note: Baseline is defined as the pre-dose HbA1c value on Day 1.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.10 ANCOVA Results on Mean Change in HbA1c from Baseline to Day 29
Double-blind Segment
Intent-to-Treat Analysis Set

				Difference between Treatments					
Treatment	n	LSMeans	Std Err LSMeans	LSMeans	Std Err LSMeans	95%-confidence Interval	P-value Treatment	P-value Baseline	P-value Center
Overall	xxx						x.xxxx	x.xxxx	x.xxxx
Placebo	xxx	x.xxx	x.xxx						
5 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
10 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
20 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
50 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		

n: Number of subjects with data available in the specific treatment group
LSMeans: Least square means
Std Err LSMeans: Standard error of the LSMeans
Note: LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on an ANCOVA with change from baseline as dependent variable and treatment as fixed effect and baseline and center as covariates. P-values are from two-sided test at 5%-level.
Note: Baseline is defined as the pre-dose HbA1c value on Day 1.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.11 Descriptive Summary of Change in 24 h UGE from Baseline to Day 28
Double-blind Segment
Intent-to-Treat Analysis Set

		Treatment Group				
	Statistic	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Baseline	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Day 1	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Day 28	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Change from baseline to Day 1	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Change from baseline to Day 28	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx

Note: Baseline is defined as the 24h UGE on Day 0.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.12 ANCOVA Results on Mean Change in 24 h UGE from Baseline to Day 28
Double-blind Segment
Intent-to-Treat Analysis Set

Treatment	n	LSMeans	Std Err LSMeans	Difference between Treatments					
				LSMeans	Std Err LSMeans	95%-confidence Interval	P-value Treatment	P-value Baseline	P-value Center
Overall	xxx						x.xxxx	x.xxxx	x.xxxx
Placebo	xxx	x.xxx	x.xxx						
5 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
10 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
20 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		
50 mg EGT0001442 vs. Placebo	xxx	x.xxx	x.xxx	x.xxx	x.xxx	x.xxx, x.xxx	x.xxxx		

n: Number of subjects with data available in the specific treatment group
LSMeans: Least square means
Std Err LSMeans: Standard error of the LSMeans
Note: LSMeans, Std Err of LSMeans, 95% confidence intervals and p-values are based on an ANCOVA with change from baseline as dependent variable and treatment as fixed effect and baseline and center as covariates. P-values are from two-sided test at 5%-level.
Note: Baseline is defined as the 24h UGE on Day 0.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.13 Summary of Plasma Concentrations of EGT0001442 (ng/mL)
Dose Escalation Segment

Dose Group	Center	Subject Number	0 hr	0.5 hr	1 hr	2 hr	3 hr	4 hr	6 hr	8 hr	10 hr	12 hr	24 hr	48 hr
5 mg EGT0001442	01	01	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
		02	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
		03	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx	xxxx
...														
		N	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx	xx
		MEAN	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		SD	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		CV%	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		MEDIAN	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		MIN	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx
		MAX	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx	xx.xx

Note: table will continue for 10mg, 20mg and 50mg dose groups.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.14 Summary of Pharmacokinetic Parameters of EGT0001442
Dose Escalation Segment

Dose Group	Subject Number	AUC0-t (ng.h/mL)	AUC0-24 (ng.h/mL)	AUC0-inf (ng.h/mL)	Cmax (ng/mL)	Tmax (h)	Thalf (h)	Kel (1/h)	Vz/F (L)	CL/F (L/h)	Ln-Transformed AUC0-t (ng.h/mL)	Ln-Transformed AUC0-24 (ng.h/mL)	Ln-Transformed AUC0-inf (ng.h/mL)	Ln-Transformed Cmax (ng/mL)
5 mg EGT0001442	01	xxxx.x	xxxx.x	xxxx.x	xxx.x	xx.x	xx.x	x.xxxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	02	xxxx.x	xxxx.x	xxxx.x	xxx.x	xx.x	xx.x	x.xxxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	...													
	N	xxxx.x	xxxx.x	xxxx.x	xxx.x	xx.x	xx.x	x.xxxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	MEAN	xxxx.x	xxxx.x	xxxx.x	xxx.x	xx.x	xx.x	x.xxxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	SD	xxxx.x	xxxx.x	xxxx.x	xxx.x	xx.x	xx.x	x.xxxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	CV%	xxxx.x	xxxx.x	xxxx.x	xxx.x	xx.x	xx.x	x.xxxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	MEDIAN	xxxx.x	xxxx.x	xxxx.x	xxx.x	xx.x	xx.x	x.xxxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	MIN	xxxx.x	xxxx.x	xxxx.x	xxx.x	xx.x	xx.x	x.xxxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	MAX	xxxx.x	xxxx.x	xxxx.x	xxx.x	xx.x	xx.x	x.xxxx	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x	xxx.x
	GM*	xxxx.x	xxxx.x	xxxx.x	xxx.x									

Note: *GM = Geometric Mean

Note: table will continue for 10mg, 20mg and 50mg dose groups.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.15 Summary of Post Prandial Blood Glucose (mg/dL) in Change from Day 0 to Day 2
Dose Escalation Segment

			Dose Group			
Day	Meal	Statistic	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Day 0	Breakfast	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Lunch	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Dinner	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
Day 2	Breakfast	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Lunch	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Dinner	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
Change from Day 0 to Day	Breakfast	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Lunch	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Dinner	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.2.16 Summary of Post Prandial Blood Glucose in AUC (mg.h/dL)
Dose Escalation Segment

Day	Statistic	Dose Group: EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Day 0	n	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
Day 2	n	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
Change from Day 0 to Day 2	n	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.1 Summary of TEAEs
Double-blind Segment
Double-blind Safety Analysis Set

	Treatment Group				
	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
All TEAEs	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E
Deaths	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E
Serious TEAEs	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E
TEAEs leading to withdrawal	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E
TEAEs related to study drug	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E

N: Number of subjects exposed in specified group
%: Percentage based on N
E: Number of TEAEs

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.2 Summary of TEAEs
Dose Escalation Segment
Dose Escalation Safety Analysis Set

	Dose Group			
	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
All TEAEs	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E
Deaths	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E
Serious TEAEs	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E
TEAEs leading to study discontinuation	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E
TEAEs related to study drug	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E	xx (xx.x%) E

N: Number of subjects exposed in specified group
%: Percentage based on N
E: Number of TEAEs

Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.3 Summary of TEAEs by System Organ Class, Preferred Term and Treatment Group
Double-blind Segment
Double-blind Safety Analysis Set

System Organ Class Preferred Term	Treatment Group Placebo (N=xx)	 EGT0001442 5 mg (N=xx)	 EGT0001442 10 mg (N=xx)	 EGT0001442 20 mg (N=xx)	 EGT0001442 50 mg (N=xx)
Subject with at least one AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PTxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PTxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one adverse event are counted only once (under the greatest reported severity).
Note: N: Number of subjects in the specified group
%: Percentage based on N

Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Similar tables:

Table 14.3.1.4 Summary of Drug-related TEAEs by System Organ Class, Preferred Term and Treatment Group
Double-blind Segment
Double-blind Safety Analysis Set

Table 14.3.1.5 Summary of TEAEs Leading to Study Discontinuation by System Organ Class, Preferred Term and Treatment Group
Double-blind Segment
Double-blind Safety Analysis Set

Table 14.3.1.6 Summary of Serious TEAEs by System Organ Class, Preferred Term and Treatment Group
Double-blind Segment
Double-blind Safety Analysis Set

Table 14.3.1.7 Summary of TEAEs by System Organ Class, Preferred Term and Dose Group
Dose Escalation Segment
Dose Escalation Safety Analysis Set

System Organ Class Preferred Term	Dose Group EGT0001442 5 mg (N=xx)	 EGT0001442 10 mg (N=xx)	 EGT0001442 20 mg (N=xx)	 EGT0001442 50 mg (N=xx)
Subject with at least one AE	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PTxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PTxx	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one adverse event are counted only once (under the greatest reported severity).
Note: N: Number of subjects in the specified group
%: Percentage based on N

Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Similar tables:

Table 14.3.1.8 Summary of Drug-related TEAEs by System Organ Class, Preferred Term and Dose Group
Dose Escalation Segment
Dose Escalation Safety Analysis Set

Table 14.3.1.9 Summary of TEAEs Leading to Study Discontinuation by System Organ Class, Preferred Term and Dose Group
Dose Escalation Segment
Dose Escalation Safety Analysis Set

Table 14.3.1.10 Summary of Serious TEAEs by System Organ Class, Preferred Term and Dose Group
Dose Escalation Segment
Dose Escalation Safety Analysis Set

Table 14.3.1.11 Summary of TEAEs by Maximum Severity
Double-blind Segment
Double-blind Safety Analysis Set

System Organ Class Preferred Term	Severity	Treatment Group Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Subject with at least one AE	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 1	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT1	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PTxx	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 2	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one adverse event are counted only once (under the greatest reported severity).
Note: N: Number of subjects in the specified group
%: Percentage based on N

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.12 Summary of TEAEs by Maximum Severity
Dose Escalation Segment
Dose Escalation Safety Analysis Set

System Organ Class Preferred Term	Severity	Treatment Group EGT0001442 5 mg (N=xx)	 EGT0001442 10 mg (N=xx)	 EGT0001442 20 mg (N=xx)	 EGT0001442 50 mg (N=xx)
Subject with at least one AE	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 1	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PT1	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
PTxx	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
SOC 2	Mild	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Moderate	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
	Severe	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: Counts reflect numbers of subjects reporting one or more adverse events that map to the MedDRA system organ class/preferred term. At each level of summarization (system organ class or preferred term), subjects reporting more than one adverse event are counted only once (under the greatest reported severity).
Note: N: Number of subjects in the specified group
%: Percentage based on N

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.13 Clinical Laboratory Evaluations in Biochemistry (Observed Values)
Double-blind Segment
Double-blind Safety Analysis Set

			Treatment Group				
	Visit Day	Statistic	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Albumin (G/L) (30 - 50)	Screening	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
	Day -2	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
	Day 1	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
	...						
ALT(SGPT) (U/L) (8 - 54)	Screening	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
...							

Note: Table will continue for other visit days 2, 8, 15, 22, 29, 35 and 43 and will continue for other lab parameters.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.14 Clinical Laboratory Evaluations in Change from Baseline in Biochemistry
Double-blind Segment
Double-blind Safety Analysis Set

	Visit Day	Statistic	Treatment Group: Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Albumin (G/L) (30 - 50)	Day 2	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
		P-value*	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
	Day 8	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
		P-value*	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
	...						
ALT(SGPT) (U/L) (8 - 54)	Day 2	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
		P-value*	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx

...

Note: Baseline is defined as the last observed measurement prior to dosing on Day 1 at Visit 5.
Note: *P-values are from paired t-test.
Note: Table will continue for other visit days 15, 22, 29, 35 and 43 and will continue for other lab parameters.

Table 14.3.1.15 Biochemistry Laboratory Shift Table
Double-blind Segment
Double-blind Safety Analysis Set

Lab Parameter	Treatment	Visit Day		Day 1 / Baseline: Missing n (%)	Below LLNR n (%)	Normal n (%)	Above ULNR n (%)	Total n (%)
Albumin (G/L) (30 - 50)	Placebo (N=xx)	Day 2	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Below LLNR	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Above ULNR	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (100.0)
		Day 8	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Below LLNR	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Above ULNR	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (100.0)
		...						
	EGT0001442 5 mg (N=xx)							
...								

Note: N: Number of subjects in the specified group
n: Number subjects with data available
%: Percentage based on N
LLNR: Lower Limit of Normal Range
ULNR: Upper Limit of Normal Range

Table will continue for other visit days 15, 22, 29, 35 and 43 and for other treatment group and other lab parameters.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Similar tables:

Table 14.3.1.16 Clinical Laboratory Evaluations in Hematology (Observed Values)
Double-blind Segment
Double-blind Safety Analysis Set

Table 14.3.1.17 Clinical Laboratory Evaluations in Change from Baseline in Hematology
Double-blind Segment
Double-blind Safety Analysis Set

Table 14.3.1.18 Hematology Laboratory Shift Table
Double-blind Segment
Double-blind Safety Analysis Set

Table 14.3.1.19 Clinical Laboratory Evaluations in Urinalysis (Observed Values)
Double-blind Segment
Double-blind Safety Analysis Set

Table 14.3.1.20 Clinical Laboratory Evaluations in Change from Baseline in Urinalysis
Double-blind Segment
Double-blind Safety Analysis Set

Table 14.3.1.21 Urinalysis Laboratory Shift Table
Double-blind Segment
Double-blind Safety Analysis Set

Lab Parameter	Treatment	Visit Day		Day 1 / Baseline: Missing n (%)	Normal n (%)	Abnormal n (%)	Total n (%)
Albumin (G/L) (30 - 50)	Placebo (N=xx)	Day 2	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (100.0)
		Day 8	Missing	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Normal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Abnormal	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
			Total	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (100.0)
		...					
	EGT0001442 5 mg (N=xx)						
...							

Note: N: Number of subjects in the specified group
n: Number subjects with data available
%: Percentage based on N

Table will continue for other visit days 15, 22, 29, 35 and 43 and for other treatment group and other lab parameters.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.22 Clinical Laboratory Evaluations in Biochemistry (Observed Values)
Dose Escalation Segment
Dose Escalation Safety Analysis Set

	Visit Day	Statistic	Dose Group: EGT0001442 5 mg (N=xx)	EGT0001442 10 mg 20 mg (N=xx)	EGT0001442 50 mg (N=xx)	EGT0001442 (N=xx)
Albumin (G/L) (30 - 50)	Screening	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Day 0	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Day 1	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	...					
ALT(SGPT) (U/L) (8 - 54)	Screening	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
...						

Note: Table will continue for other visit days 2, 3, 8, 15, 22, 23 and 43 and will continue for other lab parameters.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Similar tables:

Table 14.3.1.23 Clinical Laboratory Evaluations in Hematology (Observed Values)
Dose Escalation Segment
Dose Escalation Safety Analysis Set

Table 14.3.1.24 Clinical Laboratory Evaluations in Urinalysis (Observed Values)
Dose Escalation Segment
Dose Escalation Safety Analysis Set

Table 14.3.1.25 Summary of Vital Signs (Observed Values)
Double-blind Segment
Double-blind Safety Analysis Set

			Treatment Group				
	Visit Day	Statistic	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Pulse (beats/minute)	Screening	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
	Day -2	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
	Day 1/Pre-dose	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
	Day 2/Pre-dose						
	Day 8						
	Day 15						
	Day 22						
	Day 29						
	Day 35						
	Day 43						
Systolic BP (mmHg)	Screening	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
...							

Note: Table will continue for other vital signs.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.26 Summary of Vital Signs in Change from Baseline
Double-blind Segment
Double-blind Safety Analysis Set

	Visit Day	Statistic	Treatment Group: Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Pulse (beats/minute)	Day 2	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
		P-value*	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
	Day 8	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
		P-value*	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
	...						
Systolic BP (mmHg)	Day 2	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
		P-value*	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
...							

Note: Baseline is defined as the last observed measurement prior to dosing on Day 1 at Visit 5.
Note: *P-values are from paired t-test.
Note: Table will continue for other days 8, 15, 22, 29, 35 and 43 and will continue for other vital signs.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.27 Summary of Vital Signs (Observed Values)
Dose Escalation Segment
Dose Escalation Safety Analysis Set

	Visit Day	Statistic	Dose Group: EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Pulse (beats/minute)	Screening	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Day 0	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Day 1/Pre-dose	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Day 1/1 hr					
	Day 1/2 hr					
	Day 1/4 hr					
	Day 1/8 hr					
	Day 2/Pre-dose					
	Day 3/Pre-dose					
	Day 8					
	Day 15					
	Day 22					
	Day 29					
	Day 43					
Systolic BP (mmHg)						

Note: Table will continue for other vital signs

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.28 Summary of 12-Lead ECG (Observed Values)
Double-blind Segment
Double-blind Safety Analysis Set

	Visit Day	Statistic	Treatment Group: Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
PR Interval (ms)	Screening	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
	Day -2	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
	Day 1/Pre-dose	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
	Day 2/Pre-dose Day 29						
QRS Interval (ms)	Screening	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx

...

Note: Table will continue for other ECGs.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.29 Summary of 12-Lead ECG in Change from Baseline
Double-blind Segment
Double-blind Safety Analysis Set

	Visit Day	Statistic	Treatment Group: Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
PR Interval (ms)	Day 2	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
		P-value*	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
	Day 8	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
		P-value*	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
	...						
QRS Interval (ms)	Day 2	n	xx	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
		P-value*	x.xxxx	x.xxxx	x.xxxx	x.xxxx	x.xxxx
...							

Note: Baseline is defined as the last observed measurement prior to dosing on Day 1 at Visit 5.
Note: *P-values are from paired t-test.
Note: Table will continue for other days 15, 22 and 29 and will continue for other ECGs.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.30 Summary of 12-Lead ECG (Observed Values)
Dose Escalation Segment
Dose Escalation Safety Analysis Set

	Visit Day	Statistic	Dose Group: EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Pulse (beats/minute)	Screening	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Day 0	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Day 1/Pre-dose	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx
	Day 1/2 hr					
	Day 2/Pre-dose					
	Day 29					
Systolic BP (mmHg)	Screening	n	xx	xx	xx	xx
		Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
		Median	xx.x	xx.x	xx.x	xx.x
		Min, Max	xx , xx	xx , xx	xx , xx	xx , xx

...

Note: Table will continue for other ECGs.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.31 Summary of Fasting Plasma Glucose by Visit (Observed Values)
Double-blind Segment
Double-blind Safety Analysis Set

Visit Day	Statistic	Treatment Group: Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Screening	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Day -2	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
Day 1	n	xx	xx	xx	xx	xx
	Mean ± SD	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx	xx.x ± x.xx
	Median	xx.x	xx.x	xx.x	xx.x	xx.x
	Min, Max	xx , xx	xx , xx	xx , xx	xx , xx	xx , xx
...						

Note: Table will continue for Days 2,8,15,22,27,29,35,41 and 43.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.32 Summary of Concomitant Medication
Double-blind Segment
Double-blind Safety Analysis Set

	Treatment Group				
Preferred Medication Term	Placebo (N=xx)	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Any Medication	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ConMed 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ConMed 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ConMed 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ConMed 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: A subject is counted only once per concomitant medication.
N: Number of subjects exposed
%: Percentage is based N

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Table 14.3.1.33 Summary of Concomitant Medication
Dose Escalation Segment
Dose Escalation Safety Analysis Set

	Dose Group			
Preferred Medication Term	EGT0001442 5 mg (N=xx)	EGT0001442 10 mg (N=xx)	EGT0001442 20 mg (N=xx)	EGT0001442 50 mg (N=xx)
Any Medication	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ConMed 1	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ConMed 2	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ConMed 3	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)
ConMed 4	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)	xx (xx.x%)

Note: A subject is counted only once per concomitant medication.
N: Number of subjects in the specified group
%: Percentage is based N

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Summary Listings

Listing 16.2.1 Subject Disposition

Study Segment	Treatment	Center	Subject Number	Date Last/ Contact	Termination Status	Termination Reason
Double-blind	Placebo	02	02141	ddmmmyyyy	Completed	
			02142	ddmmmyyyy	Discontinued due to adverse event	xxxxxxxxxxxxxxxxxxx
			...			
		...				
	EGT0001442 5 mg					
	EGT0001442 10 mg					
	EGT0001442 20 mg					
	EGT0001442 50 mg					
Dose Escalation	EGT0001442 5 mg	01	003	ddmmmyyyy	Completed	
			...			
		...				
	EGT0001442 10 mg					
	EGT0001442 20 mg					
	EGT0001442 50 mg					

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.2 Protocol Deviations

Study Segment	Treatment	Center	Subject Number	Deviation Date /Time	Page ID	Deviation Category	Description of Deviation	Deviation Major/minor
Double-blind	Placebo	02	02141	ddmmmyyyy/hhmm	EX0012	DOSING	xxxxxxxxxxxx	Minor
	...	...						
	EGT0001442 5 mg							
	EGT0001442 10 mg							
	EGT0001442 20 mg							
	EGT0001442 50 mg							
Dose Escalation	EGT0001442 5 mg	01	003	ddmmmyyyy/hhmm	EX0012	DOSING	xxxxxxxxxxxxx	NA
	EGT0001442 10 mg							
	EGT0001442 20 mg							
	EGT0001442 50 mg							

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.3 Subjects Excluded from the Efficacy Analysis (Double-blind Segment)

Treatment	Center	Subject Number	Safety Population	ITT Population	PP Population
Placebo	02	02141	Yes	No	No

EGT0001442 5 mg

EGT0001442 10 mg

EGT0001442 20 mg

EGT0001442 50 mg

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.4.1 Demographics

Study Segment	Treatment	Center	Subject Number	Date of Birth	Age (yrs)	Gender	Race	Ethnicity	Height (cm)	Weight (kg)	BMI (kg/m^2)
Double-blind	Placebo	02	02141	ddmmmyyyy	xx	Male	White	Hispanic or Latino	xxx	xxx.x	xxx.x
			...								
		...									
	EGT0001442 5 mg										
	EGT0001442 10 mg										
	EGT0001442 20 mg										
	EGT0001442 50 mg										
Dose Escalation	EGT0001442 5 mg										
	EGT0001442 10 mg										
	EGT0001442 20 mg										
	EGT0001442 50 mg										

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.4.2 Medical History

Study Segment	Treatment	Center	Subject Number	Seq. No.	Body System	Medical history Findings	Start Date	Ongoing	Stop Date
Double-blind	Placebo	02	02141	1	Eyes, Ears, Nose, Throat	NORMAL			
				2	Neurological	OCCASIONAL HEADACHES	UNKUNK1989	Yes	
				3	Cardiovascular	HIGH CHOLESTEROL	UNKUNK2007	Yes	
				4	Skin	BALANITIS	21DEC2009		29DEC2009
				...					
			...						
		...							
	EGT0001442 5 mg								
	EGT0001442 10 mg								
	EGT0001442 20 mg								
	EGT0001442 50 mg								
Dose Escalation	EGT0001442 5 mg								
	EGT0001442 10 mg								
	EGT0001442 20 mg								
	EGT0001442 50 mg								

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.4.3 Prior and Concomitant Medication

Study Segment	Treatment	Center	Subject Number	ATC Classification WHO Drug Name Medication Name	Start/Stop Date	Ongoing	Drug Strength	Units	Frequency of dose	Route of Administration	Indication
Double-blind	Placebo	02	02141	xxxxxxxxxxxxxxxxxx xxxxxxxxxxxxxxxxx xxxxxxxxxxxxxx	ddmmmyyyy/ ddmmmyyy	No	xx	mg	bid	PO	xxxxxxxxx
	...										
	EGT0001442 5 mg										
	EGT0001442 10 mg										
	EGT0001442 20 mg										
	EGT0001442 50 mg										
Dose Escalation	EGT0001442 5 mg										
	EGT0001442 10 mg										
	EGT0001442 20 mg										
	EGT0001442 50 mg										

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.4.4 Inclusion/Exclusion Criteria and Exceptions

Study Segment	Treatment	Center	Subject Number	Were all Inclusion/ Exclusion Criteria met?	Consent Date	Washout Type*	Inclusion/Exclusion Category	Inclusion/Exclusion No.	Was a Waiver Granted?	Date of Waiver Granted
Double-blind	Placebo	02	02141	Yes	ddmmmyyyy	1				
			02142	No	ddmmmyyyy	2	Includion	2	Yes	ddmmmyyyy
	EGT0001442 5 mg									
	EGT0001442 10 mg									
	EGT0001442 20 mg									
	EGT0001442 50 mg									
Dose Escalation	EGT0001442 5 mg									
	EGT0001442 10 mg									
	EGT0001442 20 mg									
	EGT0001442 50 mg									

Note: *Washout Type: 1 = Diabetic Med Discontinued, 2 = Diabetic Med Naïve

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.4.5 Urine Drug Screen

Study Segment	Treatment	Center	Subject Number	Visit Day	Date/Time	Test Name	Test Results
Double-blind	Placebo	02	02141	Screening	ddmmmyyyy/hhmm	Amphetamines	Negative
						Barbiturates	Negative
						Cocaine metabolites	Negative
						Opiates	Negative
						Benzodiazepines	Negative
						Cannabinoids	Negative
						Cotinine	Negative
				Day 0	ddmmmyyyy/hhmm	Amphetamines	Negative
						Barbiturates	Negative
						Cocaine metabolites	Negative
						Opiates	Negative
						Benzodiazepines	Negative
						Cannabinoids	Negative
						Cotinine	Negative
				...			
	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						
Dose Escalation	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.5 Study Drug Administration

Study Segment	Treatment	Center	Subject Number	Dose Day	Did subject fast 10 hours Prior to dose?	Dose Date/Time	Dose Status
Double-blind	Placebo	02	02141	1	Yes	ddmmmyyyy/hhmm	Dosed
				2	Yes	ddmmmyyyy/hhmm	Dosed
				3	Yes	ddmmmyyyy/hhmm	Dosed
				4		ddmmmyyyy/hhmm	Dosed
				5		ddmmmyyyy/hhmm	Dosed
				6		ddmmmyyyy/hhmm	Dosed
				7		ddmmmyyyy/hhmm	Dosed
				...			
				27		ddmmmyyyy/hhmm	Dosed
				28		ddmmmyyyy/hhmm	Dosed
	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						
Dose Escalation	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.6.1 Fasting Plasma Glucose (mg/dL)

Study Segment	Treatment	Center	Subject Number	Visit Day	Repeat	Test Date/Time	Observed FPG Results (mg/dL)
Double-blind	Placebo	02	02141	Screening		ddmmmyyyy/hh:mm	xxxx.x
				Day -2		ddmmmyyyy/hh:mm	xxxx.x
				Day 1		ddmmmyyyy/hh:mm	xxxx.x
				Day 2		ddmmmyyyy/hh:mm	xxxx.x
				Day 8		ddmmmyyyy/hh:mm	xxxx.x
				Day 15		ddmmmyyyy/hh:mm	xxxx.x
				Day 22		ddmmmyyyy/hh:mm	xxxx.x
				Day 29		ddmmmyyyy/hh:mm	xxxx.x
				Day 35		ddmmmyyyy/hh:mm	xxxx.x
				Day 43		ddmmmyyyy/hh:mm	xxxx.x
	...						
	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						
Dose Escalation	EGT0001442 5 mg	01	003	Screening		ddmmmyyyy/hh:mm	xxxx.x
				Day 0		ddmmmyyyy/hh:mm	xxxx.x
				Day 1		ddmmmyyyy/hh:mm	xxxx.x
				Day 2		ddmmmyyyy/hh:mm	xxxx.x
				Day 3		ddmmmyyyy/hh:mm	xxxx.x
				Day 8		ddmmmyyyy/hh:mm	xxxx.x
				Day 15		ddmmmyyyy/hh:mm	xxxx.x
				Day 22		ddmmmyyyy/hh:mm	xxxx.x
				Day 29		ddmmmyyyy/hh:mm	xxxx.x
				Day 43		ddmmmyyyy/hh:mm	xxxx.x
	...						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.6.2 Weight

Study Segment	Treatment	Center	Subject Number	Visit Day	Visit Date	Weight (kg)
Double-blind	Placebo	02	02141	Screening	ddmmmyyyy	xx.x
				Day -2	ddmmmyyyy	xx.x
				Day 1	ddmmmyyyy	xx.x
				Day 8	ddmmmyyyy	xx.x
				Day 15	ddmmmyyyy	xx.x
				Day 22	ddmmmyyyy	xx.x
				Day 29	ddmmmyyyy	xx.x
				Day 35	ddmmmyyyy	xx.x
				Day 43	ddmmmyyyy	xx.x
			...			
	EGT0001442 5 mg					
	EGT0001442 10 mg					
	EGT0001442 20 mg					
	EGT0001442 50 mg					
Dose Escalation	EGT0001442 5 mg	01	003	Screening	ddmmmyyyy	xx.x
				Day 0	ddmmmyyyy	xx.x
				Day 1	ddmmmyyyy	xx.x
				Day 3	ddmmmyyyy	xx.x
				Day 15	ddmmmyyyy	xx.x
				Day 22	ddmmmyyyy	xx.x
				Day 29	ddmmmyyyy	xx.x
				Day 43	ddmmmyyyy	xx.x
	EGT0001442 10 mg					
	EGT0001442 20 mg					
	EGT0001442 50 mg					

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.6.3 Glycated Hemoglobin A1 (HbA1c) (%)

Study Segment	Treatment	Center	Subject Number	Visit Day	Repeat	Test Date/Time	Observed HbA1c Results (%)
Double-blind	Placebo	02	02141	Screening		ddmmmyyyy/hh:mm	xx.x
				Day 1		ddmmmyyyy/hh:mm	xx.x
				Day 29		ddmmmyyyy/hh:mm	xx.x
	...						
	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						
Dose Escalation	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.6.4 24 h UGE (g/day)

Study Segment	Treatment	Center	Subject Number	Visit Day	Repeat	Test Date/Time	Observed UGE Results (g/day)
Double-blind	Placebo	02	02141	Screening		ddmmmyyyy/hh:mm	xxxx.x
				Day 1		ddmmmyyyy/hh:mm	xxxx.x
				Day 29		ddmmmyyyy/hh:mm	xxxx.x
	...						
	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						
Dose Escalation	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.6.5 Blood (PK) Sample Collection (Dose Escalation Segment)

Treatment	Center	Subject Number	Sample Number	Study Hour	Scheduled Date	Scheduled Time	Actual Time	Reason for Deviation
EGT0001442 5 mg	01	003	1	PRE-DOSE	10Dec2009		0619	
			2	0.5 H	10Dec2009		0830	
			3	1 H	10Dec2009		hhmm	
			4	2 H	10Dec2009		hhmm	
			5	3 H	10Dec2009		hhmm	
			6	4 H	10Dec2009		hhmm	
			7	6 H	10Dec2009		hhmm	
			8	8 H	10Dec2009		hhmm	
			9	10 H	10Dec2009		hhmm	
			10	12 H	10Dec2009		hhmm	
			11	24 H	10Dec2009		hhmm	
			12	48 H	10Dec2009		hhmm	
EGT0001442 10 mg								
EGT0001442 20 mg								
EGT0001442 50 mg								

Note: Scheduled time is only entered if differ from actual time.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.6.6 Post Prandial Blood Glucose (mg/dL) (Dose Escalation Segment)

Treatment	Center	Subject Number	Visit Day	Time Point	Date/Time	Test Name	Observed Results (mg/dL)	Change from Pre-meal to Post-meal (mg/dL)	AUC (mg.h/dL)
EGT0001442 5 mg	01	003	Day 0	Prior to Breakfast	09Dec2009/0845	BLOOD GLUCOSE	220		
				2 Hours Post Breakfast	09Dec2009/1107	BLOOD GLUCOSE	291	71	
				Prior to Lunch	09Dec2009/1255	BLOOD GLUCOSE	176		
				2 Hours Post Lunch	09Dec2009/1517	BLOOD GLUCOSE	243	67	
				Prior to Dinner	09Dec2009/1755	BLOOD GLUCOSE	184		
				2 Hours Post Dinner	09Dec2009/2018	BLOOD GLUCOSE	241	57	
				10:00 PM	09Dec2009/2245	BLOOD GLUCOSE	220		xxxx.x
			Day 2	Prior to Breakfast	11Dec2009/0845	BLOOD GLUCOSE	220		
				2 Hours Post Breakfast	11Dec2009/1107	BLOOD GLUCOSE	272	52	
				Prior to Lunch	11Dec2009/1255	BLOOD GLUCOSE	176		
				2 Hours Post Lunch	11Dec2009/1517	BLOOD GLUCOSE	243	67	
				Prior to Dinner	11Dec2009/1755	BLOOD GLUCOSE	184		
				2 Hours Post Dinner	11Dec2009/2018	BLOOD GLUCOSE	243	59	
				10:00 PM	11Dec2009/2245	BLOOD GLUCOSE	220		xxxx.x
	...								
EGT0001442 10 mg									
EGT0001442 20 mg									
EGT0001442 50 mg									

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.7.1 Treatment Emergent Adverse Events

Study Segment	Treatment	Center	Subject Number	AE No.	System Organ Class / Preferred Term / Verbatim Term	Onset/Resolution Date	Time	Serious?*	Severity#	Relationship to Study Drug[1]	Action Taken[2]	Outcome[3]
Double-blind	Placebo	02	02141	1	xxxxxxxxxxxxxxx / xxxxxxxxxxxxx / xxxxxxxxxxx	ddmmmyyyy	hh:mm/ hh:mm	0	1	2	0	1
			...									
	EGT0001442 5 mg											
	EGT0001442 10 mg											
	EGT0001442 20 mg											
	EGT0001442 50 mg											
Dose Escalation	EGT0001442 5 mg											
	EGT0001442 10 mg											
	EGT0001442 20 mg											
	EGT0001442 50 mg											

Note: * Serious?: 1 = Yes, 2 = No
Severity: 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Relationship to study drug: 1 = Yes, 2 = No
[2] Action taken: 1 = None, 2 = Medication Administered, 3 = Non-Drug Therapy, 4 = Hospitalization, 5 = Discontinuation From Study, 6 = Other.
[3] Outcome: 1= Resolved, 2 = Continuing with Treatment, 4 = Continuing without Treatment, 10 = Death.

Sorting by: Study segment, Treatment, Center, Subject, Start Date, Start Time, End Date, End Time

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Similar Listings:

Listing 16.2.7.2 Drug-related Treatment Emergent Adverse Events

Listing 16.2.7.3 Serious Treatment Emergent Adverse Events

Listing 16.2.7.4 Treatment Emergent Adverse Events Leading to Study Discontinuation

Listing 16.2.7.5 Cardiovascular Treatment Emergent Adverse Events

Listing 16.2.7.6 Pre-treatment Adverse Events

Study Segment	Center	Subject Number	AE No.	System Organ Class Preferred Term Verbatim Term	Onset/Resolution Date Time	Serious?*	Severity#	Relationship to Study Drug[1]	Action Taken[2]	Outcome[3]
Double-blind	02	02141	1	xxxxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxx	ddmmmyyyy hh:mm/ ddmmmyyyy hh:mm	0	1	2	0	1
			...							
Dose Escalation										

Note:
* Serious?: 1 = Yes, 2 = No
# Severity: 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Relationship to study drug: 1 = Yes, 2 = No
[2] Action taken: 1 = None, 2 = Medication Administered, 3 = Non-Drug Therapy, 4 = Hospitalization, 5 = Discontinuation From Study, 6 = Other.
[3] Outcome: 1= Resolved, 2 = Continuing with Treatment, 4 = Continuing without Treatment, 10 = Death.

Sorting by: Study segment, Washout type, Center, Subject, Start Date, Start Time, End Date, End Time

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.7.7 Adverse Events during Washout Period

Study Segment	Washout Type+	Center	Subject Number	AE No.	System Organ Class Preferred Term Verbatim Term	Onset/Resolution Date	Time	Serious?*	Severity#	Relationship to Study Drug[1]	Action Taken[2]	Outcome[3]
Double-blind	1	02	02141	1	xxxxxxxxxxxxxxx xxxxxxxxxxxxx xxxxxxxxxxx	ddmmmyyyy	hh:mm/ ddmmmyyyy hh:mm	0	1	2	0	1
			...									
Dose Escalation												

Note: + Washout type: 1= Diabetic Med Discontinued, 2= Diabetic Med Naive
* Serious?: 1 = Yes, 2 = No
# Severity: 1 = Mild, 2 = Moderate, 3 = Severe.
[1] Relationship to study drug: 1 = Yes, 2 = No
[2] Action taken: 1 = None, 2 = Medication Administered, 3 = Non-Drug Therapy, 4 = Hospitalization, 5 = Discontinuation From Study, 6 = Other.
[3] Outcome: 1= Resolved, 2 = Continuing with Treatment, 4 = Continuing without Treatment, 10 = Death.

Sorting by: Study segment, Washout type, Center, Subject, Start Date, Start Time, End Date, End Time

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.8.1 Clinical Laboratory Test Results in Biochemistry

Study Segment	Treatment	Center	Subject Number	Age/ Gender	Visit Day	Visit Repeat	Lab Date	Lab Time	Lab Test	Test Results (SI Unit)	Unit (SI Unit)	Normal Range (SI Unit)	Flag *	Comments
Double-blind	Placebo	02	02141	36/M	Screening		ddmmmyyyy	hh:mm	Albumin	xx	xx	xx-xx	L(NCS)	xxxxxxxxx
									Calcium	xx	xx	xx-xx		
									Creatinine	xx	xx	xx-xx		
									...					
	EGT0001442 5 mg													
	EGT0001442 10 mg													
	EGT0001442 20 mg													
	EGT0001442 50 mg													
Dose Escalation	EGT0001442 5 mg													
	EGT0001442 10 mg													
	EGT0001442 20 mg													
	EGT0001442 50 mg													

Note: * Flag: L = Low, H = High, NCS = Not clinical significance, CS = Clinical significance

Table will continue for other biochemistry lab tests.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Similar listings:

Listing 16.2.8.2 Clinical Laboratory Test Results in Hematology

Listing 16.2.8.3 Clinical Laboratory Test Results in Urinalysis

Listing 16.2.8.4 Vital Signs

Study Segment	Treatment	Center	Subject Number	Visit Day	Seated for 5 minutes?	Heart Rate (BPM)	Systolic BP (mmHg)	Diastolic BP (mmHg)	Respiratory Rate (breaths/min)	Temperature (°C)
Double-blind	Placebo	02	02141	Screening	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day -2	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 1/Pre-dose	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 2/Pre-dose	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 8	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 15	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 22	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 29	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 35	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 43	Yes	xxx	xxx	xxx	xx.x	xx.x
	...									
	EGT0001442 5 mg									
	EGT0001442 10 mg									
	EGT0001442 20 mg									
	EGT0001442 50 mg									
Dose Escalation	EGT0001442 5 mg	01	003	Screening	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 0	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 1/Pre-dose	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 1/1 hr	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 1/2 hr	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 1/4 hr	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 1/8 hr	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 2/Pre-dose	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 3/Pre-dose	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 8	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 15	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 22	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 29	Yes	xxx	xxx	xxx	xx.x	xx.x
				Day 43	Yes	xxx	xxx	xxx	xx.x	xx.x
	EGT0001442 10 mg									
	EGT0001442 20 mg									
	EGT0001442 50 mg									

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.8.5 12-Lead ECG

Study Segment	Treatment	Center	Subject Number	Visit Day	Ventricular Rate (BPM)	PR Interval (ms)	QRS Interval (ms)	QT Interval (ms)	QTc Interval (ms)	ECG Findings (NCS/CS)	Repeat ECG Status	Description
Double-blind	Placebo	02	02141	Screening	xxx	xxx	xxx	xxx	xxx	Normal		
				Day -2	xxx	xxx	xxx	xxx	xxx	Abnormal(NCS)	NR	xxxxxxx
				Day 1/Pre-dose	xxx	xxx	xxx	xxx	xxx	Normal		
				Day 2/Pre-dose	xxx	xxx	xxx	xxx	xxx	Normal		
				Day 29	xxx	xxx	xxx	xxx	xxx	Normal		
			...									
	EGT0001442 5 mg											
	EGT0001442 10 mg											
	EGT0001442 20 mg											
	EGT0001442 50 mg											
Dose Escalation	EGT0001442 5 mg	01	003	Screening	xxx	xxx	xxx	xxx	xxx	Normal		
				Day 0	xxx	xxx	xxx	xxx	xxx	Normal		
				Day 1/Pre-dose	xxx	xxx	xxx	xxx	xxx	Normal		
				Day 1/ 2 hr	xxx	xxx	xxx	xxx	xxx	Normal		
				Day 2/Pre-dose	xxx	xxx	xxx	xxx	xxx	Normal		
				Day 29	xxx	xxx	xxx	xxx	xxx	Normal		
			...									
	EGT0001442 10 mg											
	EGT0001442 20 mg											
	EGT0001442 50 mg											

Note:
CS = Clinically Significant
NCS = Not Clinically Significant

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.8.6 Self Monitored Blood Glucose (SMBG)

Study Segment	Treatment	Center	Subject Number	Visit Day	Date	Time	Results (mg/dL)
Double-blind	Placebo	02	02141	DAY-14	ddmmmyyyy	HHMM	xxx
				DAY-13	ddmmmyyyy	HHMM	xxx
				DAY-12	ddmmmyyyy	HHMM	xxx
				DAY-11	ddmmmyyyy	HHMM	xxx
				DAY-10	ddmmmyyyy	HHMM	xxx
				DAY-9	ddmmmyyyy	HHMM	xxx
				DAY-8	ddmmmyyyy	HHMM	xxx
				DAY-7	ddmmmyyyy	HHMM	xxx
				DAY-6	ddmmmyyyy	HHMM	xxx
				DAY-5	ddmmmyyyy	HHMM	xxx
				DAY-4	ddmmmyyyy	HHMM	xxx
				DAY-3	ddmmmyyyy	HHMM	xxx
				DAY-2	ddmmmyyyy	HHMM	xxx
				DAY-1	ddmmmyyyy	HHMM	xxx
				DAY 0	ddmmmyyyy	HHMM	xxx
				DAY 1	ddmmmyyyy	HHMM	xxx
				DAY 2	ddmmmyyyy	UNK	xxx
				DAY 3	ddmmmyyyy	UNK	xxx
				...			
				Day 43	ddmmmyyyy	HHMM	xxx
		...					
	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						
Dose Escalation	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						

Note: SMBG are measured daily after washout starts till the last termination visit.
Note: table will continue for other Days.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Listing 16.2.8.7 Physical Examination

Study Segment	Treatment	Center	Subject Number	Visit Day	Change from Previous	Body System	Examination Finding
Double-blind	Placebo	02	02141	Screening		Skin	Sunburn left hand (peeling skin)
						Head	Normal
						Eyes	Normal
						Ears	Normal
						Nose	Normal
						Throat	Normal
						Neck	Normal
						Thyroid	Normal
						Lungs	Normal
						Heart	Normal
						Abdomen	Normal
						Lymph Nodes	Normal
						Extremities	Normal
				Day -2	Yes	Skin	Normal
	...						
	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						
Dose Escalation	EGT0001442 5 mg						
	EGT0001442 10 mg						
	EGT0001442 20 mg						
	EGT0001442 50 mg						

Note: table will continue for Days 1,8,15,22,29,35 and 43 for double-blind segment.
table will continue for screening, Days 0,1,3,8,15,22,29 and 43 for dose escalation segment.

(Source: path\program name Date/time of run: ddmmmyyyy:hh:mm)

Figures

Figure 14.2.1 Fasting Plasma Glucose (mean± SE) - Double-blind Segment

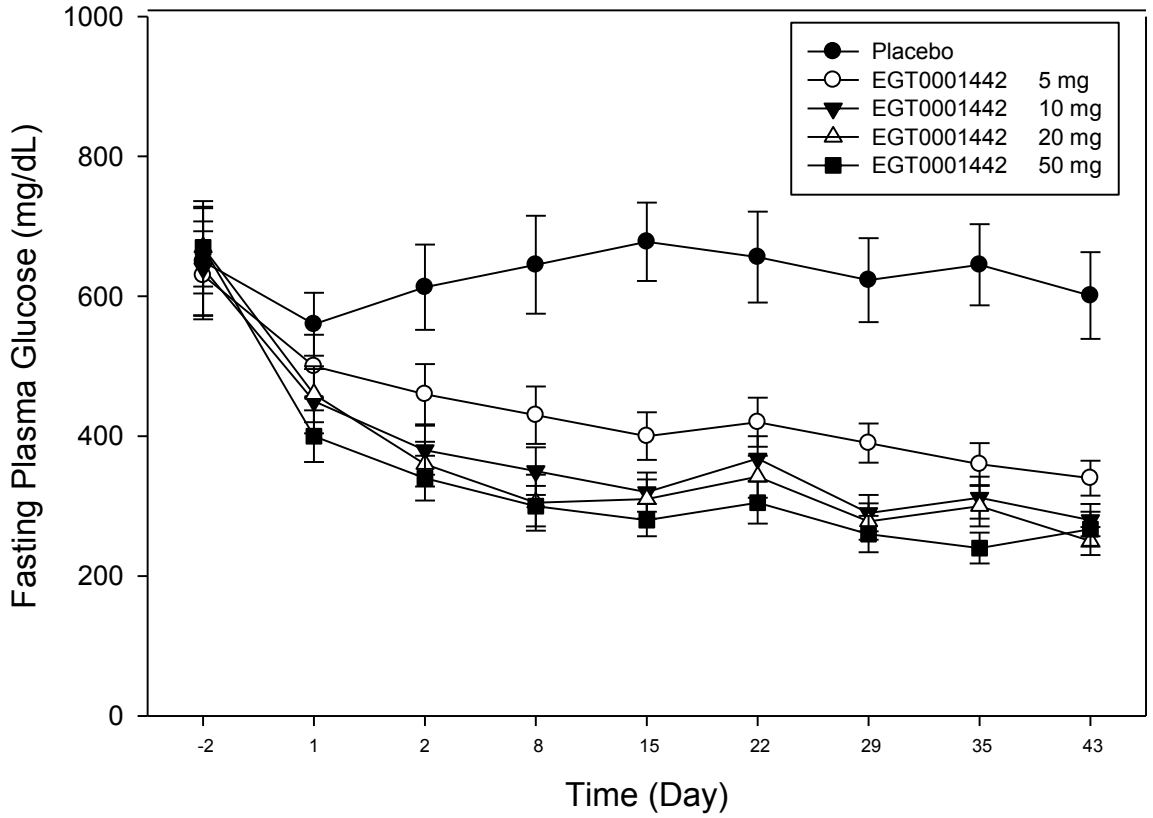
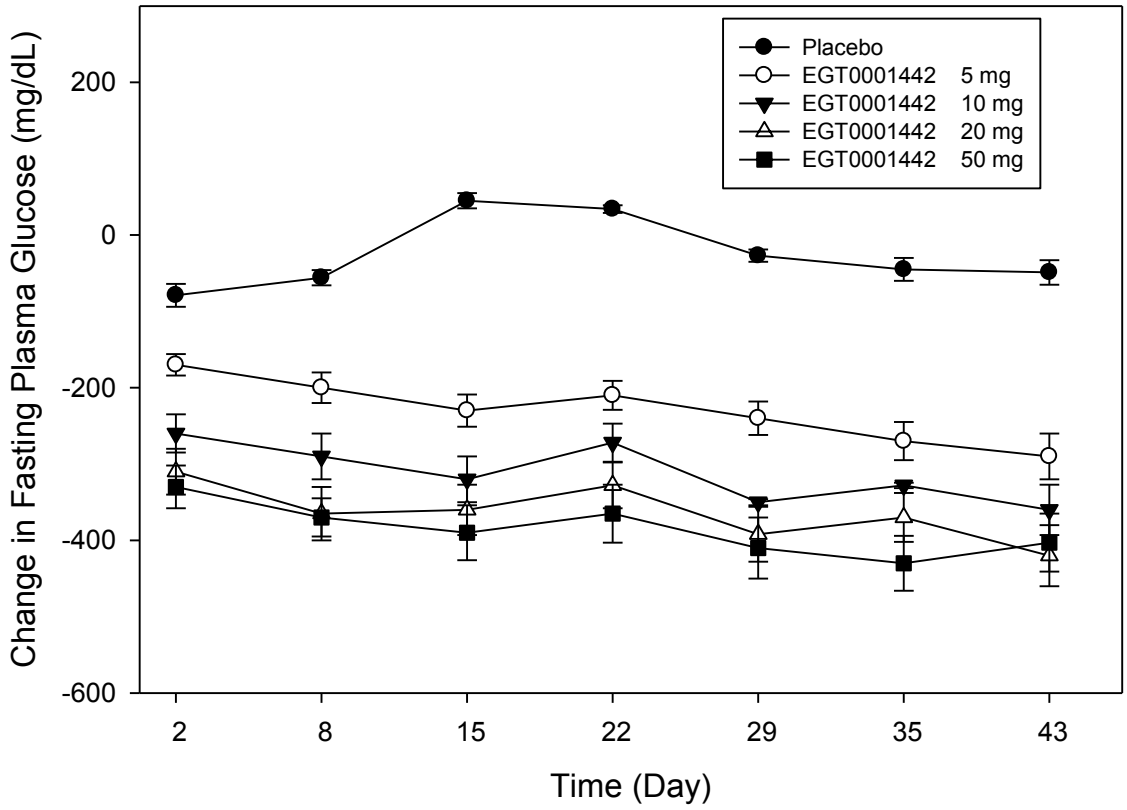


Figure 14.2.2 Fasting Plasma Glucose in Change from Baseline (mean± SE) - Double-blind Segment



Note: Baseline is defined as the mean of FPG values on day -2 and day 1.

Similar Figures:

Figure 14.2.3 Body Weight (mean± SE) - Double-blind Segment

Figure 14.2.4 Body Weight in Change from Baseline (mean± SE) - Double-blind Segment

Figure 14.2.5 HbA1c (mean± SE) - Double-blind Segment

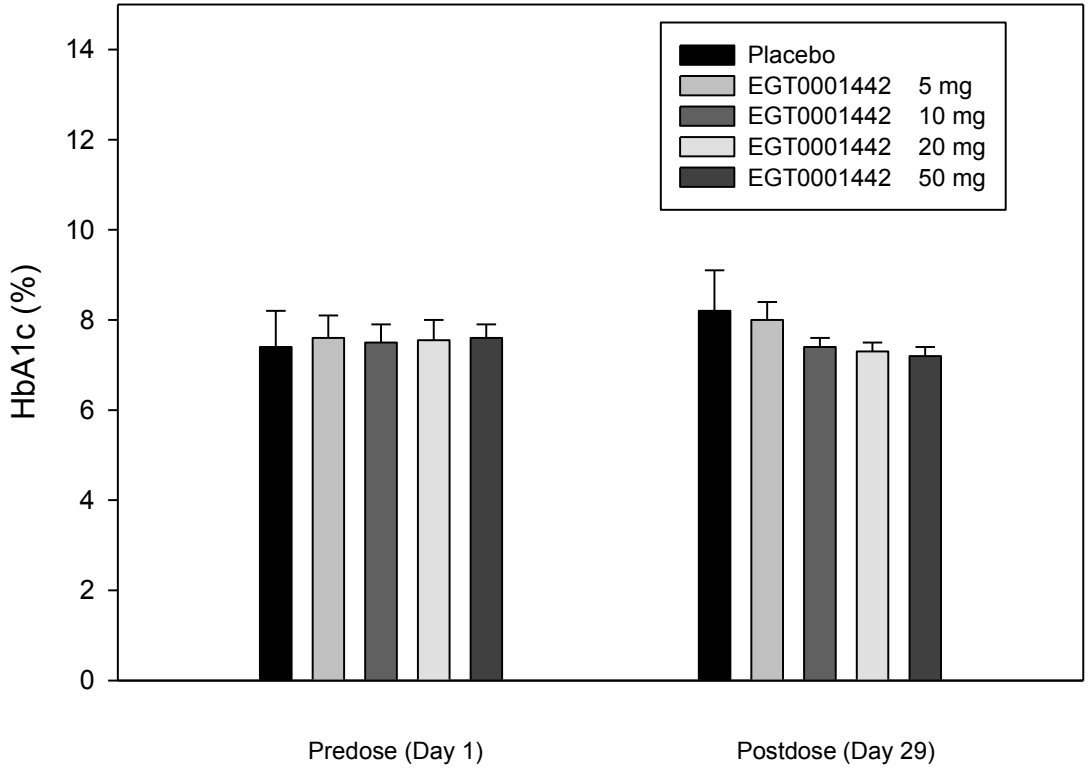


Figure 14.2.6 24h UGE (mean± SE) - Double-blind Segment

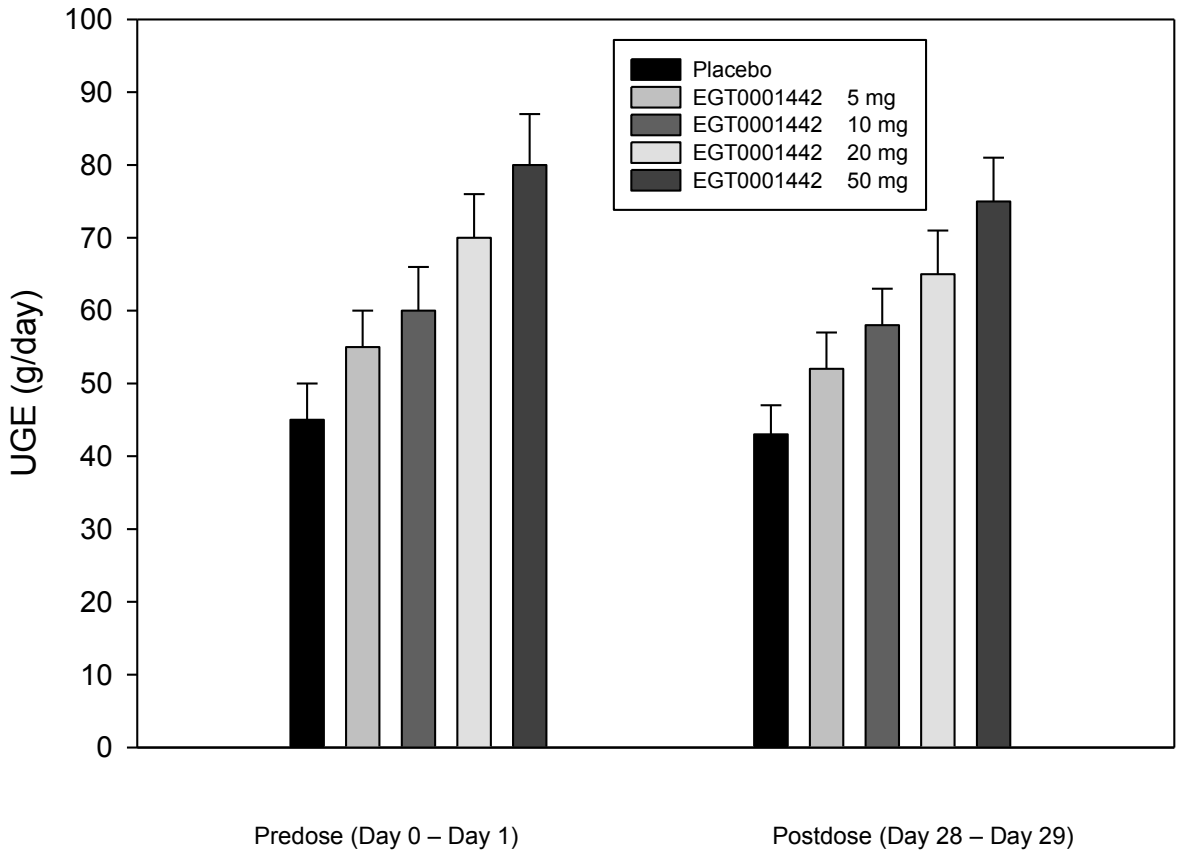
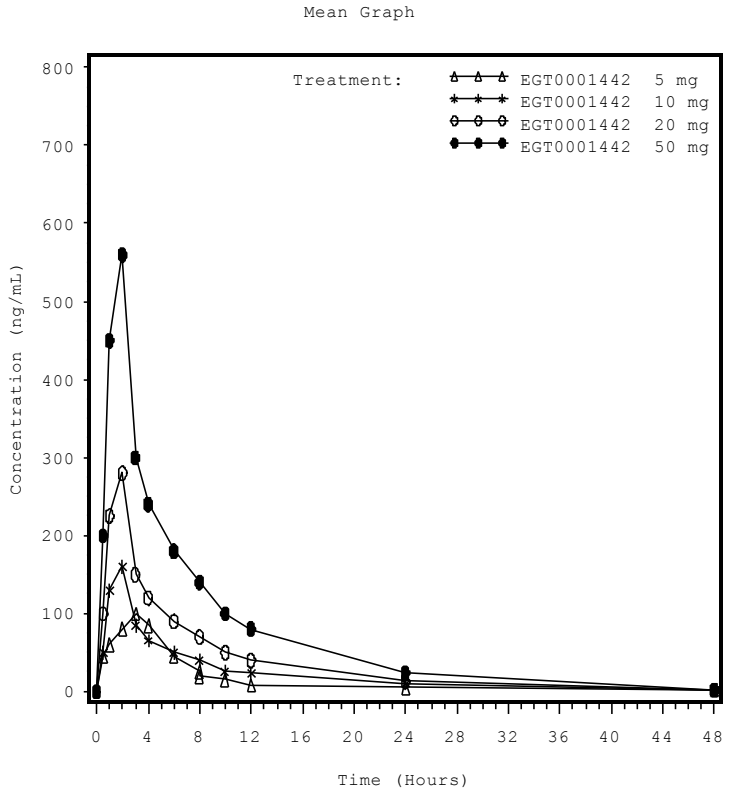
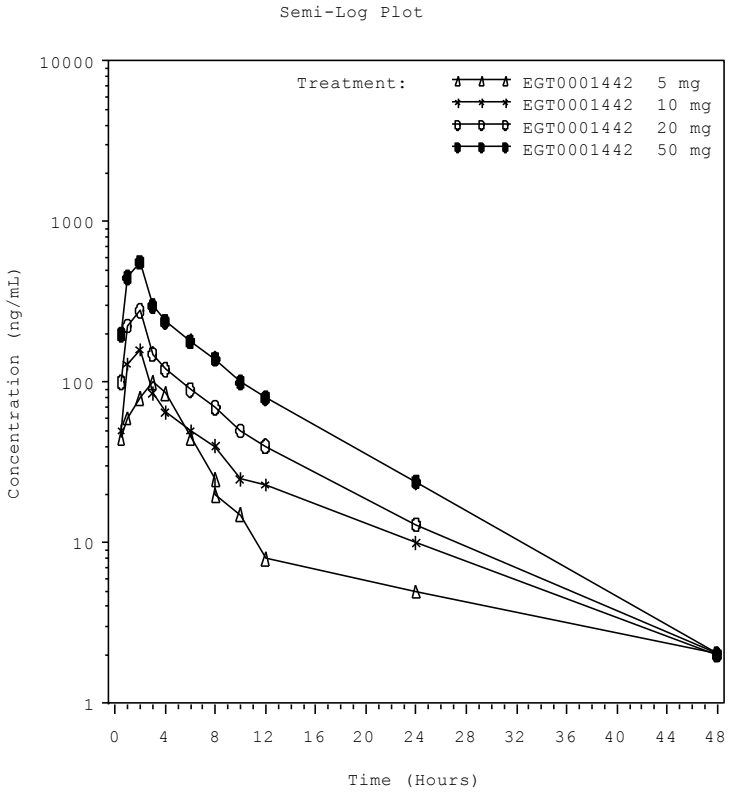


Figure 14.2.7 Mean Plasma Concentration for EGT0001442 (ng/mL) - Dose Escalation Segment





Similar Figures:

Figure 14.2.8 Individual Plasma Concentration for EGT0001442 (ng/mL) - Dose Escalation Segment