SYNOPSIS CLINICAL STUDY REPORT

A Phase 2, Multiple-Dose, Pharmacokinetic and Pharmacodynamic Study of RDEA594 in Patients with Hyperuricemia and Gout with Renal Insufficiency

Report Status: Amendment 1
Report Date: 11 July 2014

Study Drug: RDEA594

Sponsor Reference: RDEA594-204
Covance CRU Study: 8215451
EudraCT Number: 2009-014762-26

Clinical Phase 2a
Study Start Date: 25 November 2009
Study End Date: 20 April 2010

Sponsor:
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1.1.   Synopsis Clinical Study Report Amendment Summary

Amendment 1 of the Synopsis Clinical Study Report (CSR) replaces the previous final version (dated 18 April 2011). The primary changes made in this amendment were to include an informational appendix demonstrating compliance with US FDA 21 CFR 312.120 and to describe post hoc serum creatinine (sCr) analysis following the availability of results from a monotherapy Phase 3 study. Due to the nature of these corrections, the Principal Investigator signature confirming that the amendment accurately describes the conduct and results of the study was obtained. Additional changes made in this amendment were administrative in nature. Changes made in Amendment 1 of the CSR are described in the following table.

Description and Rationale for Change	Location of Change
Change in sponsor approver: Sponsor Signator~~ies~~**y**: PPD ~~Tel:~~PPD PPD ~~MD, PhD~~ ~~Tel:~~PPD PPD **, MD** **Tel:**PPD	Section 1 Title Page Appendix 16.1.5
The Study Sites section was updated to clarify that Site 003 received clinical trial material but did not enroll subjects. Subjects were enrolled at Sites 001 and 002 only**; Site 003 received clinical trial material but did not enroll subjects**.	Study Sites
The Pharmacodynamic (PD) Variables section was updated to clarify that PD results for sCr were provided for a review of safety. All pharmacodynamic **(PD)** ~~data~~**collection information** ~~were~~**was** listed **(Listing 16.2.5.3) and PD results for serum creatinine (sCr) concentrations were also** ~~but not~~ **summarized for safety purposes (Appendix 1 Table 14.2.2-8).**	Statistical Methods: Pharmacodynamic Variables

Description and Rationale for Change	Location of Change
The Safety Results section was updated to present the analysis of the post hoc sCr data. **The results for sCr analysis from the protocol-specified samples collected as part of the clinical safety (Screening, Day -1, Day 1 before dosing, Day 6, Day 8, and at the Follow-up Visit) and PD laboratory evaluations (collected at multiple timepoints on Day -3 to Day -1 and on Days 1-8) are presented in Appendix 1 Table 14.2.2-8. An exception was Subject PPD , whose sCr concentrations are provided in both the safety and PD listings (Appendix 2 Listing 16.2.8-2 and Table 14.2.2-8, respectively). Although the sCr concentrations obtained at PD timepoints were not included in SAP-specified safety analyses, these results were reviewed by the Sponsor for safety.** **As the intended study population was subjects with moderate renal impairment, all subjects had high sCr values (reference range: 0.7 to 1.4 mg/dL) at Screening and predose timepoints. Following additional review of PD assessments of sCr, in 3 of the 4 subjects, there were no clinically significant postdose increases in sCr. One subject (PPD , whose predose sCr values ranged from 1.8 to 2.0 mg/dL, experienced a maximum increase in sCr to 3.1 mg/dL at 72 hours after the Day 5 dose. The subject's sCr resolved to ≤ 1.2 x Baseline (2.2 mg/dL) at the Follow-Up Visit, 8 days after the last dose of RDEA594.**	Safety Results
The Conclusions section was updated to present the conclusions from the post hoc sCr data. RDEA594 administered as 100 mg and 200 mg for 5 days was safe and well tolerated by male and female subjects as an add-on to ongoing allopurinol treatment in gout patients with moderate renal insufficiency. **As the intended study population was subjects with moderate renal impairment, all subjects had high sCr values. One subject experienced a ≥ 1.5 x but < 2.0 x Baseline sCr elevation that resolved to ≤ 1.2 x Baseline at the Follow-Up Visit.**	Conclusions
Appendix 1 and its Table of Contents (TOC) were updated to include Table 14.2.2-8 Individual Serum Creatinine Concentrations to support post hoc sCr analysis. APPENDIX 1 • **Table 14.2.2-8 Individual Serum Creatinine Concentrations (mg/dL)**	Appendix 1

Description and Rationale for Change	Location of Change
The Appendix 2 TOC was updated to only list the number and title of each appendix section. The number and title of each individual listing were removed from the TOC and are instead presented on the appropriate appendix cover page. These changes were made in order to meet electronic submission standards. Additionally, Appendix 16.4 in the TOC was updated to specify that it is not applicable.	Appendix 2
Appendix 3 was generated to include a narrative for Subject PPD in order to describe the subject's elevated sCr concentrations identified during the post hoc analysis of sCr PD results.	Appendix 3
A list of subsections was added to the cover page of any appendix containing one or more subsections so that hyperlinks could be created in order to meet electronic submission standards.	Appendix 16.1.3 Appendix 16.2.5
Appendix 16.5 was generated to document compliance with US FDA 21 CFR 312.120.	Appendix 16.5

2.   SYNOPSIS

Title of study: A Phase 2, Multiple-Dose, Pharmacokinetic and Pharmacodynamic Study of RDEA594 in Patients with Hyperuricemia and Gout with Renal Insufficiency.

Sponsor: Ardea Biosciences, Inc.

Investigators: Michel Jadoul, MD, Wouter Haazen, MD, Christian Tielemans, MD

Study sites: (001) UCL – Cliniques Universitaires, PPD   , PPD
Belgium (002) PPD   SGS Life Sciences, PPD   Belgium (003) PPD
                                              Belgium.
Subjects were enrolled at Sites PPD and PPD only; Site PPD received clinical trial material but did not enroll subjects.

Publications: None as of the date of this report.

Period of study:	**Phase of development:**
25 November 2009 to 20 April 2010	Clinical Phase 2a

Objectives:
The objectives of the study were: to determine the safety profile of orally administered RDEA594 alone, or as an add-on to ongoing allopurinol treatment in gout patients with moderate renal insufficiency; to evaluate the pharmacokinetics (PK) of RDEA594 in gout patients with moderate renal insufficiency; to evaluate the PK interaction between RDEA594 and allopurinol/oxypurinol, and between RDEA594 and colchicine, in gout patients with moderate renal insufficiency; to evaluate the uricosuric effects of orally administered RDEA594 alone, or as an add-on to ongoing allopurinol treatment in gout patients with moderate renal insufficiency.

Methodology:
This was a multi-center, open-label, multiple-dose study of RDEA594 in patients with hyperuricemia and gout, and with moderate renal insufficiency which did not require dialysis. Two segments of up to 2 cohorts each were planned with up to 6 subjects per cohort. Segment I was to include patients not receiving urate lowering therapy and Segment II was to include patients on allopurinol at a stable dose between 100 mg to 200 mg once daily (qd) prior to entry. Segment I was planned to include Cohort 1A, in which subjects received a 200 mg qd dose of RDEA594 for 5 days, and an optional Cohort 1B, in which all subjects were to receive a dose between 100 mg and 400 mg qd RDEA594 (dependent on the data from Cohort 1A) for 5 days. Segment II was planned to include Cohort 2A, in which subjects received a 200 mg qd dose of RDEA594 for 5 days in combination with their stable allopurinol dose, and an optional Cohort 2B, in which subjects were to receive a dose of between 100 mg and 400 mg qd RDEA594 (dependent on the data from Cohort 2A) for 5 days in combination with their stable allopurinol dose. Only Cohort 2A was enrolled and the dose selected was 200 mg qd RDEA594; however, 3 out of the 4 subjects studied were mis-dosed and received 100 mg qd RDEA594 instead of the planned 200 mg qd dose.

The Sponsor decided to close enrollment following the completion of these 4 subjects as there was expected to be sufficient data available in gout patients with moderate renal impairment from Phase 2b studies and the enrollment at the study sites was much slower than expected. Since 3 out of the 4 subjects studied were mis-dosed and received 100 mg qd RDEA594 instead of the planned 200 mg qd dose, a dose not being evaluated in Phase 2b or Phase 3 studies, a synopsis report is provided for this study based on the FDA 1999 Guideline on *Submission of Abbreviated Reports and Synopses in Support of Marketing Applications* that states *Synopses* should be submitted for studies that are not relevant to the evaluation of product effectiveness or clinical pharmacology, but that provide information the reviewer needs to evaluate the safety data from the study.

Number of subjects (planned and analyzed):
It was planned to study a total of up to 24 subjects in 2 segments. Only 4 subjects were enrolled in Segment II Cohort 2A. Data for all 4 subjects were included in the safety and PK analyses.

Diagnosis and main criteria for inclusion:
Male and non-reproductive female subjects with moderate renal insufficiency (estimated creatinine clearance of $\geq$30 mL/min to <60 mL/min as determined by the Modification of Diet in Renal Disease [MDRD] method) and a diagnosis of gout by meeting one or more of the American Rheumatism Association (ARA) criteria for the classification of acute arthritis of primary gout, as defined in the protocol (Section 16.1.1, Appendix C) were eligible for enrollment in the study. Subjects were to be between 18 and 80 years of age, inclusive, with a body mass index (BMI) of $\geq$18 and $\leq$38 kg/m^2, and weight of at least 50 kg. For Segment II, Cohort 2, subjects had to have a screening serum urate level $\geq$6 mg/dL on a stable dose of allopurinol.

Test products, doses and mode of administration, batch number:
All study drugs were orally administered, between 0 to 15 minutes after finishing a full breakfast (approximately 620 kCal). RDEA594 was administered at the 200 mg qd dose level to one subject, as planned. The remaining 3 subjects received RDEA594 at the 100 mg qd dose level, in error. RDEA594 doses were administered as 100 mg capsules (lot number 09JM-250). In addition, in Segment II, Cohort 2A, subjects received their stable once daily dose of allopurinol (between 100 and 200 mg) administered as 100 mg tablets. Colchicine tablets (0.5 mg qd) were given to all 4 subjects.

Duration of treatment:
In Segment II, Cohort 2A, RDEA594 was administered qd in combination with the subject's stable dose of allopurinol for 5 days. All 4 subjects received a daily dose of 0.5 mg colchicine from Day -10 to the follow-up visit in order to reduce the incidence of gout flares (as recommended in the approved labeling for the most recently registered urate lowering therapy, febuxostat).

Reference therapy, dose and mode of administration, batch number:
Not applicable.

Criteria for evaluation:
Safety variables:
Safety was assessed by the evaluation and monitoring of adverse events, vital signs, 12-lead electrocardiogram (ECG), clinical laboratory evaluations, and physical examination.

Pharmacokinetic variables:
Plasma samples were to be collected for PK assessments at the following time points: Baseline (Day -3 to Day -1): 0, 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 10, 12, and 24 hours (collected during the same 24-hour time period as baseline 24-hour urine collection); on Days 1 and 5: pre-dose (within 30 minutes prior to dosing) and at 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 10, and 12 hours post-dose; pre-dose (within 30 minutes prior to dosing) on Days 2-4; and at 24, 36, 48, and 72 hours following the last dose of study drug (Days 6-8). Plasma samples were to be analyzed for RDEA594 and colchicine and also for allopurinol and oxypurinol. The baseline plasma samples were not evaluated for RDEA594.

Urine (total catch) samples for PK assessments were to be collected over the following intervals: Baseline (Day -3 to Day -1): 0 to 6, 6 to 12, 12 to 24 hours; on Days 1 and 5: 0 to 6, 6 to 12, 12 to 24 hours post-dose; 0 to 12 and 12 to 24 hours post-dose on Day 2; 0 to 24 hours post-dose on Days 3-4; and 24 to 36, 36 to 48, and 48 to 72 hours following the last dose (Days 6-8). Urine samples were to be analyzed for RDEA594 and also for allopurinol and oxypurinol.

Pharmacodynamic variables:
Serum samples for urate, creatinine and Cystatin C measurements were to be collected at the following time points: Baseline (Day -3 to Day -1): 0, 6, 12, and 24 hours (collected during the same 24-hour time period as baseline 24-hour urine collection); on Days 1 and 5: pre-dose at 0 hours (within 30 minutes prior to dosing), and at 6 and 12 hours post-dose; pre-dose (within 30 minutes prior to dosing) on Days 2-4; and 24, 36, 48, and 72 hours following the last dose of study drug (Days 6-8).

Urine samples from each of the PK collections were to be assayed for uric acid and creatinine.

Other:
Blood samples were collected but were not analyzed for plasma total protein level and protein binding of RDEA594, since protein binding data from subjects with varying degrees of renal function were obtained from Study RDEA594-104.

Statistical Methods:
Safety Variables:
Adverse events were coded according to the Medical Dictionary for Regulatory Activities Terminology (MedDRA) (Version 12.1). In addition to the Investigator's severity grading (according to the Rheumatology Common Toxicity [RCT] Criteria v2.0), adverse events were graded for severity according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events v4.0 (CTCAE).

A baseline sign or symptom was defined as an adverse event that started after the subject provided written informed consent and resolved prior to the first dosing occasion with RDEA594, or an adverse event that started prior to the first dosing occasion and did not increase in severity after dosing. A treatment emergent adverse event was defined as an adverse event that occurred after dosing with RDEA594 or that was present pre-dose and became more severe post-dose.

All adverse events were listed and summarized. Treatment emergent adverse events were summarized by treatment, RCT severity, NCI severity, and relationship to the study drug. The frequency (the number of adverse events, the number of subjects experiencing an adverse event and the percentage of subjects experiencing an adverse event) of treatment emergent adverse events were summarized by treatment, MedDRA system organ class, and preferred term. The summary and frequency adverse event tables were presented for all causalities and those considered related to the study drug (possible relationship). Any RCT severe, NCI Grade 3 or above, and serious adverse events were tabulated.

Previous and concomitant medications were coded using the World Health Organization (WHO) drug dictionary (Version September 2009, Q3) and listed.

For the serum biochemistry, hematology, and coagulation data, percentage (%) change from baseline (Day -1) was calculated by subtracting the individual subject's baseline value from the value at the desired time point and then dividing this calculated value by the individual subject's baseline value and multiplying by 100. Data (absolute and percentage change from baseline) were summarized by treatment and shift tables were presented. In addition, all serum biochemistry, hematology, coagulation and urinalysis data outside the reference ranges were summarized by parameter and treatment. Values for any serum biochemistry, hematology, coagulation, and urinalysis results outside the laboratory reference ranges were flagged on the individual subject data listings.

Vital signs, including supine blood pressure and pulse rate, oral body temperature and respiratory rate, were listed and summarized by treatment together with changes from baseline (Day 1, pre-dose). Values for vital signs that were outside the reference ranges were flagged on the individual subject data listings.

The ECG data were summarized by treatment together with changes from baseline (Day 1, pre-dose). The frequency of subjects with a maximum increase from baseline in QTcB and QTcF interval were summarized for each treatment according to the following categories: >30 ms and >60 ms. In addition, the frequency of subjects with QTcB and QTcF post-dose values were summarized by treatment according to the following categories: >450 ms, >480 ms and >500 ms. Values for ECG parameters outside the reference ranges were flagged on the individual subject listings.

All other safety assessments were listed, but not summarized or statistically analyzed.

Pharmacokinetic Variables:
Abbreviated plasma and urinary parameters were summarized for RDEA594, allopurinol, oxypurinol and colchicine. Key plasma and urinary PK parameters calculated were: the area under the plasma concentration-versus-time curve (AUC) from time zero over the dosing interval (AUC_{0-24}), the maximum observed plasma concentration (C_{max}), and the time of occurrence of C_{max} (T_{max}) on full PK days (Days 1 and 5). Key urinary PK parameters were the amount excreted in urine (Ae), fractional excretion (fe%) and renal clearance (CLr) of RDEA594.

Pharmacodynamic Variables:
The percentage (%) time-matched changes from baseline (Day -1) for serum and urinary urate and creatinine, and serum Cystatin C concentrations were calculated. The absolute and % changes from baseline (time-matched, Day -1) were calculated for the following serum and urinary urate parameters: amount

recovered in urine (Ae_{UR} and $Ae_{UR,CB}$, respectively), renal clearance (CL_{UR} and $CL_{UR,CB}$, respectively) and fractional excretion of urate (FEUA and $FEUA_{,CB}$, respectively). The amount of creatinine in urine (Ae_{Cr}) and estimated creatinine clearance (CL_{Cr}) were calculated. All pharmacodynamic (PD) collection information was listed (Listing 16.2.5.3) and PD results for serum creatinine (sCr) concentrations were also summarized for safety purposes (Appendix 1 Table 14.2.2-8).

Changes in the Conduct of the Study:
It was planned to study at least 2 cohorts (Cohort 1A and Cohort 2A), with 2 further optional cohorts (Cohorts 1B and 2B). Only 4 subjects were enrolled in Cohort 2A (Segment II of the study), before the Sponsor decided to close enrollment, as there was expected to be sufficient data available in gout patients with moderate renal impairment from Phase 2b studies and enrollment was slow in this study.

Subject disposition:
Subject disposition data are provided in Section 16.2.1 (Listing 16.2.1-1) and Section 16.2.5.1 (Listing 16.2.5.1-1 and Listing 16.2.5.1-2).

Four subjects entered and completed the study. Three of the four subjects received the incorrect study treatment of 100 mg RDEA594, rather than 200 mg RDEA594, for 5 days.

Demographic and Other Baseline Characteristics:
Demographic and baseline characteristics data are provided in Section 16.2.4 (Listing 16.2.4-1 to Listing 16.2.4-15).

The subject who received 200 mg RDEA594 was a PPD-year old female; one PPD-year old female subject and 2 male subjects aged PPD and PPD years received 100 mg RDEA594. All 4 subjects were White.

The screening estimated creatinine clearance (determined by the MDRD method) ranged from 33 to 46 mL/min for all 4 subjects. All 4 subjects were diagnosed with gout, with its duration ranging from approximately 1 year to 12 years.

Protocol Deviations:
Protocol deviations were reported for the following subjects. Subjects PPD, PPD and PPD were mis-dosed and received 100 mg qd RDEA594 (instead of the planned dose of 200 mg qd RDEA594) in combination with their stable dose of allopurinol. In error, the central clinical laboratory did not measure Cystatin C at Screening, Day -1 and Follow-up. Subject PPD was receiving a stable allopurinol dose of 300 mg/day, instead of the 100 to 200 mg/day stated in the inclusion criterion of the protocol; however, an exemption was prospectively granted for the inclusion of this subject in the study. Subject PPD was not re-consented to Version 3 of the Informed Consent Form. The 24-hour PK blood sample on Day -1 for Subject PPD was collected 45 minutes earlier than scheduled.

Previous and Concomitant Medications:
Details of previous and concomitant medications are provided in Section 16.2.4 and Section 16.2.8 (Listing 16.2.4-6 and Listing 16.2.8-1, respectively).

All 4 subjects received a range of medications for the treatment of hypertension and hyperlipidemia both prior to and during the study. One subject (PPD) received a concomitant medication of paracetamol administered intermittently over a 6-day period for the treatment of an adverse event of pain in calves.

Drug Exposure and Treatment Compliance:
Drug exposure and treatment compliance data are provided in Section 16.2.5 (Listing 16.2.5.1-2).

One subject (PPD) received a total of 5 x 200 mg oral doses of RDEA594 (total exposure of 1000 mg). Three subjects (PPD, PPD and PPD) received a total of 5 x 100 mg doses of RDEA594 (total exposure of 500 mg). All 4 subjects received concomitant treatment with qd doses of allopurinol during the study: 2 subjects received 150 mg, 1 subject received 300 mg and 1 subject received 100 mg.

Safety results:

Summaries of all safety data are provided in Appendix 1. Adverse events listings are provided in Section 16.2.7 with all other safety data listings in Section 16.2.8.

RDEA594 was safe and well tolerated by male and female subjects with moderate renal insufficiency and a diagnosis of gout when administered as 100 mg and 200 mg for 5 days as an add-on to ongoing allopurinol treatment.

The one subject who received 200 mg RDEA594 reported no adverse events and 2 of the 3 subjects who received 100 mg RDEA594 reported 16 adverse events during the study. All adverse events were mild in severity. There were no serious adverse events and no subjects were discontinued due to adverse events. A single episode of diarrhea reported by one subject on Day 5 following 100 mg RDEA594 was the only event considered to have a possible relationship to RDEA594.

The results for sCr analysis from the protocol-specified samples collected as part of the clinical safety (Screening, Day -1, Day 1 before dosing, Day 6, Day 8, and at the Follow-up Visit) and PD laboratory evaluations (collected at multiple timepoints on Day -3 to Day -1 and on Days 1-8) are presented in Appendix 1 Table 14.2.2-8. An exception was Subject PPD, whose sCr concentrations are provided in both the safety and PD listings (Appendix 2 Listing 16.2.8-2 and Table 14.2.2-8, respectively). Although the sCr concentrations obtained at PD timepoints were not included in SAP-specified safety analyses, these results were reviewed by the Sponsor for safety.

As the intended study population was subjects with moderate renal impairment, all subjects had high sCr values (reference range: 0.7 to 1.4 mg/dL) at Screening and predose timepoints. Following additional review of PD assessments of sCr, in 3 of the 4 subjects, there were no clinically significant postdose increases in sCr. One subject PPD, whose predose sCr values ranged from 1.8 to 2.0 mg/dL, experienced a maximum increase in sCr to 3.1 mg/dL at 72 hours after the Day 5 dose. The subject's sCr resolved to ≤ 1.2 x Baseline (2.2 mg/dL) at the Follow-Up Visit, 8 days after the last dose of RDEA594.

As expected, serum urate concentrations were decreased following administration of RDEA594. There were no other trends in the serum biochemistry, hematology, coagulation, or urinalysis data during the study. Although results for some clinical laboratory parameters were outside the appropriate reference ranges, these findings were transient and occurred at isolated time points only. No findings were considered to be of clinical importance.

There were no clinically significant trends in supine systolic and diastolic blood pressure, respiratory rate, or body temperature. Although transient changes were noted at isolated time points for some subjects, none of these findings were considered to be clinically significant.

No apparent trends in the 12-lead ECG parameters were noted. No subjects had an increase in QTcB or QTcF interval greater than 60 ms or a QTcB or QTcF interval >480 ms. Two subjects who received 100 mg RDEA594 had an increase in QTcB interval greater than 30 ms, although the absolute values were less than 450 ms and just above 450 (457 ms), and were not considered to be clinically significant.

There were no clinically significant findings in physical examinations for any individual subjects.

Pharmacokinetic Results:

Plasma exposure (C_{max} and AUC) and half-life of RDEA594 were not profoundly different between Day 1 and at steady state on Day 5. Plasma exposures of allopurinol and oxypurinol appeared to slightly decrease in subjects with the addition of repeated RDEA594 co-administration, but this is not conclusive due to the limited number of subjects and various doses administered. Colchicine plasma exposures appeared unchanged with RDEA594 co-administration. No summary statistics or other statistical evaluations were performed due to the dosing errors noted.

Conclusions:
RDEA594 administered as 100 mg and 200 mg for 5 days was safe and well tolerated by male and female subjects as an add-on to ongoing allopurinol treatment in gout patients with moderate renal insufficiency. As the intended study population was subjects with moderate renal impairment, all subjects had high sCr values. One subject experienced a ≥ 1.5 x but < 2.0 x Baseline sCr elevation that resolved to ≤ 1.2 x Baseline at the Follow-Up Visit.

APPENDIX 1

Table 14.2.2-8 Individual Serum Creatinine Concentrations (mg/dL)

Study Population: Pharmacodynamic
Treatment: 100 mg RDEA594 + allopurinol

Subject number	Screening	unscheduled	Day -1 0 h	Day -1 6 h	Day -1 12 h	Day -1 24 h	Day 1 Pre dose	Day 1 Pre dose mean	Day 1 6 h	Day 1 12 h	Day 2 Pre dose
PPD	1.6		1.6	1.7	1.6	1.5	1.5	1.5	1.4	1.5	1.5
PPD	1.9		1.9	2.0	1.9	1.8	1.8	1.8	1.8	1.7	1.8
PPD	1.7	1.7	1.6	1.6	1.5	1.5	1.5	1.5	1.5	1.5	1.6

Subject PPD required a second screening visit because the first screening visit fell outside the window of dates specified by the protocol.
Day 1, Pre-dose mean is the mean of Day -1, 24h and Day 1, Pre-dose
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\PD\SAS\TPDCONCS Program Run: 08APR2011 17:13 PPD
Program Status: FINAL

Table 14.2.2-8 Individual Serum Creatinine Concentrations (mg/dL)

Study Population: Pharmacodynamic
Treatment: 100 mg RDEA594 + allopurinol

Subject number	Day 3 Pre dose	Day 4 Pre dose	Day 5 Pre dose	Day 5 6 h	Day 5 12 h	Day 5 24 h	Day 5 36 h	Day 5 48 h	Day 5 72 h	Follow up
PPD	1.5	1.5	1.6	1.5	1.5	1.5	1.6	0.6	1.6	1.6
PPD	1.8	1.8	1.7	1.7	1.7	1.9	2.1	2.5	3.1	2.2
PPD	1.5	1.6	1.6	1.5	1.5	1.6	1.5	1.5	1.5	1.7

PPD required a second screening visit because the first screening visit fell outside the window of dates specified by the protocol.
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\PD\SAS\TPDCONCS Program Run: 08APR2011 17:13 PPD
Program Status: FINAL

Table 14.2.2-8 Individual Serum Creatinine Concentrations (mg/dL)

Study Population: Pharmacodynamic
Treatment: 200 mg RDEA594 + allopurinol

Subject number	Screening	Day -1 0 h	Day -1 6 h	Day -1 12 h	Day -1 24 h	Day 1 Pre dose	Day 1 Pre dose mean	Day 1 6 h	Day 1 12 h	Day 2 Pre dose
PPD	1.6	1.4	1.4	1.4	1.3	1.3	1.3	1.6	1.5	1.4

Day 1, Pre-dose mean is the mean of Day -1, 24h and Day 1, Pre-dose
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\PD\SAS\TPDCONCS Program Run: 08APR2011 17:13 PPD
Program Status: FINAL

Table 14.2.2-8 Individual Serum Creatinine Concentrations (mg/dL)

Study Population: Pharmacodynamic
Treatment: 200 mg RDEA594 + allopurinol

Subject number	Day 3 Pre dose	Day 4 Pre dose	Day 5 Pre dose	Day 5 6 h	Day 5 12 h	Day 5 24 h	Day 5 36 h	Day 5 48 h	Day 5 72 h	Follow up
PPD	1.6	1.4	1.5	1.8	1.7	1.6	1.7	1.6	1.5	1.4

Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\PD\SAS\TPDCONCS Program Run: 08APR2011 17:13 PPD
Program Status: FINAL

Table 14.3.1-1   Summary of Treatment Emergent Adverse Events   (Page 1 of 2)
Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
Subjects with adverse events	2 (67%)	0
Number of adverse events	16	0
Subjects with serious adverse events	0	0
Subjects discontinued due to adverse events	0	0
RCT Severity (all adverse events)		
Mild	2 (67%) [16]	0
Moderate	0	0
Severe	0	0
Total	2 (67%) [16]	0
RCT Severity (possibly related)		
Mild	1 (33%) [1]	0
Moderate	0	0
Severe	0	0
Total	1 (33%) [1]	0

( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events   N = number of subjects in treatment group
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-1   Summary of Treatment Emergent Adverse Events   (Page 2 of 2)
Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
NCI Severity (all adverse events)		
Grade 1 (Mild)	2 (67%) [16]	0
Grade 2 (Moderate)	0	0
Grade 3 (Severe)	0	0
Grade 4 (Life-threat	0	0
Grade 5 (Death)	0	0
Total	2 (67%) [16]	0
NCI Severity (possibly related)		
Grade 1 (Mild)	1 (33%) [1]	0
Grade 2 (Moderate)	0	0
Grade 3 (Severe)	0	0
Grade 4 (Life-threat	0	0
Grade 5 (Death)	0	0
Total	1 (33%) [1]	0
Relationship to study drug		
Not related	1 (33%) [3]	0
Unlikely	2 (67%) [12]	0
Possible	1 (33%) [1]	0

( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events   N = number of subjects in treatment group
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-2   Frequency of Treatment Emergent Adverse Events (All Causalities)

(Page 1 of 2)

Study Population: Safety

System Organ Class Preferred Term	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
Overall Total	2 (67%) [16]	0
GASTROINTESTINAL DISORDERS	2 (67%) [5]	0
DRY MOUTH	1 (33%) [2]	0
ABDOMINAL PAIN UPPER	1 (33%) [1]	0
DIARRHOEA	1 (33%) [1]	0
GASTROINTESTINAL SOUNDS ABNORMAL	1 (33%) [1]	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	1 (33%) [7]	0
JOINT SWELLING	1 (33%) [4]	0
BACK PAIN	1 (33%) [2]	0
PAIN IN EXTREMITY	1 (33%) [1]	0

Events were coded using MedDRA (Version 12.1)
N = Number of subjects in treatment group   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS2 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-2   Frequency of Treatment Emergent Adverse Events (All Causalities)

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Study Population: Safety

System Organ Class Preferred Term	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
NERVOUS SYSTEM DISORDERS	1 (33%) [2]	0
DYSGEUSIA	1 (33%) [1]	0
HEADACHE	1 (33%) [1]	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	1 (33%) [1]	0
DISCOMFORT	1 (33%) [1]	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	1 (33%) [1]	0
DRY SKIN	1 (33%) [1]	0

Events were coded using MedDRA (Version 12.1)
N = Number of subjects in treatment group   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS2 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-3   Frequency of Treatment Emergent Adverse Events by RCT Severity (All Causalities)

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Study Population: Safety

System Organ Class Preferred Term	RCT Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
Overall Total		2 (67%) [16]	0
GASTROINTESTINAL DISORDERS			
DRY MOUTH	Total	1 (33%) [2]	0
	Mild	1 (33%) [2]	0
	Moderate	0	0
	Severe	0	0
ABDOMINAL PAIN UPPER	Total	1 (33%) [1]	0
	Mild	1 (33%) [1]	0
	Moderate	0	0
	Severe	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS3 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-3   Frequency of Treatment Emergent Adverse Events by RCT Severity (All Causalities)

(Page 2 of 6)

Study Population: Safety

System Organ Class Preferred Term	RCT Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
GASTROINTESTINAL DISORDERS			
DIARRHOEA	Total	1 (33%) [1]	0
	Mild	1 (33%) [1]	0
	Moderate	0	0
	Severe	0	0
GASTROINTESTINAL SOUNDS ABNORMAL	Total	1 (33%) [1]	0
	Mild	1 (33%) [1]	0
	Moderate	0	0
	Severe	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS3 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-3   Frequency of Treatment Emergent Adverse Events by RCT Severity (All Causalities)

(Page 3 of 6)

Study Population: Safety

System Organ Class Preferred Term	RCT Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			
JOINT SWELLING	Total	1 (33%) [4]	0
	Mild	1 (33%) [4]	0
	Moderate	0	0
	Severe	0	0
BACK PAIN	Total	1 (33%) [2]	0
	Mild	1 (33%) [2]	0
	Moderate	0	0
	Severe	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS3 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-3   Frequency of Treatment Emergent Adverse Events by RCT Severity (All Causalities)

(Page 4 of 6)

Study Population: Safety

System Organ Class Preferred Term	RCT Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			
PAIN IN EXTREMITY	Total	1 (33%) [1]	0
	Mild	1 (33%) [1]	0
	Moderate	0	0
	Severe	0	0
NERVOUS SYSTEM DISORDERS			
DYSGEUSIA	Total	1 (33%) [1]	0
	Mild	1 (33%) [1]	0
	Moderate	0	0
	Severe	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS3 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-3   Frequency of Treatment Emergent Adverse Events by RCT Severity (All Causalities)

(Page 5 of 6)

Study Population: Safety

System Organ Class Preferred Term	RCT Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
NERVOUS SYSTEM DISORDERS			
HEADACHE	Total	1 (33%) [1]	0
	Mild	1 (33%) [1]	0
	Moderate	0	0
	Severe	0	0
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			
DISCOMFORT	Total	1 (33%) [1]	0
	Mild	1 (33%) [1]	0
	Moderate	0	0
	Severe	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS3 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-3   Frequency of Treatment Emergent Adverse Events by RCT Severity (All Causalities)

(Page 6 of 6)

Study Population: Safety

System Organ Class Preferred Term	RCT Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			
DRY SKIN	Total	1 (33%) [1]	0
	Mild	1 (33%) [1]	0
	Moderate	0	0
	Severe	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS3 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-4   Frequency of Treatment Emergent Adverse Events by NCI Severity (All Causalities)

(Page 1 of 6)

Study Population: Safety

System Organ Class Preferred Term	NCI Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
Overall Total		2 (67%) [16]	0
GASTROINTESTINAL DISORDERS			
DRY MOUTH	Total	1 (33%) [2]	0
	Grade 1 (Mild)	1 (33%) [2]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS4 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-4   Frequency of Treatment Emergent Adverse Events by NCI Severity (All Causalities)

(Page 2 of 6)

Study Population: Safety

System Organ Class Preferred Term	NCI Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
GASTROINTESTINAL DISORDERS			
ABDOMINAL PAIN UPPER	Total	1 (33%) [1]	0
	Grade 1 (Mild)	1 (33%) [1]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0
DIARRHOEA	Total	1 (33%) [1]	0
	Grade 1 (Mild)	1 (33%) [1]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS4 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-4   Frequency of Treatment Emergent Adverse Events by NCI Severity (All Causalities)

(Page 3 of 6)

Study Population: Safety

System Organ Class Preferred Term	NCI Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
GASTROINTESTINAL DISORDERS			
GASTROINTESTINAL SOUNDS ABNORMAL	Total	1 (33%) [1]	0
	Grade 1 (Mild)	1 (33%) [1]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			
JOINT SWELLING	Total	1 (33%) [4]	0
	Grade 1 (Mild)	1 (33%) [4]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS4 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-4   Frequency of Treatment Emergent Adverse Events by NCI Severity (All Causalities)

(Page 4 of 6)

Study Population: Safety

System Organ Class Preferred Term	NCI Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS			
BACK PAIN	Total	1 (33%) [2]	0
	Grade 1 (Mild)	1 (33%) [2]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0
PAIN IN EXTREMITY	Total	1 (33%) [1]	0
	Grade 1 (Mild)	1 (33%) [1]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS4 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-4   Frequency of Treatment Emergent Adverse Events by NCI Severity (All Causalities)

(Page 5 of 6)

Study Population: Safety

System Organ Class Preferred Term	NCI Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
NERVOUS SYSTEM DISORDERS			
DYSGEUSIA	Total	1 (33%) [1]	0
	Grade 1 (Mild)	1 (33%) [1]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0
HEADACHE	Total	1 (33%) [1]	0
	Grade 1 (Mild)	1 (33%) [1]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS4 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-4   Frequency of Treatment Emergent Adverse Events by NCI Severity (All Causalities)

(Page 6 of 6)

Study Population: Safety

System Organ Class Preferred Term	NCI Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS			
DISCOMFORT	Total	1 (33%) [1]	0
	Grade 1 (Mild)	1 (33%) [1]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0
SKIN AND SUBCUTANEOUS TISSUE DISORDERS			
DRY SKIN	Total	1 (33%) [1]	0
	Grade 1 (Mild)	1 (33%) [1]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS4 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-5   Frequency of Treatment Emergent Adverse Events (Related to Study Drug*)

(Page 1 of 1)

Study Population: Safety

System Organ Class Preferred Term	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
Overall Total	1 (33%) [1]	0
GASTROINTESTINAL DISORDERS	1 (33%) [1]	0
DIARRHOEA	1 (33%) [1]	0

Events were coded using MedDRA (Version 12.1)
N = Number of subjects in treatment group   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
* Relationship possible
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS2 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-6   Frequency of Treatment Emergent Adverse Events by RCT Severity (Related to Study Drug*)

(Page 1 of 1)

Study Population: Safety

System Organ Class Preferred Term	RCT Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
Overall Total		1 (33%) [1]	0
GASTROINTESTINAL DISORDERS			
DIARRHOEA	Total	1 (33%) [1]	0
	Mild	1 (33%) [1]	0
	Moderate	0	0
	Severe	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
* Relationship possible
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS3 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-7 Frequency of Treatment Emergent Adverse Events by NCI Severity (Related to Study Drug*)

(Page 1 of 1)

Study Population: Safety

System Organ Class Preferred Term	NCI Severity	100 mg RDEA594 + allopurinol (N=3)	200 mg RDEA594 + allopurinol (N=1)
Overall Total		1 (33%) [1]	0
GASTROINTESTINAL DISORDERS			
DIARRHOEA	Total	1 (33%) [1]	0
	Grade 1 (Mild)	1 (33%) [1]	0
	Grade 2 (Moderate)	0	0
	Grade 3 (Severe)	0	0
	Grade 4 (Life-threatening)	0	0
	Grade 5 (Death)	0	0

Events were coded using MedDRA (Version 12.1)
N = number of subjects studied   ( ) = Percentage of subjects with adverse events   [ ] = Number of adverse events
* Relationship possible
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS4 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.7-1

Table 14.3.1-8   RCT Severe Treatment Emergent Adverse Events

Study Population: Safety

Subject/Gender/Age/ Treatment	Adverse Event [MedDRA Preferred Term] (System Organ Class)	Period	Day	Start Date [Start Time]	Stop Date [Stop Time]	Onset Time Postdose day:h:min	Duration day:h:min	Severity/ SAE	Relationship to Study Drug	Action	Outcome
				No RCT severe treatment emergent adverse events reported							

Adverse Events were coded using MedDRA (Version 12.1)
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS6 Program Run: 08APR2011 16:59 lwheatcr
Program Status: FINAL

Table 14.3.1-9   NCI Grade 3 or Worse Treatment Emergent Adverse Events

(Page 1 of 1)

Study Population: Safety

Subject/Gender/Age/ Treatment	Adverse Event [MedDRA Preferred Term] (System Organ Class)	Period	Day	Start Date [Start Time]	Stop Date [Stop Time]	Onset Time Postdose day:h:min	Duration day:h:min	Severity/ SAE	Relationship to Study Drug	Action	Outcome

No NCI grade 3 or worse treatment emergent adverse events reported

Adverse Events were coded using MedDRA (Version 12.1)
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS6 Program Run: 08APR2011 16:59 lwheatcr
Program Status: FINAL

Table 14.3.1-10   Serious Treatment Emergent Adverse Events

(Page 1 of 1)

Study Population: Safety

Subject/Gender/Age/ Treatment	Adverse Event [MedDRA Preferred Term] (System Organ Class)	Period	Day	Start Date [Start Time]	Stop Date [Stop Time]	Onset Time Postdose day:h:min	Duration day:h:min	Severity/ SAE	Relationship to Study Drug	Action	Outcome
				No serious treatment emergent adverse events reported							

Adverse Events were coded using MedDRA (Version 12.1)
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TADVERS6 Program Run: 08APR2011 16:59 lwheatcr
Program Status: FINAL

Table 14.3.2-1 Summary of Serum Biochemistry Data   (Page 1 of 145)

Study Population: Safety
Parameter: ALANINE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	25.67	
		SD	13.429	
		Median	20.00	
		Min	16.00	
		Max	41.00	
	Day -1	N	3	
		Mean	28.00	
		SD	17.349	
		Median	19.00	
		Min	17.00	
		Max	48.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 2 of 145)

Study Population: Safety
Parameter: ALANINE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	29.33	
		SD	16.442	
		Median	23.00	
		Min	17.00	
		Max	48.00	
	Day 6	N	3	3
		Mean	31.00	5.2
		SD	17.349	11.67
		Median	27.00	4.2
		Min	16.00	-5.9
		Max	50.00	17.4

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 3 of 145)

Study Population: Safety
Parameter: ALANINE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	38.00	27.1
		SD	23.065	8.35
		Median	30.00	30.4
		Min	20.00	17.6
		Max	64.00	33.3
	Follow up	N	3	3
		Mean	30.00	13.8
		SD	7.550	31.87
		Median	31.00	29.4
		Min	22.00	-22.9
		Max	37.00	34.8

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 4 of 145)

Study Population: Safety
Parameter: ALANINE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	22.00	
		Max	22.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	25.00	
		Max	25.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 5 of 145)

Study Population: Safety
Parameter: ALANINE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	25.00	
		Max	25.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	22.00	-12.0
		Max	22.00	-12.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 6 of 145)

Study Population: Safety
Parameter: ALANINE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	29.00	16.0
		Max	29.00	16.0
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	29.00	16.0
		Max	29.00	16.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: ALBUMIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	41.33	
		SD	2.082	
		Median	42.00	
		Min	39.00	
		Max	43.00	
	Day -1	N	3	
		Mean	40.00	
		SD	1.732	
		Median	39.00	
		Min	39.00	
		Max	42.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 8 of 145)

Study Population: Safety
Parameter: ALBUMIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	40.33	
		SD	2.082	
		Median	41.00	
		Min	38.00	
		Max	42.00	
	Day 6	N	3	3
		Mean	41.33	2.8
		SD	2.517	11.28
		Median	41.00	-2.4
		Min	39.00	-4.9
		Max	44.00	15.8

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 9 of 145)

Study Population: Safety
Parameter: ALBUMIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	43.33	7.6
		SD	1.528	5.37
		Median	43.00	7.1
		Min	42.00	2.4
		Max	45.00	13.2
	Follow up	N	3	3
		Mean	40.67	0.9
		SD	2.082	2.83
		Median	40.00	2.4
		Min	39.00	-2.4
		Max	43.00	2.6

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 10 of 145)

Study Population: Safety
Parameter: ALBUMIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	43.00	
		Max	43.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	40.00	
		Max	40.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 11 of 145)

Study Population: Safety
Parameter: ALBUMIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	36.00	
		Max	36.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	40.00	11.1
		Max	40.00	11.1

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: ALBUMIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	43.00	19.4
		Max	43.00	19.4
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	42.00	16.7
		Max	42.00	16.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 13 of 145)

Study Population: Safety
Parameter: ALKALINE PHOSPHATASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	89.00	
		SD	16.523	
		Median	90.00	
		Min	72.00	
		Max	105.00	
	Day -1	N	3	
		Mean	84.67	
		SD	21.455	
		Median	95.00	
		Min	60.00	
		Max	99.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 14 of 145)

Study Population: Safety
Parameter: ALKALINE PHOSPHATASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	82.33	
		SD	17.156	
		Median	85.00	
		Min	64.00	
		Max	98.00	
	Day 6	N	3	3
		Mean	82.67	0.1
		SD	20.648	12.20
		Median	92.00	-6.1
		Min	59.00	-7.8
		Max	97.00	14.1

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data (Page 15 of 145)

Study Population: Safety
Parameter: ALKALINE PHOSPHATASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	85.00	3.5
		SD	16.371	2.12
		Median	89.00	4.7
		Min	67.00	1.0
		Max	99.00	4.7
	Follow up	N	3	3
		Mean	83.33	1.4
		SD	16.503	2.26
		Median	88.00	1.6
		Min	65.00	-1.0
		Max	97.00	3.5

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 16 of 145)

Study Population: Safety
Parameter: ALKALINE PHOSPHATASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	76.00	
		Max	76.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	64.00	
		Max	64.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 17 of 145)

Study Population: Safety
Parameter: ALKALINE PHOSPHATASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	62.00	
		Max	62.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	70.00	12.9
		Max	70.00	12.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 18 of 145)

Study Population: Safety
Parameter: ALKALINE PHOSPHATASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	74.00	19.4
		Max	74.00	19.4
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	72.00	16.1
		Max	72.00	16.1

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 19 of 145)

Study Population: Safety
Parameter: ASPARTATE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	25.67	
		SD	7.024	
		Median	25.00	
		Min	19.00	
		Max	33.00	
	Day -1	N	3	
		Mean	27.33	
		SD	12.342	
		Median	24.00	
		Min	17.00	
		Max	41.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 20 of 145)

Study Population: Safety
Parameter: ASPARTATE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	32.67	
		SD	19.858	
		Median	26.00	
		Min	17.00	
		Max	55.00	
	Day 6	N	3	3
		Mean	30.00	0.6
		SD	11.136	21.54
		Median	28.00	7.7
		Min	20.00	-23.6
		Max	42.00	17.6

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 21 of 145)

Study Population: Safety
Parameter: ASPARTATE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	31.33	1.0
		SD	16.197	19.58
		Median	23.00	-9.1
		Min	21.00	-11.5
		Max	50.00	23.5
	Follow up	N	3	3
		Mean	27.00	-3.5
		SD	5.568	34.83
		Median	26.00	0.0
		Min	22.00	-40.0
		Max	33.00	29.4

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 22 of 145)

Study Population: Safety
Parameter: ASPARTATE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	18.00	
		Max	18.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	19.00	
		Max	19.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 23 of 145)

Study Population: Safety
Parameter: ASPARTATE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	17.00	
		Max	17.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	14.00	-17.6
		Max	14.00	-17.6

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 24 of 145)

Study Population: Safety
Parameter: ASPARTATE AMINOTRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	19.00	11.8
		Max	19.00	11.8
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	18.00	5.9
		Max	18.00	5.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: BLOOD UREA NITROGEN (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	9.88	
		SD	0.546	
		Median	10.00	
		Min	9.28	
		Max	10.35	
	Day -1	N	3	
		Mean	10.23	
		SD	1.608	
		Median	10.35	
		Min	8.57	
		Max	11.78	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: BLOOD UREA NITROGEN (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	9.28	
		SD	1.984	
		Median	8.93	
		Min	7.50	
		Max	11.42	
	Day 6	N	3	3
		Mean	10.35	13.0
		SD	1.287	10.32
		Median	10.00	12.0
		Min	9.28	3.2
		Max	11.78	23.7

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data (Page 27 of 145)

Study Population: Safety
Parameter: BLOOD UREA NITROGEN (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	12.62	36.6
		SD	3.785	37.53
		Median	13.21	15.7
		Min	8.57	14.3
		Max	16.07	80.0
	Follow up	N	3	3
		Mean	12.02	31.1
		SD	2.032	18.94
		Median	11.42	25.0
		Min	10.35	15.9
		Max	14.28	52.3

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: BLOOD UREA NITROGEN (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	17.14	
		Max	17.14	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	17.49	
		Max	17.49	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 29 of 145)

Study Population: Safety
Parameter: BLOOD UREA NITROGEN (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	15.35	
		Max	15.35	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	19.64	27.9
		Max	19.64	27.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 30 of 145)

Study Population: Safety
Parameter: BLOOD UREA NITROGEN (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	16.78	9.3
		Max	16.78	9.3
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	18.56	20.9
		Max	18.56	20.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: C REACTIVE PROTEIN (mg/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	1.80	
		SD	1.400	
		Median	1.80	
		Min	0.40	
		Max	3.20	
	Day -1	N	3	
		Mean	1.13	
		SD	0.643	
		Median	1.40	
		Min	0.40	
		Max	1.60	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: C REACTIVE PROTEIN (mg/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	1.20	
		SD	0.800	
		Median	1.20	
		Min	0.40	
		Max	2.00	
	Day 6	N	3	3
		Mean	2.67	77.8
		SD	3.329	129.19
		Median	1.00	25.0
		Min	0.50	-16.7
		Max	6.50	225.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

(Page 33 of 145)

Study Population: Safety
Parameter: C REACTIVE PROTEIN (mg/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	4.53	170.0
		SD	6.643	295.51
		Median	0.90	25.0
		Min	0.50	-25.0
		Max	12.20	510.0
	Follow up	N	3	3
		Mean	1.33	8.9
		SD	1.193	36.89
		Median	0.80	25.0
		Min	0.50	-33.3
		Max	2.70	35.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: C REACTIVE PROTEIN (mg/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.70	
		Max	2.70	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.30	
		Max	1.30	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: C REACTIVE PROTEIN (mg/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.80	
		Max	0.80	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.80	0.0
		Max	0.80	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 36 of 145)

Study Population: Safety
Parameter: C REACTIVE PROTEIN (mg/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.90	12.5
		Max	0.90	12.5
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.60	100.0
		Max	1.60	100.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 37 of 145)

Study Population: Safety
Parameter: CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	2.39	
		SD	0.121	
		Median	2.43	
		Min	2.25	
		Max	2.48	
	Day -1	N	3	
		Mean	2.29	
		SD	0.101	
		Median	2.28	
		Min	2.20	
		Max	2.40	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 38 of 145)

Study Population: Safety
Parameter: CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	2.31	
		SD	0.058	
		Median	2.28	
		Min	2.28	
		Max	2.38	
	Day 6	N	3	3
		Mean	2.29	-1.1
		SD	0.040	3.20
		Median	2.28	-1.3
		Min	2.25	-4.2
		Max	2.33	2.2

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 39 of 145)

Study Population: Safety
Parameter: CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	2.33	0.7
		SD	0.050	1.27
		Median	2.33	0.0
		Min	2.28	0.0
		Max	2.38	2.2
	Follow up	N	3	3
		Mean	2.35	1.6
		SD	0.100	5.08
		Median	2.35	-1.3
		Min	2.25	-1.3
		Max	2.45	7.5

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 40 of 145)

Study Population: Safety
Parameter: CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.65	
		Max	2.65	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.73	
		Max	2.73	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 41 of 145)

Study Population: Safety
Parameter: CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.60	
		Max	2.60	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.70	3.8
		Max	2.70	3.8

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.73	5.0
		Max	2.73	5.0
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.85	9.6
		Max	2.85	9.6

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CHLORIDE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	104.67	
		SD	5.033	
		Median	104.00	
		Min	100.00	
		Max	110.00	
	Day -1	N	3	
		Mean	103.67	
		SD	3.055	
		Median	103.00	
		Min	101.00	
		Max	107.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CHLORIDE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	104.67	
		SD	3.786	
		Median	103.00	
		Min	102.00	
		Max	109.00	
	Day 6	N	3	3
		Mean	103.33	-1.3
		SD	3.512	1.10
		Median	103.00	-1.8
		Min	100.00	-2.0
		Max	107.00	0.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CHLORIDE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	102.00	-2.5
		SD	3.606	1.46
		Median	101.00	-2.8
		Min	99.00	-3.9
		Max	106.00	-1.0
	Follow up	N	3	3
		Mean	104.67	0.1
		SD	4.163	5.05
		Median	106.00	-2.8
		Min	100.00	-2.9
		Max	108.00	5.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 46 of 145)

Study Population: Safety
Parameter: CHLORIDE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	102.00	
		Max	102.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	111.00	
		Max	111.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 47 of 145)

Study Population: Safety
Parameter: CHLORIDE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	104.00	
		Max	104.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	102.00	-1.9
		Max	102.00	-1.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CHLORIDE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	101.00	-2.9
		Max	101.00	-2.9
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	101.00	-2.9
		Max	101.00	-2.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	4.46	
		SD	0.985	
		Median	5.00	
		Min	3.32	
		Max	5.05	
	Day -1	N	3	
		Mean	4.54	
		SD	0.929	
		Median	4.69	
		Min	3.55	
		Max	5.39	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 50 of 145)

Study Population: Safety
Parameter: CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	4.59	
		SD	1.034	
		Median	4.95	
		Min	3.42	
		Max	5.39	
	Day 6	N	3	3
		Mean	4.26	-6.6
		SD	0.843	6.34
		Median	4.64	-3.8
		Min	3.29	-13.9
		Max	4.84	-2.2

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 51 of 145)

Study Population: Safety
Parameter: CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	4.41	-1.6
		SD	0.584	17.18
		Median	4.14	-5.8
		Min	4.01	-16.4
		Max	5.08	17.3
	Follow up	N	3	3
		Mean	3.78	-15.1
		SD	1.116	27.95
		Median	3.73	-8.7
		Min	2.69	-45.7
		Max	4.92	9.1

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 52 of 145)

Study Population: Safety
Parameter: CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	3.50	
		Max	3.50	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	3.83	
		Max	3.83	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 53 of 145)

Study Population: Safety
Parameter: CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	3.65	
		Max	3.65	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	3.55	-2.7
		Max	3.55	-2.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	3.89	6.6
		Max	3.89	6.6
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	3.68	0.8
		Max	3.68	0.8

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 55 of 145)

Study Population: Safety
Parameter: CORRECTED CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	2.36	
		SD	0.157	
		Median	2.39	
		Min	2.19	
		Max	2.50	
	Day -1	N	3	
		Mean	2.29	
		SD	0.130	
		Median	2.30	
		Min	2.16	
		Max	2.42	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 56 of 145)

Study Population: Safety
Parameter: CORRECTED CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	2.31	
		SD	0.061	
		Median	2.32	
		Min	2.24	
		Max	2.36	
	Day 6	N	3	3
		Mean	2.26	-2.0
		SD	0.036	1.37
		Median	2.25	-2.5
		Min	2.23	-3.0
		Max	2.30	-0.4

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CORRECTED CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	2.26	-1.9
		SD	0.067	2.12
		Median	2.23	-0.8
		Min	2.22	-4.3
		Max	2.34	-0.4
	Follow up	N	3	3
		Mean	2.34	1.4
		SD	0.061	4.71
		Median	2.35	-0.4
		Min	2.27	-2.2
		Max	2.39	6.7

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CORRECTED CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.59	
		Max	2.59	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.73	
		Max	2.73	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 59 of 145)

Study Population: Safety
Parameter: CORRECTED CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.68	
		Max	2.68	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.70	0.7
		Max	2.70	0.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 60 of 145)

Study Population: Safety
Parameter: CORRECTED CALCIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.67	-0.4
		Max	2.67	-0.4
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.81	4.9
		Max	2.81	4.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 61 of 145)

Study Population: Safety
Parameter: CREATINE KINASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	168.00	
		SD	134.443	
		Median	98.00	
		Min	83.00	
		Max	323.00	
	Day -1	N	3	
		Mean	236.00	
		SD	221.712	
		Median	110.00	
		Min	106.00	
		Max	492.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 62 of 145)

Study Population: Safety
Parameter: CREATINE KINASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	209.67	
		SD	194.660	
		Median	120.00	
		Min	76.00	
		Max	433.00	
	Day 6	N	3	3
		Mean	181.67	-11.1
		SD	168.334	16.72
		Median	88.00	-13.2
		Min	81.00	-26.7
		Max	376.00	6.6

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

(Page 63 of 145)

Study Population: Safety
Parameter: CREATINE KINASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	205.00	3.3
		SD	181.033	21.54
		Median	104.00	-4.4
		Min	97.00	-13.3
		Max	414.00	27.6
	Follow up	N	3	3
		Mean	254.00	14.2
		SD	265.949	21.82
		Median	107.00	23.7
		Min	94.00	-10.8
		Max	561.00	29.6

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 64 of 145)

Study Population: Safety
Parameter: CREATINE KINASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	115.00	
		Max	115.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	85.00	
		Max	85.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 65 of 145)

Study Population: Safety
Parameter: CREATINE KINASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	66.00	
		Max	66.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	74.00	12.1
		Max	74.00	12.1

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CREATINE KINASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	84.00	27.3
		Max	84.00	27.3
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	69.00	4.5
		Max	69.00	4.5

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 67 of 145)

Study Population: Safety
Parameter: CREATININE (mg/dL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.50	
		Max	1.50	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.60	6.7
		Max	1.60	6.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 68 of 145)

Study Population: Safety
Parameter: CREATININE (mg/dL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.60	6.7
		Max	1.60	6.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CYSTATIN C (nmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	96.62	
		SD	23.780	
		Median	105.61	
		Min	69.66	
		Max	114.60	
	Day 6	N	3	3
		Mean	102.61	6.2
		SD	25.760	2.49
		Median	109.35	6.4
		Min	74.15	3.5
		Max	124.33	8.5

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CYSTATIN C (nmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	128.58	28.4
		SD	67.829	42.75
		Median	110.10	4.3
		Min	71.90	3.2
		Max	203.73	77.8
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	101.12	
		Max	101.12	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: CYSTATIN C (nmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	122.09	20.7
		Max	122.09	20.7
	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	116.10	14.8
		Max	116.10	14.8

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 72 of 145)

Study Population: Safety
Parameter: DIRECT BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	2.51	
		SD	0.265	
		Median	2.57	
		Min	2.22	
		Max	2.74	
	Day -1	N	3	
		Mean	1.94	
		SD	2.043	
		Median	1.03	
		Min	0.51	
		Max	4.28	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 73 of 145)

Study Population: Safety
Parameter: DIRECT BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	2	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.71	
		Max	3.25	
	Day 6	N	3	2
		Mean	2.22	NC
		SD	0.455	NC
		Median	2.05	NC
		Min	1.88	-36.9
		Max	2.74	9.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: DIRECT BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	2
		Mean	2.62	NC
		SD	1.002	NC
		Median	2.22	NC
		Min	1.88	15.7
		Max	3.76	29.8
	Follow up	N	3	2
		Mean	2.45	NC
		SD	0.552	NC
		Median	2.22	NC
		Min	2.05	-5.2
		Max	3.08	19.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data (Page 75 of 145)

Study Population: Safety
Parameter: DIRECT BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.88	
		Max	1.88	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.71	
		Max	1.71	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 76 of 145)

Study Population: Safety
Parameter: DIRECT BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.54	
		Max	1.54	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.54	0.0
		Max	1.54	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: DIRECT BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.03	-33.1
		Max	1.03	-33.1
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.54	0.0
		Max	1.54	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 78 of 145)

Study Population: Safety
Parameter: GAMMA GLUTAMYL TRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	29.33	
		SD	12.055	
		Median	28.00	
		Min	18.00	
		Max	42.00	
	Day -1	N	3	
		Mean	28.33	
		SD	10.066	
		Median	27.00	
		Min	19.00	
		Max	39.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 79 of 145)

Study Population: Safety
Parameter: GAMMA GLUTAMYL TRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	26.67	
		SD	7.638	
		Median	25.00	
		Min	20.00	
		Max	35.00	
	Day 6	N	3	3
		Mean	29.67	10.8
		SD	9.292	3.21
		Median	27.00	10.0
		Min	22.00	8.0
		Max	40.00	14.3

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: GAMMA GLUTAMYL TRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	30.67	14.0
		SD	10.263	5.29
		Median	28.00	12.0
		Min	22.00	10.0
		Max	42.00	20.0
	Follow up	N	3	3
		Mean	28.33	7.3
		SD	6.807	6.69
		Median	26.00	4.0
		Min	23.00	2.9
		Max	36.00	15.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 81 of 145)

Study Population: Safety
Parameter: GAMMA GLUTAMYL TRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	22.00	
		Max	22.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	28.00	
		Max	28.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 82 of 145)

Study Population: Safety
Parameter: GAMMA GLUTAMYL TRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	27.00	
		Max	27.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	26.00	-3.7
		Max	26.00	-3.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: GAMMA GLUTAMYL TRANSFERASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	26.00	-3.7
		Max	26.00	-3.7
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	28.00	3.7
		Max	28.00	3.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 84 of 145)

Study Population: Safety
Parameter: HDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	1.21	
		SD	0.149	
		Median	1.27	
		Min	1.04	
		Max	1.32	
	Day -1	N	3	
		Mean	1.20	
		SD	0.248	
		Median	1.24	
		Min	0.93	
		Max	1.42	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: HDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	1.22	
		SD	0.206	
		Median	1.24	
		Min	1.01	
		Max	1.42	
	Day 6	N	3	3
		Mean	1.25	3.2
		SD	0.142	8.93
		Median	1.32	7.9
		Min	1.09	-7.0
		Max	1.35	8.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 86 of 145)

Study Population: Safety
Parameter: HDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	1.33	7.8
		SD	0.327	11.36
		Median	1.45	11.3
		Min	0.96	-5.0
		Max	1.58	16.9
	Follow up	N	3	3
		Mean	1.15	-8.0
		SD	0.433	24.92
		Median	1.40	-1.4
		Min	0.65	-35.6
		Max	1.40	12.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 87 of 145)

Study Population: Safety
Parameter: HDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.40	
		Max	1.40	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.19	
		Max	1.19	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 88 of 145)

Study Population: Safety
Parameter: HDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.14	
		Max	1.14	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.14	0.0
		Max	1.14	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 89 of 145)

Study Population: Safety
Parameter: HDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.24	8.8
		Max	1.24	8.8
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.32	15.8
		Max	1.32	15.8

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: LACTATE DEHYDROGENASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	175.33	
		SD	23.288	
		Median	165.00	
		Min	159.00	
		Max	202.00	
	Day -1	N	3	
		Mean	180.67	
		SD	31.565	
		Median	165.00	
		Min	160.00	
		Max	217.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data
(Page 91 of 145)

Study Population: Safety
Parameter: LACTATE DEHYDROGENASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	231.33	
		SD	132.670	
		Median	166.00	
		Min	144.00	
		Max	384.00	
	Day 6	N	3	3
		Mean	174.00	-14.5
		SD	31.432	27.11
		Median	160.00	-3.6
		Min	152.00	-45.3
		Max	210.00	5.6

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: LACTATE DEHYDROGENASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	173.67	-12.7
		SD	19.348	32.33
		Median	163.00	-2.4
		Min	162.00	-49.0
		Max	196.00	13.2
	Follow up	N	3	3
		Mean	169.33	-16.7
		SD	30.892	26.73
		Median	152.00	-8.4
		Min	151.00	-46.6
		Max	205.00	4.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: LACTATE DEHYDROGENASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	179.00	
		Max	179.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	164.00	
		Max	164.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 94 of 145)

Study Population: Safety
Parameter: LACTATE DEHYDROGENASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	150.00	
		Max	150.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	146.00	-2.7
		Max	146.00	-2.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 95 of 145)

Study Population: Safety
Parameter: LACTATE DEHYDROGENASE (IU/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	170.00	13.3
		Max	170.00	13.3
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	171.00	14.0
		Max	171.00	14.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: LDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	2.35	
		SD	0.632	
		Median	2.49	
		Min	1.66	
		Max	2.90	
	Day -1	N	3	
		Mean	2.39	
		SD	0.847	
		Median	2.20	
		Min	1.66	
		Max	3.32	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: LDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	2.35	
		SD	0.887	
		Median	2.15	
		Min	1.58	
		Max	3.32	
	Day 6	N	3	3
		Mean	2.22	-2.1
		SD	0.537	17.39
		Median	2.43	1.9
		Min	1.61	-21.1
		Max	2.62	13.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data (Page 98 of 145)

Study Population: Safety
Parameter: LDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	2.47	10.1
		SD	0.471	20.00
		Median	2.38	10.7
		Min	2.05	-10.2
		Max	2.98	29.7
	Follow up	N	3	3
		Mean	1.89	-16.1
		SD	0.856	37.94
		Median	1.94	-18.1
		Min	1.01	-53.0
		Max	2.72	22.8

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: LDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.63	
		Max	1.63	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.84	
		Max	1.84	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 100 of 145)

Study Population: Safety
Parameter: LDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.81	
		Max	1.81	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.61	-11.0
		Max	1.61	-11.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 101 of 145)

Study Population: Safety
Parameter: LDL CHOLESTEROL (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.71	-5.5
		Max	1.71	-5.5
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.55	-14.4
		Max	1.55	-14.4

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 102 of 145)

Study Population: Safety
Parameter: MAGNESIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	0.93	
		SD	0.153	
		Median	0.90	
		Min	0.80	
		Max	1.10	
	Day -1	N	3	
		Mean	0.88	
		SD	0.104	
		Median	0.85	
		Min	0.80	
		Max	1.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 103 of 145)

Study Population: Safety
Parameter: MAGNESIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	0.88	
		SD	0.144	
		Median	0.80	
		Min	0.80	
		Max	1.05	
	Day 6	N	3	3
		Mean	0.90	2.6
		SD	0.087	6.36
		Median	0.85	6.3
		Min	0.85	-4.8
		Max	1.00	6.3

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data (Page 104 of 145)

Study Population: Safety
Parameter: MAGNESIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	0.87	-1.6
		SD	0.115	2.75
		Median	0.80	0.0
		Min	0.80	-4.8
		Max	1.00	0.0
	Follow up	N	3	3
		Mean	0.98	11.5
		SD	0.153	6.49
		Median	0.95	9.5
		Min	0.85	6.3
		Max	1.15	18.8

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: MAGNESIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.00	
		Max	1.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.00	
		Max	1.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 106 of 145)

Study Population: Safety
Parameter: MAGNESIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.05	
		Max	1.05	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.95	-9.5
		Max	0.95	-9.5

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: MAGNESIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.95	-9.5
		Max	0.95	-9.5
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.05	0.0
		Max	1.05	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 108 of 145)

Study Population: Safety
Parameter: PHOSPHATE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	1.00	
		SD	0.227	
		Median	1.10	
		Min	0.74	
		Max	1.16	
	Day -1	N	3	
		Mean	1.20	
		SD	0.203	
		Median	1.26	
		Min	0.97	
		Max	1.36	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 109 of 145)

Study Population: Safety
Parameter: PHOSPHATE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	1.25	
		SD	0.161	
		Median	1.23	
		Min	1.10	
		Max	1.42	
	Day 6	N	3	3
		Mean	0.98	-20.9
		SD	0.106	11.84
		Median	0.94	-18.2
		Min	0.90	-33.8
		Max	1.10	-10.6

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: PHOSPHATE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	1.30	3.7
		SD	0.250	8.93
		Median	1.36	7.0
		Min	1.03	-6.4
		Max	1.52	10.6
	Follow up	N	3	3
		Mean	1.00	-18.3
		SD	0.212	22.22
		Median	0.97	-11.8
		Min	0.81	-43.0
		Max	1.23	0.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data (Page 111 of 145)

Study Population: Safety
Parameter: PHOSPHATE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.13	
		Max	1.13	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.16	
		Max	1.16	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 112 of 145)

Study Population: Safety
Parameter: PHOSPHATE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.29	
		Max	1.29	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.39	7.8
		Max	1.39	7.8

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 113 of 145)

Study Population: Safety
Parameter: PHOSPHATE (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.23	-4.7
		Max	1.23	-4.7
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.58	22.5
		Max	1.58	22.5

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 114 of 145)

Study Population: Safety
Parameter: POTASSIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	4.07	
		SD	0.351	
		Median	4.10	
		Min	3.70	
		Max	4.40	
	Day -1	N	3	
		Mean	3.87	
		SD	0.208	
		Median	3.80	
		Min	3.70	
		Max	4.10	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 115 of 145)

Study Population: Safety
Parameter: POTASSIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	4.23	
		SD	0.115	
		Median	4.30	
		Min	4.10	
		Max	4.30	
	Day 6	N	3	3
		Mean	4.07	-3.8
		SD	0.586	14.84
		Median	4.30	4.7
		Min	3.40	-20.9
		Max	4.50	4.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 116 of 145)

Study Population: Safety
Parameter: POTASSIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	3.93	-6.9
		SD	0.473	13.05
		Median	4.10	-4.7
		Min	3.40	-20.9
		Max	4.30	4.9
	Follow up	N	3	3
		Mean	4.53	7.5
		SD	0.751	20.59
		Median	4.50	4.7
		Min	3.80	-11.6
		Max	5.30	29.3

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 117 of 145)

Study Population: Safety
Parameter: POTASSIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	4.00	
		Max	4.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	4.10	
		Max	4.10	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 118 of 145)

Study Population: Safety
Parameter: POTASSIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	3.90	
		Max	3.90	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	3.90	0.0
		Max	3.90	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 119 of 145)

Study Population: Safety
Parameter: POTASSIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	3.80	-2.6
		Max	3.80	-2.6
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	4.20	7.7
		Max	4.20	7.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: PROTEIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	68.00	
		SD	1.732	
		Median	69.00	
		Min	66.00	
		Max	69.00	
	Day -1	N	3	
		Mean	65.67	
		SD	1.155	
		Median	65.00	
		Min	65.00	
		Max	67.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 121 of 145)

Study Population: Safety
Parameter: PROTEIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	65.00	
		SD	1.732	
		Median	64.00	
		Min	64.00	
		Max	67.00	
	Day 6	N	3	3
		Mean	66.67	2.5
		SD	5.508	5.68
		Median	64.00	0.0
		Min	63.00	-1.6
		Max	73.00	9.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 122 of 145)

Study Population: Safety
Parameter: PROTEIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	69.67	7.2
		SD	3.055	2.21
		Median	69.00	7.8
		Min	67.00	4.7
		Max	73.00	9.0
	Follow up	N	3	3
		Mean	66.67	2.7
		SD	1.528	4.97
		Median	67.00	4.7
		Min	65.00	-3.0
		Max	68.00	6.3

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 123 of 145)

Study Population: Safety
Parameter: PROTEIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	72.00	
		Max	72.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	63.00	
		Max	63.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: PROTEIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	62.00	
		Max	62.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	66.00	6.5
		Max	66.00	6.5

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: PROTEIN (g/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	69.00	11.3
		Max	69.00	11.3
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	69.00	11.3
		Max	69.00	11.3

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 126 of 145)

Study Population: Safety
Parameter: SODIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	142.00	
		SD	1.000	
		Median	142.00	
		Min	141.00	
		Max	143.00	
	Day -1	N	3	
		Mean	140.33	
		SD	2.309	
		Median	139.00	
		Min	139.00	
		Max	143.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data (Page 127 of 145)

Study Population: Safety
Parameter: SODIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	140.33	
		SD	3.215	
		Median	139.00	
		Min	138.00	
		Max	144.00	
	Day 6	N	3	3
		Mean	142.00	1.2
		SD	1.000	1.81
		Median	142.00	1.4
		Min	141.00	-0.7
		Max	143.00	2.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 128 of 145)

Study Population: Safety
Parameter: SODIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	140.67	0.2
		SD	3.786	0.40
		Median	139.00	0.0
		Min	138.00	0.0
		Max	145.00	0.7
	Follow up	N	3	3
		Mean	140.00	-0.2
		SD	3.464	2.74
		Median	142.00	-1.4
		Min	136.00	-2.2
		Max	142.00	2.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 129 of 145)

Study Population: Safety
Parameter: SODIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	142.00	
		Max	142.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	145.00	
		Max	145.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: SODIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	143.00	
		Max	143.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	143.00	0.0
		Max	143.00	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data (Page 131 of 145)

Study Population: Safety
Parameter: SODIUM (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	138.00	-3.5
		Max	138.00	-3.5
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	138.00	-3.5
		Max	138.00	-3.5

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: TOTAL BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	7.07	
		SD	0.393	
		Median	6.84	
		Min	6.84	
		Max	7.52	
	Day -1	N	3	
		Mean	8.49	
		SD	5.413	
		Median	6.84	
		Min	4.10	
		Max	14.54	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: TOTAL BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	6.44	
		SD	2.749	
		Median	5.30	
		Min	4.45	
		Max	9.58	
	Day 6	N	3	3
		Mean	7.98	36.5
		SD	1.374	49.08
		Median	7.87	49.9
		Min	6.67	-17.8
		Max	9.41	77.5

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 134 of 145)

Study Population: Safety
Parameter: TOTAL BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	9.12	52.8
		SD	1.713	49.05
		Median	9.23	38.7
		Min	7.35	12.4
		Max	10.77	107.4
	Follow up	N	3	3
		Mean	6.56	8.7
		SD	1.713	35.79
		Median	6.67	-9.6
		Min	4.79	-14.3
		Max	8.21	49.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 135 of 145)

Study Population: Safety
Parameter: TOTAL BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	4.96	
		Max	4.96	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	4.79	
		Max	4.79	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data (Page 136 of 145)

Study Population: Safety
Parameter: TOTAL BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	3.93	
		Max	3.93	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	4.45	13.2
		Max	4.45	13.2

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS   Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: TOTAL BILIRUBIN (umol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	5.64	43.5
		Max	5.64	43.5
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	5.64	43.5
		Max	5.64	43.5

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: TRIGLYCERIDES (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	1.96	
		SD	1.240	
		Median	1.94	
		Min	0.73	
		Max	3.21	
	Day -1	N	3	
		Mean	2.06	
		SD	1.194	
		Median	1.79	
		Min	1.03	
		Max	3.37	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 139 of 145)

Study Population: Safety
Parameter: TRIGLYCERIDES (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	2.21	
		SD	1.512	
		Median	1.83	
		Min	0.93	
		Max	3.88	
	Day 6	N	3	3
		Mean	1.70	-20.7
		SD	1.059	5.16
		Median	1.47	-19.7
		Min	0.78	-26.3
		Max	2.86	-16.1

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: TRIGLYCERIDES (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	1.33	-29.3
		SD	0.464	23.03
		Median	1.40	-23.5
		Min	0.84	-54.6
		Max	1.76	-9.7
	Follow up	N	3	3
		Mean	1.61	-18.6
		SD	0.711	20.74
		Median	1.76	-9.7
		Min	0.84	-42.3
		Max	2.24	-3.8

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 141 of 145)

Study Population: Safety
Parameter: TRIGLYCERIDES (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.99	
		Max	0.99	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.73	
		Max	1.73	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 142 of 145)

Study Population: Safety
Parameter: TRIGLYCERIDES (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.53	
		Max	1.53	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.73	13.1
		Max	1.73	13.1

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data

Study Population: Safety
Parameter: TRIGLYCERIDES (mmol/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.05	34.0
		Max	2.05	34.0
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.76	15.0
		Max	1.76	15.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 144 of 145)

Study Population: Safety
Parameter: URATE (mg/dL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	5.70	
		Max	5.70	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	5.30	-7.0
		Max	5.30	-7.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-1   Summary of Serum Biochemistry Data   (Page 145 of 145)

Study Population: Safety
Parameter: URATE (mg/dL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	5.80	1.8
		Max	5.80	1.8

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-2   Summary of Hematology Data   (Page 1 of 120)

Study Population: Safety
Parameter: BASOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	0.00	
		SD	0.000	
		Median	0.00	
		Min	0.00	
		Max	0.00	
	Day -1	N	3	
		Mean	0.00	
		SD	0.000	
		Median	0.00	
		Min	0.00	
		Max	0.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 2 of 120)

Study Population: Safety
Parameter: BASOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	0.00	
		SD	0.000	
		Median	0.00	
		Min	0.00	
		Max	0.00	
	Day 6	N	3	
		Mean	0.00	
		SD	0.000	
		Median	0.00	
		Min	0.00	
		Max	0.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 3 of 120)

Study Population: Safety
Parameter: BASOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	
		Mean	0.03	
		SD	0.058	
		Median	0.00	
		Min	0.00	
		Max	0.10	
	Follow up	N	3	
		Mean	0.03	
		SD	0.058	
		Median	0.00	
		Min	0.00	
		Max	0.10	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 4 of 120)

Study Population: Safety
Parameter: BASOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: BASOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	
	Day 6	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 6 of 120)

Study Population: Safety
Parameter: BASOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	
	Follow up	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: BASOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	0.43	
		SD	0.115	
		Median	0.50	
		Min	0.30	
		Max	0.50	
	Day -1	N	3	
		Mean	0.40	
		SD	0.200	
		Median	0.40	
		Min	0.20	
		Max	0.60	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 8 of 120)

Study Population: Safety
Parameter: BASOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	0.33	
		SD	0.153	
		Median	0.30	
		Min	0.20	
		Max	0.50	
	Day 6	N	3	3
		Mean	0.33	20.0
		SD	0.058	72.11
		Median	0.30	0.0
		Min	0.30	-40.0
		Max	0.40	100.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 9 of 120)

Study Population: Safety
Parameter: BASOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	0.43	65.6
		SD	0.252	159.87
		Median	0.40	-20.0
		Min	0.20	-33.3
		Max	0.70	250.0
	Follow up	N	3	3
		Mean	0.37	51.1
		SD	0.252	140.85
		Median	0.40	33.3
		Min	0.10	-80.0
		Max	0.60	200.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 10 of 120)

Study Population: Safety
Parameter: BASOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.10	
		Max	0.10	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.10	
		Max	0.10	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: BASOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.50	
		Max	0.50	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.30	-40.0
		Max	0.30	-40.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 12 of 120)

Study Population: Safety
Parameter: BASOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.30	-40.0
		Max	0.30	-40.0
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.10	-80.0
		Max	0.10	-80.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 13 of 120)

Study Population: Safety
Parameter: EOSINOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	0.13	
		SD	0.115	
		Median	0.20	
		Min	0.00	
		Max	0.20	
	Day -1	N	3	
		Mean	0.23	
		SD	0.153	
		Median	0.20	
		Min	0.10	
		Max	0.40	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data (Page 14 of 120)

Study Population: Safety
Parameter: EOSINOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	0.20	
		SD	0.100	
		Median	0.20	
		Min	0.10	
		Max	0.30	
	Day 6	N	3	3
		Mean	0.20	0.0
		SD	0.100	0.00
		Median	0.20	0.0
		Min	0.10	0.0
		Max	0.30	0.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: EOSINOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	0.23	11.1
		SD	0.153	19.25
		Median	0.20	0.0
		Min	0.10	0.0
		Max	0.40	33.3
	Follow up	N	3	3
		Mean	0.17	-33.3
		SD	0.153	57.74
		Median	0.20	0.0
		Min	0.00	-100.0
		Max	0.30	0.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 16 of 120)

Study Population: Safety
Parameter: EOSINOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 17 of 120)

Study Population: Safety
Parameter: EOSINOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	
	Day 6	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: EOSINOPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	
	Follow up	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: EOSINOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	2.23	
		SD	1.155	
		Median	2.90	
		Min	0.90	
		Max	2.90	
	Day -1	N	3	
		Mean	3.47	
		SD	1.464	
		Median	3.70	
		Min	1.90	
		Max	4.80	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 20 of 120)

Study Population: Safety
Parameter: EOSINOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	3.07	
		SD	1.193	
		Median	3.60	
		Min	1.70	
		Max	3.90	
	Day 6	N	3	3
		Mean	2.90	-6.2
		SD	1.539	24.25
		Median	2.50	-5.9
		Min	1.60	-30.6
		Max	4.60	17.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: EOSINOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	2.97	-2.4
		SD	1.607	30.45
		Median	2.30	5.9
		Min	1.80	-36.1
		Max	4.80	23.1
	Follow up	N	3	3
		Mean	2.53	-20.6
		SD	1.242	12.91
		Median	3.20	-15.4
		Min	1.10	-35.3
		Max	3.30	-11.1

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 22 of 120)

Study Population: Safety
Parameter: EOSINOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.00	
		Max	0.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: EOSINOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.10	
		Max	0.10	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.10	0.0
		Max	0.10	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data (Page 24 of 120)

Study Population: Safety
Parameter: EOSINOPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.10	0.0
		Max	0.10	0.0
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.10	0.0
		Max	0.10	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HEMOGLOBIN (pg)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	31.47	
		SD	3.009	
		Median	33.00	
		Min	28.00	
		Max	33.40	
	Day -1	N	3	
		Mean	31.63	
		SD	3.166	
		Median	33.10	
		Min	28.00	
		Max	33.80	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HEMOGLOBIN (pg)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	31.57	
		SD	3.265	
		Median	33.30	
		Min	27.80	
		Max	33.60	
	Day 6	N	3	3
		Mean	32.07	1.5
		SD	3.925	3.11
		Median	33.20	-0.3
		Min	27.70	-0.4
		Max	35.30	5.1

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 27 of 120)

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HEMOGLOBIN (pg)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	31.50	-0.3
		SD	3.554	1.35
		Median	33.40	-0.6
		Min	27.40	-1.4
		Max	33.70	1.2
	Follow up	N	3	3
		Mean	31.53	-0.1
		SD	3.147	0.72
		Median	33.30	0.3
		Min	27.90	-0.9
		Max	33.40	0.4

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HEMOGLOBIN (pg)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	30.50	
		Max	30.50	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	29.50	
		Max	29.50	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 29 of 120)

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HEMOGLOBIN (pg)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	29.70	
		Max	29.70	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	30.00	1.0
		Max	30.00	1.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 30 of 120)

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HEMOGLOBIN (pg)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	30.00	1.0
		Max	30.00	1.0
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	30.00	1.0
		Max	30.00	1.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HGB CONCENTRATION (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	33.57	
		SD	0.551	
		Median	33.60	
		Min	33.00	
		Max	34.10	
	Day -1	N	3	
		Mean	33.70	
		SD	0.557	
		Median	33.80	
		Min	33.10	
		Max	34.20	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HGB CONCENTRATION (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	33.47	
		SD	0.723	
		Median	33.10	
		Min	33.00	
		Max	34.30	
	Day 6	N	3	3
		Mean	34.23	2.3
		SD	1.137	1.50
		Median	33.90	2.7
		Min	33.30	0.6
		Max	35.50	3.5

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 33 of 120)

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HGB CONCENTRATION (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	33.13	-1.0
		SD	0.379	2.07
		Median	33.30	-1.2
		Min	32.70	-2.9
		Max	33.40	1.2
	Follow up	N	3	3
		Mean	33.50	0.1
		SD	0.265	2.53
		Median	33.40	0.6
		Min	33.30	-2.6
		Max	33.80	2.4

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HGB CONCENTRATION (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	33.80	
		Max	33.80	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	32.80	
		Max	32.80	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 35 of 120)

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HGB CONCENTRATION (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	33.60	
		Max	33.60	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	33.30	-0.9
		Max	33.30	-0.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR HGB CONCENTRATION (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	34.20	1.8
		Max	34.20	1.8
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	33.50	-0.3
		Max	33.50	-0.3

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 37 of 120)

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	93.53	
		SD	7.829	
		Median	96.80	
		Min	84.60	
		Max	99.20	
	Day -1	N	3	
		Mean	93.70	
		SD	7.894	
		Median	97.80	
		Min	84.60	
		Max	98.70	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 38 of 120)

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	94.27	
		SD	9.034	
		Median	97.80	
		Min	84.00	
		Max	101.00	
	Day 6	N	3	3
		Mean	93.57	-0.7
		SD	8.927	2.41
		Median	97.90	-0.8
		Min	83.30	-3.1
		Max	99.50	1.7

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 39 of 120)

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	94.97	0.7
		SD	9.677	1.52
		Median	100.20	-0.1
		Min	83.80	-0.2
		Max	100.90	2.5
	Follow up	N	3	3
		Mean	94.10	-0.2
		SD	9.100	1.97
		Median	99.00	-0.5
		Min	83.60	-2.0
		Max	99.70	1.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	90.20	
		Max	90.20	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	89.80	
		Max	89.80	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 41 of 120)

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	88.30	
		Max	88.30	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	90.20	2.2
		Max	90.20	2.2

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERY. MEAN CORPUSCULAR VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	87.60	-0.8
		Max	87.60	-0.8
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	89.40	1.2
		Max	89.40	1.2

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data (Page 43 of 120)

Study Population: Safety
Parameter: ERYTHROCYTES (x10^12/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	4.51	
		SD	0.752	
		Median	4.58	
		Min	3.73	
		Max	5.23	
	Day -1	N	3	
		Mean	4.43	
		SD	0.614	
		Median	4.51	
		Min	3.78	
		Max	5.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERYTHROCYTES (x10^12/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	4.46	
		SD	0.666	
		Median	4.50	
		Min	3.78	
		Max	5.11	
	Day 6	N	3	3
		Mean	4.49	0.0
		SD	0.941	7.06
		Median	4.26	-2.6
		Min	3.68	-5.3
		Max	5.52	8.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data (Page 45 of 120)

Study Population: Safety
Parameter: ERYTHROCYTES (x10^12/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	4.57	1.7
		SD	0.985	7.06
		Median	4.45	-1.1
		Min	3.65	-3.4
		Max	5.61	9.8
	Follow up	N	3	3
		Mean	4.27	-4.1
		SD	0.601	5.79
		Median	4.60	-5.3
		Min	3.58	-9.2
		Max	4.64	2.2

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERYTHROCYTES (x10^12/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	4.49	
		Max	4.49	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	4.04	
		Max	4.04	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERYTHROCYTES (x10^12/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	4.01	
		Max	4.01	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	4.11	2.5
		Max	4.11	2.5

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 48 of 120)

Study Population: Safety
Parameter: ERYTHROCYTES (x10^12/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	4.36	8.7
		Max	4.36	8.7
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	4.17	4.0
		Max	4.17	4.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERYTHROCYTES DISTRIBUTION WIDTH (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	14.63	
		SD	0.777	
		Median	14.40	
		Min	14.00	
		Max	15.50	
	Day -1	N	3	
		Mean	14.93	
		SD	0.473	
		Median	15.10	
		Min	14.40	
		Max	15.30	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 50 of 120)

Study Population: Safety
Parameter: ERYTHROCYTES DISTRIBUTION WIDTH (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	14.50	
		SD	0.173	
		Median	14.60	
		Min	14.30	
		Max	14.60	
	Day 6	N	3	3
		Mean	14.77	1.9
		SD	0.153	1.76
		Median	14.80	2.1
		Min	14.60	0.0
		Max	14.90	3.5

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 51 of 120)

Study Population: Safety
Parameter: ERYTHROCYTES DISTRIBUTION WIDTH (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	15.20	4.9
		SD	0.300	3.23
		Median	15.20	4.1
		Min	14.90	2.1
		Max	15.50	8.4
	Follow up	N	3	3
		Mean	15.00	3.5
		SD	0.173	1.18
		Median	14.90	4.1
		Min	14.90	2.1
		Max	15.20	4.2

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: ERYTHROCYTES DISTRIBUTION WIDTH (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	14.70	
		Max	14.70	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	15.20	
		Max	15.20	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 53 of 120)

Study Population: Safety
Parameter: ERYTHROCYTES DISTRIBUTION WIDTH (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	15.20	
		Max	15.20	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	15.50	2.0
		Max	15.50	2.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 54 of 120)

Study Population: Safety
Parameter: ERYTHROCYTES DISTRIBUTION WIDTH (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	14.80	-2.6
		Max	14.80	-2.6
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	14.80	-2.6
		Max	14.80	-2.6

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 55 of 120)

Study Population: Safety
Parameter: HEMATOCRIT (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	0.42	
		SD	0.040	
		Median	0.44	
		Min	0.37	
		Max	0.44	
	Day -1	N	3	
		Mean	0.41	
		SD	0.036	
		Median	0.42	
		Min	0.37	
		Max	0.44	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: HEMATOCRIT (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	0.42	
		SD	0.032	
		Median	0.43	
		Min	0.38	
		Max	0.44	
	Day 6	N	3	3
		Mean	0.41	-0.9
		SD	0.050	6.87
		Median	0.42	-4.5
		Min	0.36	-5.3
		Max	0.46	7.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: HEMATOCRIT (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	0.43	3.0
		SD	0.053	6.00
		Median	0.45	2.3
		Min	0.37	-2.6
		Max	0.47	9.3
	Follow up	N	3	3
		Mean	0.40	-3.4
		SD	0.051	7.10
		Median	0.39	-5.3
		Min	0.36	-9.3
		Max	0.46	4.5

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 58 of 120)

Study Population: Safety
Parameter: HEMATOCRIT (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.41	
		Max	0.41	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.36	
		Max	0.36	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 59 of 120)

Study Population: Safety
Parameter: HEMATOCRIT (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.36	
		Max	0.36	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.37	2.8
		Max	0.37	2.8

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: HEMATOCRIT (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.38	5.6
		Max	0.38	5.6
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.37	2.8
		Max	0.37	2.8

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 61 of 120)

Study Population: Safety
Parameter: HEMOGLOBIN (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	14.07	
		SD	1.380	
		Median	14.60	
		Min	12.50	
		Max	15.10	
	Day -1	N	3	
		Mean	13.90	
		SD	1.054	
		Median	14.00	
		Min	12.80	
		Max	14.90	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 62 of 120)

Study Population: Safety
Parameter: HEMOGLOBIN (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	13.97	
		SD	1.266	
		Median	14.20	
		Min	12.60	
		Max	15.10	
	Day 6	N	3	3
		Mean	14.20	1.5
		SD	1.735	5.62
		Median	15.10	0.0
		Min	12.20	-3.2
		Max	15.30	7.7

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 63 of 120)

Study Population: Safety
Parameter: HEMOGLOBIN (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	14.20	1.6
		SD	1.664	5.97
		Median	14.90	-1.3
		Min	12.30	-2.4
		Max	15.40	8.5
	Follow up	N	3	3
		Mean	13.40	-4.2
		SD	1.706	5.27
		Median	12.90	-4.8
		Min	12.00	-9.2
		Max	15.30	1.3

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 64 of 120)

Study Population: Safety
Parameter: HEMOGLOBIN (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	13.70	
		Max	13.70	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	11.90	
		Max	11.90	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 65 of 120)

Study Population: Safety
Parameter: HEMOGLOBIN (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	11.90	
		Max	11.90	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	12.30	3.4
		Max	12.30	3.4

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data (Page 66 of 120)

Study Population: Safety
Parameter: HEMOGLOBIN (g/dL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	13.10	10.1
		Max	13.10	10.1
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	12.50	5.0
		Max	12.50	5.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 67 of 120)

Study Population: Safety
Parameter: LEUKOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	6.33	
		SD	1.922	
		Median	6.00	
		Min	4.60	
		Max	8.40	
	Day -1	N	3	
		Mean	6.43	
		SD	1.266	
		Median	6.20	
		Min	5.30	
		Max	7.80	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2 Summary of Hematology Data

(Page 68 of 120)

Study Population: Safety
Parameter: LEUKOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	6.47	
		SD	1.677	
		Median	5.60	
		Min	5.40	
		Max	8.40	
	Day 6	N	3	3
		Mean	6.57	3.8
		SD	1.537	27.63
		Median	7.30	-11.1
		Min	4.80	-13.1
		Max	7.60	35.7

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 69 of 120)

Study Population: Safety
Parameter: LEUKOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	6.87	7.1
		SD	1.724	19.00
		Median	7.20	0.0
		Min	5.00	-7.4
		Max	8.40	28.6
	Follow up	N	3	3
		Mean	6.03	-9.4
		SD	2.702	17.14
		Median	5.00	-10.7
		Min	4.00	-25.9
		Max	9.10	8.3

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 70 of 120)

Study Population: Safety
Parameter: LEUKOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	5.90	
		Max	5.90	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	4.80	
		Max	4.80	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: LEUKOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	4.70	
		Max	4.70	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	5.00	6.4
		Max	5.00	6.4

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: LEUKOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	6.00	27.7
		Max	6.00	27.7
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	5.30	12.8
		Max	5.30	12.8

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: LYMPHOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	1.93	
		SD	0.666	
		Median	2.10	
		Min	1.20	
		Max	2.50	
	Day -1	N	3	
		Mean	2.83	
		SD	0.643	
		Median	3.10	
		Min	2.10	
		Max	3.30	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 74 of 120)

Study Population: Safety
Parameter: LYMPHOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	2.53	
		SD	0.666	
		Median	2.70	
		Min	1.80	
		Max	3.10	
	Day 6	N	3	3
		Mean	1.73	-31.6
		SD	0.945	27.86
		Median	1.40	-22.2
		Min	1.00	-63.0
		Max	2.80	-9.7

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: LYMPHOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	2.60	1.6
		SD	0.889	18.05
		Median	2.90	-6.5
		Min	1.60	-11.1
		Max	3.30	22.2
	Follow up	N	3	3
		Mean	2.10	-20.0
		SD	0.964	24.06
		Median	2.50	-19.4
		Min	1.00	-44.4
		Max	2.80	3.7

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: LYMPHOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.10	
		Max	2.10	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.30	
		Max	2.30	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 77 of 120)

Study Population: Safety
Parameter: LYMPHOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.20	
		Max	2.20	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.00	-9.1
		Max	2.00	-9.1

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: LYMPHOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	3.00	36.4
		Max	3.00	36.4
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.20	0.0
		Max	2.20	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: LYMPHOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	30.87	
		SD	9.122	
		Median	26.90	
		Min	24.40	
		Max	41.30	
	Day -1	N	3	
		Mean	44.20	
		SD	7.491	
		Median	40.70	
		Min	39.10	
		Max	52.80	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data (Page 80 of 120)

Study Population: Safety
Parameter: LYMPHOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	39.03	
		SD	7.674	
		Median	36.30	
		Min	33.10	
		Max	47.70	
	Day 6	N	3	3
		Mean	27.30	-25.0
		SD	13.093	42.09
		Median	30.20	-8.8
		Min	13.00	-72.7
		Max	38.70	6.6

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 81 of 120)

Study Population: Safety
Parameter: LYMPHOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	37.70	-3.5
		SD	7.622	1.29
		Median	34.50	-2.7
		Min	32.20	-5.0
		Max	46.40	-2.7
	Follow up	N	3	3
		Mean	36.43	-9.5
		SD	16.626	22.65
		Median	27.80	-21.8
		Min	25.90	-23.4
		Max	55.60	16.6

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data (Page 82 of 120)

Study Population: Safety
Parameter: LYMPHOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	34.70	
		Max	34.70	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	47.40	
		Max	47.40	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 83 of 120)

Study Population: Safety
Parameter: LYMPHOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	45.60	
		Max	45.60	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	40.70	-10.7
		Max	40.70	-10.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: LYMPHOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	50.10	9.9
		Max	50.10	9.9
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	42.00	-7.9
		Max	42.00	-7.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 85 of 120)

Study Population: Safety
Parameter: MEAN PLATELET VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	8.33	
		SD	0.577	
		Median	8.00	
		Min	8.00	
		Max	9.00	
	Day -1	N	3	
		Mean	9.00	
		SD	1.000	
		Median	9.00	
		Min	8.00	
		Max	10.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: MEAN PLATELET VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	9.00	
		SD	1.000	
		Median	9.00	
		Min	8.00	
		Max	10.00	
	Day 6	N	3	3
		Mean	8.67	-3.3
		SD	0.577	5.77
		Median	9.00	0.0
		Min	8.00	-10.0
		Max	9.00	0.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 87 of 120)

Study Population: Safety
Parameter: MEAN PLATELET VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	8.67	-3.3
		SD	0.577	5.77
		Median	9.00	0.0
		Min	8.00	-10.0
		Max	9.00	0.0
	Follow up	N	3	3
		Mean	8.67	-3.3
		SD	0.577	5.77
		Median	9.00	0.0
		Min	8.00	-10.0
		Max	9.00	0.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 88 of 120)

Study Population: Safety
Parameter: MEAN PLATELET VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	8.00	
		Max	8.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	8.00	
		Max	8.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: MEAN PLATELET VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	7.00	
		Max	7.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	8.00	14.3
		Max	8.00	14.3

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: MEAN PLATELET VOLUME (fL)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	8.00	14.3
		Max	8.00	14.3
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	8.00	14.3
		Max	8.00	14.3

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: MONOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	0.50	
		SD	0.173	
		Median	0.60	
		Min	0.30	
		Max	0.60	
	Day -1	N	3	
		Mean	0.43	
		SD	0.115	
		Median	0.50	
		Min	0.30	
		Max	0.50	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: MONOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	0.37	
		SD	0.058	
		Median	0.40	
		Min	0.30	
		Max	0.40	
	Day 6	N	3	3
		Mean	0.43	16.7
		SD	0.115	14.43
		Median	0.50	25.0
		Min	0.30	0.0
		Max	0.50	25.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: MONOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	0.47	25.0
		SD	0.153	25.00
		Median	0.50	25.0
		Min	0.30	0.0
		Max	0.60	50.0
	Follow up	N	3	3
		Mean	0.37	-2.8
		SD	0.208	45.89
		Median	0.30	-25.0
		Min	0.20	-33.3
		Max	0.60	50.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 94 of 120)

Study Population: Safety
Parameter: MONOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.20	
		Max	0.20	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.20	
		Max	0.20	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 95 of 120)

Study Population: Safety
Parameter: MONOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	0.40	
		Max	0.40	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.30	-25.0
		Max	0.30	-25.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 96 of 120)

Study Population: Safety
Parameter: MONOCYTES (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.30	-25.0
		Max	0.30	-25.0
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	0.20	-50.0
		Max	0.20	-50.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 97 of 120)

Study Population: Safety
Parameter: MONOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	8.30	
		SD	1.480	
		Median	7.60	
		Min	7.30	
		Max	10.00	
	Day -1	N	3	
		Mean	6.50	
		SD	1.100	
		Median	6.50	
		Min	5.40	
		Max	7.60	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2 Summary of Hematology Data (Page 98 of 120)

Study Population: Safety
Parameter: MONOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	5.90	
		SD	1.493	
		Median	5.30	
		Min	4.80	
		Max	7.60	
	Day 6	N	3	3
		Mean	6.33	10.6
		SD	0.603	21.43
		Median	6.40	7.5
		Min	5.70	-9.2
		Max	6.90	33.3

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 99 of 120)

Study Population: Safety
Parameter: MONOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	6.90	21.4
		SD	0.794	31.56
		Median	7.20	13.2
		Min	6.00	-5.3
		Max	7.50	56.3
	Follow up	N	3	3
		Mean	5.90	5.6
		SD	0.624	33.48
		Median	6.10	15.1
		Min	5.20	-31.6
		Max	6.40	33.3

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: MONOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	4.10	
		Max	4.10	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	5.00	
		Max	5.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 101 of 120)

Study Population: Safety
Parameter: MONOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	7.50	
		Max	7.50	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	6.70	-10.7
		Max	6.70	-10.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: MONOCYTES/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	5.60	-25.3
		Max	5.60	-25.3
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	3.90	-48.0
		Max	3.90	-48.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: NEUTROPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	3.67	
		SD	1.504	
		Median	2.90	
		Min	2.70	
		Max	5.40	
	Day -1	N	3	
		Mean	2.93	
		SD	0.874	
		Median	2.70	
		Min	2.20	
		Max	3.90	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: NEUTROPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	3.37	
		SD	1.159	
		Median	3.20	
		Min	2.30	
		Max	4.60	
	Day 6	N	3	3
		Mean	4.20	43.6
		SD	1.513	98.05
		Median	3.70	-6.3
		Min	3.00	-19.6
		Max	5.90	156.5

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: NEUTROPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	3.50	8.1
		SD	0.781	23.16
		Median	3.10	-4.3
		Min	3.00	-6.3
		Max	4.40	34.8
	Follow up	N	3	3
		Mean	3.37	-5.2
		SD	1.986	23.49
		Median	2.70	-15.6
		Min	1.80	-21.7
		Max	5.60	21.7

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 106 of 120)

Study Population: Safety
Parameter: NEUTROPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	3.60	
		Max	3.60	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.30	
		Max	2.30	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 107 of 120)

Study Population: Safety
Parameter: NEUTROPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	2.20	
		Max	2.20	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.60	18.2
		Max	2.60	18.2

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 108 of 120)

Study Population: Safety
Parameter: NEUTROPHILS (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.60	18.2
		Max	2.60	18.2
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	2.80	27.3
		Max	2.80	27.3

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 109 of 120)

Study Population: Safety
Parameter: NEUTROPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	58.17	
		SD	11.147	
		Median	64.30	
		Min	45.30	
		Max	64.90	
	Day -1	N	3	
		Mean	45.43	
		SD	8.871	
		Median	49.20	
		Min	35.30	
		Max	51.80	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 110 of 120)

Study Population: Safety
Parameter: NEUTROPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	51.67	
		SD	9.880	
		Median	54.80	
		Min	40.60	
		Max	59.60	
	Day 6	N	3	3
		Mean	63.13	28.6
		SD	13.724	53.92
		Median	62.20	4.4
		Min	49.90	-8.9
		Max	77.30	90.4

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 111 of 120)

Study Population: Safety
Parameter: NEUTROPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	52.00	1.3
		SD	8.062	5.97
		Median	52.50	0.3
		Min	43.70	-4.2
		Max	59.80	7.6
	Follow up	N	3	3
		Mean	54.77	4.3
		SD	16.500	13.82
		Median	61.90	11.6
		Min	35.90	-11.6
		Max	66.50	13.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 112 of 120)

Study Population: Safety
Parameter: NEUTROPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	61.10	
		Max	61.10	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	47.50	
		Max	47.50	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 113 of 120)

Study Population: Safety
Parameter: NEUTROPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	46.30	
		Max	46.30	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	52.20	12.7
		Max	52.20	12.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 114 of 120)

Study Population: Safety
Parameter: NEUTROPHILS/LEUKOCYTES (%)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	43.90	-5.2
		Max	43.90	-5.2
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	53.90	16.4
		Max	53.90	16.4

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 115 of 120)

Study Population: Safety
Parameter: PLATELET (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	164.00	
		SD	28.000	
		Median	164.00	
		Min	136.00	
		Max	192.00	
	Day -1	N	3	
		Mean	164.00	
		SD	34.395	
		Median	158.00	
		Min	133.00	
		Max	201.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 116 of 120)

Study Population: Safety
Parameter: PLATELET (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	162.67	
		SD	31.896	
		Median	154.00	
		Min	136.00	
		Max	198.00	
	Day 6	N	3	3
		Mean	157.67	-3.3
		SD	34.775	2.69
		Median	145.00	-3.7
		Min	131.00	-5.8
		Max	197.00	-0.5

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 117 of 120)

Study Population: Safety
Parameter: PLATELET (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	3	3
		Mean	181.00	12.1
		SD	35.930	19.41
		Median	196.00	2.9
		Min	140.00	-1.0
		Max	207.00	34.4
	Follow up	N	3	3
		Mean	174.67	8.1
		SD	25.027	7.02
		Median	176.00	9.6
		Min	149.00	0.5
		Max	199.00	14.3

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: PLATELET (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	266.00	
		Max	266.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	228.00	
		Max	228.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data

Study Population: Safety
Parameter: PLATELET (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	239.00	
		Max	239.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	227.00	-5.0
		Max	227.00	-5.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-2   Summary of Hematology Data   (Page 120 of 120)

Study Population: Safety
Parameter: PLATELET (x10^9/L)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	266.00	11.3
		Max	266.00	11.3
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	229.00	-4.2
		Max	229.00	-4.2

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-3   Summary of Coagulation Data   (Page 1 of 18)

Study Population: Safety
Parameter: ACTIVATED PARTIAL THROMBOPLASTIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	28.90	
		SD	1.852	
		Median	29.00	
		Min	27.00	
		Max	30.70	
	Day -1	N	3	
		Mean	28.90	
		SD	2.707	
		Median	27.70	
		Min	27.00	
		Max	32.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 2 of 18)

Study Population: Safety
Parameter: ACTIVATED PARTIAL THROMBOPLASTIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	30.13	
		SD	3.958	
		Median	28.00	
		Min	27.70	
		Max	34.70	
	Day 6	N	3	3
		Mean	28.57	-4.8
		SD	2.401	5.06
		Median	28.00	-4.3
		Min	26.50	-10.1
		Max	31.20	0.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 3 of 18)

Study Population: Safety
Parameter: ACTIVATED PARTIAL THROMBOPLASTIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	2	2
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	26.70	-11.5
		Max	30.70	-3.6
	Follow up	N	3	3
		Mean	27.97	-6.6
		SD	1.553	6.81
		Median	27.50	-3.6
		Min	26.70	-14.4
		Max	29.70	-1.8

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 4 of 18)

Study Population: Safety
Parameter: ACTIVATED PARTIAL THROMBOPLASTIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	32.00	
		Max	32.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	42.00	
		Max	42.00	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 5 of 18)

Study Population: Safety
Parameter: ACTIVATED PARTIAL THROMBOPLASTIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	32.00	
		Max	32.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	30.70	-4.1
		Max	30.70	-4.1

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 6 of 18)

Study Population: Safety
Parameter: ACTIVATED PARTIAL THROMBOPLASTIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	33.00	3.1
		Max	33.00	3.1
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	30.50	-4.7
		Max	30.50	-4.7

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 7 of 18)

Study Population: Safety
Parameter: PROTHROMBIN INTL. NORMALIZED RATIO (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	1.00	
		SD	0.100	
		Median	1.00	
		Min	0.90	
		Max	1.10	
	Day -1	N	3	
		Mean	0.97	
		SD	0.058	
		Median	1.00	
		Min	0.90	
		Max	1.00	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 8 of 18)

Study Population: Safety
Parameter: PROTHROMBIN INTL. NORMALIZED RATIO (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	1.03	
		SD	0.058	
		Median	1.00	
		Min	1.00	
		Max	1.10	
	Day 6	N	3	3
		Mean	1.03	0.0
		SD	0.058	0.00
		Median	1.00	0.0
		Min	1.00	0.0
		Max	1.10	0.0

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data (Page 9 of 18)

Study Population: Safety
Parameter: PROTHROMBIN INTL. NORMALIZED RATIO (RATIO)

Treatment	Time point	Statistic	Result	% change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	2	2
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.00	0.0
		Max	1.10	0.0
	Follow up	N	3	3
		Mean	0.97	-6.4
		SD	0.058	5.53
		Median	1.00	-9.1
		Min	0.90	-10.0
		Max	1.00	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 10 of 18)

Study Population: Safety
Parameter: PROTHROMBIN INTL. NORMALIZED RATIO (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.00	
		Max	1.00	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.10	
		Max	1.10	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 11 of 18)

Study Population: Safety
Parameter: PROTHROMBIN INTL. NORMALIZED RATIO (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	1.00	
		Max	1.00	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.00	0.0
		Max	1.00	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 12 of 18)

Study Population: Safety
Parameter: PROTHROMBIN INTL. NORMALIZED RATIO (RATIO)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.00	0.0
		Max	1.00	0.0
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	1.00	0.0
		Max	1.00	0.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 13 of 18)

Study Population: Safety
Parameter: PROTHROMBIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Screening	N	3	
		Mean	10.87	
		SD	0.839	
		Median	11.30	
		Min	9.90	
		Max	11.40	
	Day -1	N	3	
		Mean	10.77	
		SD	0.611	
		Median	10.90	
		Min	10.10	
		Max	11.30	

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 14 of 18)

Study Population: Safety
Parameter: PROTHROMBIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	3	
		Mean	10.67	
		SD	0.643	
		Median	10.40	
		Min	10.20	
		Max	11.40	
	Day 6	N	3	3
		Mean	10.83	1.5
		SD	0.777	3.07
		Median	10.60	2.6
		Min	10.20	-1.9
		Max	11.70	3.9

* Baseline value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data (Page 15 of 18)

Study Population: Safety
Parameter: PROTHROMBIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
100 mg RDEA594 + allopurinol	Day 8	N	2	2
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	10.50	1.0
		Max	12.00	5.3
	Follow up	N	3	3
		Mean	10.60	-0.6
		SD	0.500	2.28
		Median	10.60	-1.0
		Min	10.10	-2.6
		Max	11.10	1.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 16 of 18)

Study Population: Safety
Parameter: PROTHROMBIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Screening	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	10.40	
		Max	10.40	
	Day -1	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	11.90	
		Max	11.90	

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data

Study Population: Safety
Parameter: PROTHROMBIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 1, Pre-dose*	N	1	
		Mean	NC	
		SD	NC	
		Median	NC	
		Min	10.50	
		Max	10.50	
	Day 6	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	10.40	-1.0
		Max	10.40	-1.0

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-3   Summary of Coagulation Data   (Page 18 of 18)

Study Population: Safety
Parameter: PROTHROMBIN TIME (sec)

Treatment	Time point	Statistic	Result	%change from baseline
200 mg RDEA594 + allopurinol	Day 8	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	10.40	-1.0
		Max	10.40	-1.0
	Follow up	N	1	1
		Mean	NC	NC
		SD	NC	NC
		Median	NC	NC
		Min	10.20	-2.9
		Max	10.20	-2.9

* Baseline value
NC = Not calculable
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-4 Serum Biochemistry Data Outside the Reference Range   (Page 1 of 7)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
ALANINE AMINOTRANSFERASE (IU/L)							
PPD	10-40	41.00 H	48.00 H	48.00 H	50.00 H	64.00 H	37.00
ASPARTATE AMINOTRANSFERASE (IU/L)							
PPD	10-43	33.00	41.00	55.00 H	42.00	50.00 H	33.00
BLOOD UREA NITROGEN (mmol/L)							
PPD	1.79-7.14	17.14 H	17.49 H	15.35 H	19.64 H	16.78 H	18.56 H
PPD	1.79-7.14	10.00 H	11.78 H	11.42 H	11.78 H	13.21 H	14.28 H
PPD	1.79-7.14	9.28 H	10.35 H	8.93 H	10.00 H	16.07 H	10.35 H
PPD	1.79-7.14	10.35 H	8.57 H	7.50 H	9.28 H	8.57 H	11.42 H

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-4   Serum Biochemistry Data Outside the Reference Range   (Page 2 of 7)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
C REACTIVE PROTEIN (mg/L)							
PPD	<=5	3.20	1.40	2.00	6.50 H	12.20 H	2.70
CALCIUM (mmol/L)							
PPD	2.13-2.63	2.65 H	2.73 H	2.60	2.70 H	2.73 H	2.85 H
CHLORIDE (mmol/L)							
PPD	95-110	102.00	111.00 H	104.00	102.00	101.00	101.00
CHOLESTEROL (mmol/L)							
PPD	3.24-5.18	5.05	5.39 H	5.39 H	4.64	5.08	4.92

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-4   Serum Biochemistry Data Outside the Reference Range   (Page 3 of 7)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
CHOLESTEROL (mmol/L)							
PPD	3.24-5.18	5.00	4.69	4.95	4.84	4.14	2.69 L
CORRECTED CALCIUM (mmol/L)							
PPD	2.07-2.57	2.59 H				2.67 H	
	2.09-2.59						2.81 H
	2.13-2.63		2.73 H		2.70 H		
	2.21-2.71			2.68			
CREATINE KINASE (IU/L)							
PPD	24-207	323.00 H	492.00 H	433.00 H	376.00 H	414.00 H	561.00 H

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-4   Serum Biochemistry Data Outside the Reference Range   (Page 4 of 7)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
CREATININE (mg/dL)							
PPD	0.7-1.4			1.50 H	1.60 H	1.60 H	
CYSTATIN C (nmol/L)							
PPD	39.7-71.16			101.12 H	122.09 H	116.10 H	
PPD	39.7-71.16			105.61 H	109.35 H	110.10 H	
PPD	39.7-71.16			114.60 H	124.33 H	203.73 H	
PPD	39.7-71.16			69.66	74.15 H	71.90 H	
GLUCOSE (mmol/L)							
PPD	3.33-6.38	6.33	6.88 H	6.94 H	6.22	6.38	7.16 H

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-4   Serum Biochemistry Data Outside the Reference Range   (Page 5 of 7)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
GLUCOSE (mmol/L)							
PPD	3.33-6.38	7.05 H	8.55 H	6.44 H	7.10 H	7.10 H	6.60 H
HDL CHOLESTEROL (mmol/L)							
PPD	1.04-1.55	1.04	0.93 L	1.01 L	1.09	0.96 L	0.65 L
PPD	1.04-1.55	1.32	1.42	1.42	1.32	1.58 H	1.40
LACTATE DEHYDROGENASE (IU/L)							
PPD	135-281	202.00	217.00	384.00 H	210.00	196.00	205.00

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-4   Serum Biochemistry Data Outside the Reference Range   (Page 6 of 7)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
LDL CHOLESTEROL (mmol/L)							
PPD	1.3-4.14	2.49	2.20	2.15	2.43	2.38	1.01 L
MAGNESIUM (mmol/L)							
PPD	0.55-0.95	1.00 H	1.00 H	1.05 H	0.95	0.95	1.05 H
PPD	0.55-0.95	1.10 H	1.00 H	1.05 H	1.00 H	1.00 H	1.15 H
PHOSPHATE (mmol/L)							
PPD	0.81-1.45	1.13	1.16	1.29	1.39	1.23	1.58 H
PPD	0.81-1.45	1.10	1.26	1.42	0.94	1.52 H	0.81
PPD	0.81-1.45	0.74 L	0.97	1.10	0.90	1.03	0.97

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-4   Serum Biochemistry Data Outside the Reference Range   (Page 7 of 7)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
POTASSIUM (mmol/L)							
PPD	3.5-5	3.70	3.70	4.30	3.40 L	3.40 L	3.80
PPD	3.5-5	4.10	3.80	4.10	4.30	4.30	5.30 H
TRIGLYCERIDES (mmol/L)							
PPD	0.51-2.26	3.21 H	3.37 H	3.88 H	2.86 H	1.76	2.24

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-5   Hematology Data Outside the Reference Range   (Page 1 of 3)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
ERY. MEAN CORPUSCULAR HEMOGLOBIN (pg)							
PPD	27-34	33.00	33.10	33.60	35.30 H	33.40	33.30
ERY. MEAN CORPUSCULAR VOLUME (fL)							
PPD	78-100	96.80	97.80	97.80	99.50	100.20 H	99.70
ERYTHROCYTES (x10^12/L)							
PPD	3.7-5.2	3.73	3.78	3.78	3.68 L	3.65 L	3.58 L
PPD	4-5.6	5.23	5.00	5.11	5.52	5.61 H	4.64

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-5   Hematology Data Outside the Reference Range   (Page 2 of 3)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
ERYTHROCYTES DISTRIBUTION WIDTH (%)							
PPD	11.5-14.5	14.70 H	15.20 H	15.20 H	15.50 H	14.80 H	14.80 H
PPD	11.5-14.5	14.00	14.40	14.60 H	14.90 H	15.20 H	14.90 H
PPD	11.5-14.5	15.50 H	15.30 H	14.60 H	14.60 H	14.90 H	15.20 H
PPD	11.5-14.5	14.40	15.10 H	14.30	14.80 H	15.50 H	14.90 H
LYMPHOCYTES/LEUKOCYTES (%)							
PPD	12-46	34.70	47.40 H	45.60	40.70	50.10 H	42.00
PPD	12-46	41.30	52.80 H	47.70 H	13.00	46.40 H	55.60 H

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-5   Hematology Data Outside the Reference Range   (Page 3 of 3)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
NEUTROPHILS/LEUKOCYTES (%)							
PPD	46-72	61.10	47.50	46.30	52.20	43.90 L	53.90
PPD	46-72	45.30 L	35.30 L	40.60 L	77.30 H	43.70 L	35.90 L

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-6   Coagulation Data Outside the Reference Range   (Page 1 of 1)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
ACTIVATED PARTIAL THROMBOPLASTIN TIME (sec)							
PPD	25.1-36.5	32.00	42.00 H	32.00	30.70	33.00	30.50

H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-7   Urinalysis Data Outside the Reference Range   (Page 1 of 2)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
BLOOD							
PPD	NEGATIVE	TRACE A	NEGATIVE	NEGATIVE	NEGATIVE	TRACE A	SMALL A
PPD	NEGATIVE	MODERATE A	TRACE A	TRACE A	NEGATIVE	SMALL A	SMALL A
PPD	NEGATIVE	TRACE A	TRACE A	NEGATIVE	NEGATIVE	NEGATIVE	SMALL A
LEUKOCYTE ESTERASE							
PPD	NEGATIVE	SMALL A	SMALL A	MODERATE A	SMALL A	MODERATE A	MODERATE A
PPD	NEGATIVE	NEGATIVE	TRACE A	NEGATIVE	SMALL A	NEGATIVE	SMALL A
PROTEIN (mg/dL)							
PPD	NEGATIVE	30.00 H	100.00 H	30.00 H	TRACE A	100.00 H	TRACE A

A=Abnormal, H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-7   Urinalysis Data Outside the Reference Range   (Page 2 of 2)

Study Population: Safety

Parameter Subject	Reference Range	Screening	Day -1	Day 1 Pre-dose	Day 6	Day 8	Follow Up
PROTEIN (mg/dL)							
PPD	NEGATIVE	30.00 H	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE	NEGATIVE
PPD	NEGATIVE	300.00 H	300.00 H	300.00 H	300.00 H	300.00 H	100.00 H
PPD	NEGATIVE	100.00 H	30.00 H	30.00 H	30.00 H	100.00 H	100.00 H

A=Abnormal, H=higher than the reference range, L=lower than the reference range
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS2 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ALANINE AMINOTRANSFERASE (IU/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ALANINE AMINOTRANSFERASE (IU/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ALANINE AMINOTRANSFERASE (IU/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ALBUMIN (g/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ALBUMIN (g/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ALBUMIN (g/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
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Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ALKALINE PHOSPHATASE (IU/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ALKALINE PHOSPHATASE (IU/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ALKALINE PHOSPHATASE (IU/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ASPARTATE AMINOTRANSFERASE (IU/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ASPARTATE AMINOTRANSFERASE (IU/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ASPARTATE AMINOTRANSFERASE (IU/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
BLOOD UREA NITROGEN (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	3 (100%)	1 (100%)
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	0	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
BLOOD UREA NITROGEN (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	3 (100%)	1 (100%)
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	0	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
BLOOD UREA NITROGEN (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	3 (100%)	1 (100%)
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	0	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
C REACTIVE PROTEIN (mg/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
C REACTIVE PROTEIN (mg/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
C REACTIVE PROTEIN (mg/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CALCIUM (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	1 (100%)
Normal -> Low	0	0
Normal -> Normal	3 (100%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CALCIUM (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	1 (100%)
Normal -> Low	0	0
Normal -> Normal	3 (100%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CALCIUM (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	1 (100%)
Normal -> Low	0	0
Normal -> Normal	3 (100%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CHLORIDE (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CHLORIDE (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
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Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CHLORIDE (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CHOLESTEROL (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CHOLESTEROL (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CHOLESTEROL (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	1 (33%)	0
Normal -> Normal	1 (33%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CORRECTED CALCIUM (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	1 (100%)
Normal -> Low	0	0
Normal -> Normal	3 (100%)	0

* Includes subjects with test performed at both baseline and corresponding visit
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CORRECTED CALCIUM (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	1 (100%)
Normal -> Low	0	0
Normal -> Normal	3 (100%)	0

* Includes subjects with test performed at both baseline and corresponding visit
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CORRECTED CALCIUM (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	1 (100%)
Normal -> Low	0	0
Normal -> Normal	3 (100%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CREATINE KINASE (IU/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CREATINE KINASE (IU/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CREATINE KINASE (IU/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CREATININE (mg/dL)		
Baseline to Day 6		
Subjects with the test done *	1	0
High -> High	1 (100%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	0	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CREATININE (mg/dL)		
Baseline to Day 8		
Subjects with the test done *	1	0
High -> High	1 (100%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	0	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CYSTATIN C (nmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	2 (67%)	1 (100%)
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	0	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
CYSTATIN C (nmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	2 (67%)	1 (100%)
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	0	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
DIRECT BILIRUBIN (umol/L)		
Baseline to Day 6		
Subjects with the test done *	2	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
DIRECT BILIRUBIN (umol/L)		
Baseline to Day 8		
Subjects with the test done *	2	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
DIRECT BILIRUBIN (umol/L)		
Baseline to Follow up		
Subjects with the test done *	2	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
GAMMA GLUTAMYL TRANSFERASE (IU/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
GAMMA GLUTAMYL TRANSFERASE (IU/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
GAMMA GLUTAMYL TRANSFERASE (IU/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
HDL CHOLESTEROL (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	1 (33%)	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
HDL CHOLESTEROL (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	1 (33%)	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	1 (33%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
HDL CHOLESTEROL (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	1 (33%)	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LACTATE DEHYDROGENASE (IU/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LACTATE DEHYDROGENASE (IU/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LACTATE DEHYDROGENASE (IU/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LDL CHOLESTEROL (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LDL CHOLESTEROL (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LDL CHOLESTEROL (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	1 (33%)	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MAGNESIUM (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	1 (100%)
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MAGNESIUM (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	1 (100%)
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MAGNESIUM (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	1 (33%)	1 (100%)
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PHOSPHATE (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PHOSPHATE (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PHOSPHATE (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	1 (100%)
Normal -> Low	0	0
Normal -> Normal	3 (100%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
POTASSIUM (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	1 (33%)	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
POTASSIUM (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	1 (33%)	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
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Table 14.3.2-8   Shift Table of Serum Biochemistry Data

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	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
POTASSIUM (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
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Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PROTEIN (g/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PROTEIN (g/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PROTEIN (g/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
SODIUM (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
SODIUM (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
SODIUM (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
TOTAL BILIRUBIN (umol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
TOTAL BILIRUBIN (umol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
TOTAL BILIRUBIN (umol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
TRIGLYCERIDES (mmol/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
TRIGLYCERIDES (mmol/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
TRIGLYCERIDES (mmol/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
URATE (mg/dL)		
Baseline to Day 6		
Subjects with the test done *	1	0
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	1 (100%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-8   Shift Table of Serum Biochemistry Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
URATE (mg/dL)		
Baseline to Day 8		
Subjects with the test done *	1	0
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	1 (100%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-2

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
BASOPHILS (x10^9/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
BASOPHILS (x10^9/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
BASOPHILS (x10^9/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
BASOPHILS/LEUKOCYTES (%)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
BASOPHILS/LEUKOCYTES (%)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
BASOPHILS/LEUKOCYTES (%)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
EOSINOPHILS (x10^9/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
EOSINOPHILS (x10^9/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
EOSINOPHILS (x10^9/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
EOSINOPHILS/LEUKOCYTES (%)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
EOSINOPHILS/LEUKOCYTES (%)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
EOSINOPHILS/LEUKOCYTES (%)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERY. MEAN CORPUSCULAR HEMOGLOBIN (pg)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERY. MEAN CORPUSCULAR HEMOGLOBIN (pg)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERY. MEAN CORPUSCULAR HEMOGLOBIN (pg)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERY. MEAN CORPUSCULAR HGB CONCENTRATION (g/dL)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERY. MEAN CORPUSCULAR HGB CONCENTRATION (g/dL)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERY. MEAN CORPUSCULAR HGB CONCENTRATION (g/dL)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERY. MEAN CORPUSCULAR VOLUME (fL)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERY. MEAN CORPUSCULAR VOLUME (fL)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERY. MEAN CORPUSCULAR VOLUME (fL)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERYTHROCYTES (x10^12/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	1 (33%)	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERYTHROCYTES (x10^12/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	1 (33%)	0
Normal -> Normal	1 (33%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERYTHROCYTES (x10^12/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	1 (33%)	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERYTHROCYTES DISTRIBUTION WIDTH (%)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	2 (67%)	1 (100%)
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	0	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERYTHROCYTES DISTRIBUTION WIDTH (%)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	2 (67%)	1 (100%)
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	0	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
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Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ERYTHROCYTES DISTRIBUTION WIDTH (%)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	2 (67%)	1 (100%)
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	1 (33%)	0
Normal -> Low	0	0
Normal -> Normal	0	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
HEMATOCRIT (RATIO)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
HEMATOCRIT (RATIO)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
HEMATOCRIT (RATIO)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
HEMOGLOBIN (g/dL)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
HEMOGLOBIN (g/dL)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
HEMOGLOBIN (g/dL)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LEUKOCYTES (x10^9/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LEUKOCYTES (x10^9/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LEUKOCYTES (x10^9/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LYMPHOCYTES (x10^9/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LYMPHOCYTES (x10^9/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LYMPHOCYTES (x10^9/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LYMPHOCYTES/LEUKOCYTES (%)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	1 (33%)	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LYMPHOCYTES/LEUKOCYTES (%)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	1 (100%)
Normal -> Low	0	0
Normal -> Normal	2 (67%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
LYMPHOCYTES/LEUKOCYTES (%)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	1 (33%)	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
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Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MEAN PLATELET VOLUME (fL)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
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Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MEAN PLATELET VOLUME (fL)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MEAN PLATELET VOLUME (fL)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MONOCYTES (x10^9/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MONOCYTES (x10^9/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MONOCYTES (x10^9/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MONOCYTES/LEUKOCYTES (%)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MONOCYTES/LEUKOCYTES (%)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
MONOCYTES/LEUKOCYTES (%)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
NEUTROPHILS (x10^9/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
NEUTROPHILS (x10^9/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

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Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
NEUTROPHILS (x10^9/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
NEUTROPHILS/LEUKOCYTES (%)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	1 (33%)	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
NEUTROPHILS/LEUKOCYTES (%)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	1 (33%)	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	1 (100%)
Normal -> Normal	2 (67%)	0

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
NEUTROPHILS/LEUKOCYTES (%)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	1 (33%)	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (67%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PLATELET (x10^9/L)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PLATELET (x10^9/L)		
Baseline to Day 8		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-9   Shift Table of Hematology Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PLATELET (x10^9/L)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-3

Table 14.3.2-10   Shift Table of Coagulation Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ACTIVATED PARTIAL THROMBOPLASTIN TIME (sec)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-10   Shift Table of Coagulation Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ACTIVATED PARTIAL THROMBOPLASTIN TIME (sec)		
Baseline to Day 8		
Subjects with the test done *	2	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-10   Shift Table of Coagulation Data

(Page 3 of 9)

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
ACTIVATED PARTIAL THROMBOPLASTIN TIME (sec)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-10   Shift Table of Coagulation Data

(Page 4 of 9)

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PROTHROMBIN INTL. NORMALIZED RATIO (RATIO)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-10   Shift Table of Coagulation Data

(Page 5 of 9)

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PROTHROMBIN INTL. NORMALIZED RATIO (RATIO)		
Baseline to Day 8		
Subjects with the test done *	2	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-10   Shift Table of Coagulation Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PROTHROMBIN INTL. NORMALIZED RATIO (RATIO)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-10   Shift Table of Coagulation Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PROTHROMBIN TIME (sec)		
Baseline to Day 6		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-10   Shift Table of Coagulation Data

(Page 8 of 9)

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PROTHROMBIN TIME (sec)		
Baseline to Day 8		
Subjects with the test done *	2	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	2 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.2-10   Shift Table of Coagulation Data

Study Population: Safety

	100 mg RDEA594 + allopurinol (N=3) n(%)	200 mg RDEA594 + allopurinol (N=1) n(%)
PROTHROMBIN TIME (sec)		
Baseline to Follow up		
Subjects with the test done *	3	1
High -> High	0	0
High -> Low	0	0
High -> Normal	0	0
Low -> High	0	0
Low -> Low	0	0
Low -> Normal	0	0
Normal -> High	0	0
Normal -> Low	0	0
Normal -> Normal	3 (100%)	1 (100%)

* Includes subjects with test performed at both baseline and corresponding visit
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\LABS\SAS\TLABS3 Program Run: 08APR2011 17:01 PPD
Program Status: FINAL
Reference: Listing 16.2.8-4

Table 14.3.3-1   Summary of Vital Signs Data

Study Population: Safety

Parameter: Supine Systolic Blood Pressure (mmHg)

Treatment	Statistic	Screening	Day -3 to Day -1	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	119	114	114	117	114	113	117	118
	SD	10.1	8.5	8.5	10.5	12.1	9.5	10.7	4.0
	Median	118	114	114	118	112	114	111	119
	Min	110	106	106	106	103	103	110	114
	Max	130	123	123	127	127	122	129	122
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	112	143	143	117	129	110	110	114
	Max	112	143	143	117	129	110	110	114

Reference range is 90 - 190mmHg
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-1   Summary of Vital Signs Data

(Page 2 of 10)

Study Population: Safety

Parameter: Supine Systolic Blood Pressure (mmHg)

Treatment	Statistic	Day 3 Pre-dose	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	124	121	118	120	114	114	119	122
	SD	13.6	11.0	21.6	9.8	18.9	23.2	19.5	12.3
	Median	129	120	116	123	110	111	112	117
	Min	109	110	98	109	98	93	104	113
	Max	135	132	141	128	135	139	141	136
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	117	122	127	116	116	100	113	122
	Max	117	122	127	116	116	100	113	122

Reference range is 90 - 190mmHg
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-1 Summary of Vital Signs Data

(Page 3 of 10)

Study Population: Safety

Parameter: Supine Diastolic Blood Pressure (mmHg)

Treatment	Statistic	Screening	Day -3 to Day -1	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	76	72	72	73	70	70	72	77
	SD	9.1	8.7	8.7	10.3	13.1	14.4	13.3	3.6
	Median	72	70	70	70	69	66	65	76
	Min	69	65	65	64	58	58	63	74
	Max	86	82	82	84	84	86	87	81
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	77	94	94	78	77	71	69	77
	Max	77	94	94	78	77	71	69	77

Reference range is 45 - 110mmHg
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-1   Summary of Vital Signs Data

(Page 4 of 10)

Study Population: Safety

Parameter: Supine Diastolic Blood Pressure (mmHg)

Treatment	Statistic	Day 3 Pre-dose	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	79	76	76	75	70	75	75	75
	SD	11.4	11.0	15.4	10.4	18.0	21.0	15.8	9.0
	Median	84	71	72	70	62	74	71	74
	Min	66	69	63	68	58	54	61	66
	Max	87	89	93	87	91	96	92	84
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	77	79	81	67	69	65	81	91
	Max	77	79	81	67	69	65	81	91

Reference range is 45 - 110mmHg
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-1   Summary of Vital Signs Data

(Page 5 of 10)

Study Population: Safety

Parameter: Supine Pulse Rate (bpm)

Treatment	Statistic	Screening	Day -3 to Day -1	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	61	57	57	56	63	61	61	63
	SD	2.5	2.6	2.6	2.3	5.5	8.0	7.5	9.0
	Median	61	56	56	55	60	61	61	64
	Min	58	55	55	55	59	53	53	54
	Max	63	60	60	59	69	69	68	72
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	66	62	62	57	61	67	68	63
	Max	66	62	62	57	61	67	68	63

Reference range is 40 - 100 bpm
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-1   Summary of Vital Signs Data

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Study Population: Safety

Parameter: Supine Pulse Rate (bpm)

Treatment	Statistic	Day 3 Pre-dose	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	61	66	63	69	64	63	66	66
	SD	4.2	12.3	10.8	13.0	8.0	11.1	10.3	6.1
	Median	60	63	60	62	63	61	63	69
	Min	58	56	54	61	56	53	57	59
	Max	66	80	75	84	72	75	77	70
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	55	54	56	71	64	67	63	88
	Max	55	54	56	71	64	67	63	88

Reference range is 40 - 100 bpm
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-1   Summary of Vital Signs Data

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Study Population: Safety

Parameter: Respiratory Rate (breaths/min)

Treatment	Statistic	Screening	Day -3 to Day -1	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	16	13	13	15	15	15	15	13
	SD	2.9	1.7	1.7	2.5	1.7	2.5	3.5	1.0
	Median	18	14	14	15	16	15	15	13
	Min	13	11	11	12	13	12	11	12
	Max	18	14	14	17	16	17	18	14
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	16	12	12	16	16	16	12	16
	Max	16	12	12	16	16	16	12	16

Reference range is 8 - 20 breaths/minute
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-1   Summary of Vital Signs Data

(Page 8 of 10)

Study Population: Safety

Parameter: Respiratory Rate (breaths/min)

Treatment	Statistic	Day 3 Pre-dose	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	13	15	15	15	16	16	15	14
	SD	1.2	3.1	1.0	2.1	1.2	2.0	3.2	2.6
	Median	12	14	15	14	15	16	14	13
	Min	12	12	14	13	15	14	13	12
	Max	14	18	16	17	17	18	19	17
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	16	16	16	16	16	16	16	12
	Max	16	16	16	16	16	16	16	12

Reference range is 8 - 20 breaths/minute
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-1   Summary of Vital Signs Data

(Page 9 of 10)

Study Population: Safety

Parameter: Oral Body Temperature (°C)

Treatment	Statistic	Screening	Day -3 to Day -1	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	37.0	37.0	37.0	37.0	37.0	37.0	37.0	37.0
	SD	0.12	0.26	0.26	0.12	0.26	0.06	0.21	0.12
	Median	37.0	37.0	37.0	37.0	37.0	37.0	37.0	37.0
	Min	36.5	36.3	36.3	36.5	36.5	36.6	36.6	36.7
	Max	36.7	36.8	36.8	36.7	37.0	36.7	37.0	36.9
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	36.2	36.2	36.2	36.4	36.2	36.0	36.4	36.3
	Max	36.2	36.2	36.2	36.4	36.2	36.0	36.4	36.3

Reference range is 35.0 - 37.5 °C
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-1   Summary of Vital Signs Data

(Page 10 of 10)

Study Population: Safety

Parameter: Oral Body Temperature (°C)

Treatment	Statistic	Day 3 Pre-dose	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	37.0	37.0	37.0	37.0	37.0	37.0	37.0	36.0
	SD	0.12	0.15	0.20	0.06	0.06	0.15	0.23	0.15
	Median	37.0	37.0	37.0	37.0	37.0	37.0	37.0	37.0
	Min	36.7	36.4	36.6	36.6	36.5	36.5	36.6	36.3
	Max	36.9	36.7	37.0	36.7	36.6	36.8	37.0	36.6
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	36.1	36.1	36.3	36.1	36.1	36.4	36.2	36.5
	Max	36.1	36.1	36.3	36.1	36.1	36.4	36.2	36.5

Reference range is 35.0 - 37.5 °C
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-2   Summary of Changes from Baseline (Day 1, pre-dose) in Vital Signs Data

(Page 1 of 10)

Study Population: Safety

Parameter: Supine Systolic Blood Pressure (mmHg)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose	Day 4 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	117	-3	-4	0	1	7	4
	SD	10.5	3.0	1.0	6.8	6.5	4.0	1.5
	Median	118	-3	-4	2	1	8	4
	Min	106	-6	-5	-8	-5	3	2
	Max	127	0	-3	5	8	11	5
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	117	12	-7	-7	-3	0	5
	Max	117	12	-7	-7	-3	0	5

[a] Actual Value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-2   Summary of Changes from Baseline (Day 1, pre-dose) in Vital Signs Data

(Page 2 of 10)

Study Population: Safety

Parameter: Supine Systolic Blood Pressure (mmHg)

Treatment	Statistic	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	1	3	-3	-3	2	5
	SD	11.4	2.0	9.2	13.1	10.6	5.3
	Median	-2	3	-8	-7	-2	7
	Min	-8	1	-8	-13	-6	-1
	Max	14	5	8	12	14	9
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	10	-1	-1	-17	-4	5
	Max	10	-1	-1	-17	-4	5

[a] Actual Value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-2   Summary of Changes from Baseline (Day 1, pre-dose) in Vital Signs Data

(Page 3 of 10)

Study Population: Safety

Parameter: Supine Diastolic Blood Pressure (mmHg)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose	Day 4 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	73	-2	-3	-1	4	6	4
	SD	10.3	3.2	4.2	4.0	6.7	6.7	4.2
	Median	70	-1	-4	-1	6	3	5
	Min	64	-6	-6	-5	-3	2	-1
	Max	84	0	2	3	10	14	7
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	78	-1	-7	-9	-1	-1	1
	Max	78	-1	-7	-9	-1	-1	1

[a] Actual Value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-2   Summary of Changes from Baseline (Day 1, pre-dose) in Vital Signs Data

(Page 4 of 10)

Study Population: Safety

Parameter: Supine Diastolic Blood Pressure (mmHg)

Treatment	Statistic	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	3	2	-2	2	2	2
	SD	5.1	2.1	8.1	11.1	5.6	2.0
	Median	2	3	-6	4	1	2
	Min	-1	0	-8	-10	-3	0
	Max	9	4	7	12	8	4
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	3	-11	-9	-13	3	13
	Max	3	-11	-9	-13	3	13

[a] Actual Value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-2   Summary of Changes from Baseline (Day 1, pre-dose) in Vital Signs Data

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Study Population: Safety

Parameter: Supine Pulse Rate (bpm)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose	Day 4 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	56	6	5	4	7	5	10
	SD	2.3	3.2	6.1	5.7	7.2	2.0	10.1
	Median	55	5	6	6	9	5	8
	Min	55	4	-2	-2	-1	3	1
	Max	59	10	10	9	13	7	21
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	57	4	10	11	6	-2	-3
	Max	57	4	10	11	6	-2	-3

[a] Actual Value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-2   Summary of Changes from Baseline (Day 1, pre-dose) in Vital Signs Data

(Page 6 of 10)

Study Population: Safety

Parameter: Supine Pulse Rate (bpm)

Treatment	Statistic	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	7	13	7	7	9	10
	SD	8.6	10.7	6.0	9.0	11.0	5.1
	Median	5	7	8	6	4	11
	Min	-1	6	1	-2	2	4
	Max	16	25	13	16	22	14
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	-1	14	7	10	6	31
	Max	-1	14	7	10	6	31

[a] Actual Value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-2   Summary of Changes from Baseline (Day 1, pre-dose) in Vital Signs Data

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Study Population: Safety

Parameter: Respiratory Rate (breaths/min)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose	Day 4 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	15	0	0	0	-2	-2	0
	SD	2.5	1.2	2.0	2.6	2.1	1.7	3.0
	Median	15	1	0	-1	-1	-3	0
	Min	12	-1	-2	-2	-4	-3	-3
	Max	17	1	2	3	0	0	3
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	16	0	0	-4	0	0	0
	Max	16	0	0	-4	0	0	0

[a] Actual Value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-2   Summary of Changes from Baseline (Day 1, pre-dose) in Vital Signs Data

(Page 8 of 10)

Study Population: Safety

Parameter: Respiratory Rate (breaths/min)

Treatment	Statistic	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	0	0	1	1	1	-1
	SD	2.1	2.6	2.6	2.1	3.5	3.1
	Median	1	1	2	2	1	0
	Min	-2	-3	-2	-1	-3	-4
	Max	2	2	3	3	4	2
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	0	0	0	0	0	-4
	Max	0	0	0	0	0	-4

[a] Actual Value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-2   Summary of Changes from Baseline (Day 1, pre-dose) in Vital Signs Data

(Page 9 of 10)

Study Population: Safety

Parameter: Oral Body Temperature (°C)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose	Day 4 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	37.0	0.0	0.0	0.0	0.0	0.0	0.0
	SD	0.12	0.32	0.15	0.30	0.20	0.20	0.06
	Median	37.0	0.0	0.0	0.0	0.0	0.0	0.0
	Min	36.5	-0.1	-0.1	-0.1	0.0	0.0	-0.1
	Max	36.7	0.5	0.2	0.5	0.4	0.4	0.0
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	36.4	-0.2	-0.4	0.0	-0.1	-0.3	-0.3
	Max	36.4	-0.2	-0.4	0.0	-0.1	-0.3	-0.3

[a] Actual Value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.3-2   Summary of Changes from Baseline (Day 1, pre-dose) in Vital Signs Data

(Page 10 of 10)

Study Population: Safety

Parameter: Oral Body Temperature (°C)

Treatment	Statistic	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	0.0	0.0	0.0	0.0	0.0	0.0
	SD	0.23	0.06	0.10	0.21	0.35	0.17
	Median	0.0	0.0	0.0	0.0	1.0	0.0
	Min	0.1	0.0	-0.1	-0.1	-0.1	-0.2
	Max	0.5	0.1	0.1	0.3	0.5	0.1
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	-0.1	-0.3	-0.3	0.0	-0.2	0.1
	Max	-0.1	-0.3	-0.3	0.0	-0.2	0.1

[a] Actual Value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TVITALS Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-6

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

(Page 1 of 14)

Study Population: Safety

Parameter: PR Interval (msec)

Treatment	Statistic	Screening	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	183	183	184	184	183	183	186	184
	SD	40.5	42.2	45.1	46.8	47.3	48.0	44.9	48.2
	Median	162	160	164	158	160	158	166	157
	Min	158	158	153	156	151	152	154	156
	Max	230	232	236	238	237	238	237	240
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	204	212	208	201	187	191	211	214
	Max	204	212	208	201	187	191	211	214

Reference range is 110-220 msec
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

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Study Population: Safety

Parameter: PR Interval (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	186	181	185	185	186	171	181
	SD	50.0	51.2	53.5	55.1	53.4	23.9	43.5
	Median	159	154	157	154	156	160	163
	Min	156	149	152	153	155	154	150
	Max	244	240	247	249	248	198	231
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	217	213	216	208	202	197	195
	Max	217	213	216	208	202	197	195

Reference range is 110-220 msec
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

(Page 3 of 14)

Study Population: Safety

Parameter: RR Interval (msec)

Treatment	Statistic	Screening	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	1011	1029	1017	912	944	951	984	956
	SD	52.5	54.2	71.5	69.6	105.7	73.5	63.5	76.8
	Median	1013	1042	1031	908	936	977	1020	972
	Min	957	969	940	844	842	868	911	872
	Max	1062	1075	1081	983	1053	1008	1022	1023
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	961	969	1065	1005	878	855	1007	999
	Max	961	969	1065	1005	878	855	1007	999

NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

(Page 4 of 14)

Study Population: Safety

Parameter: RR Interval (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	921	937	887	909	949	893	925
	SD	125.6	140.3	142.0	106.9	132.9	131.6	70.6
	Median	992	948	934	940	990	931	908
	Min	776	791	727	790	800	747	865
	Max	995	1071	999	997	1056	1002	1003
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	1034	1000	945	931	898	965	745
	Max	1034	1000	945	931	898	965	745

NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

(Page 5 of 14)

Study Population: Safety

Parameter: QT Interval (msec)

Treatment	Statistic	Screening	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	415	427	418	409	407	409	415	405
	SD	8.1	3.8	9.7	5.9	7.2	13.7	7.5	9.2
	Median	419	425	416	407	405	412	419	403
	Min	406	424	410	405	401	394	406	397
	Max	421	431	429	416	415	421	419	415
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	404	434	429	419	393	390	420	439
	Max	404	434	429	419	393	390	420	439

NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

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Study Population: Safety

Parameter: QT Interval (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	409	407	399	401	412	403	405
	SD	16.4	22.0	15.5	9.0	12.3	16.4	7.0
	Median	413	408	399	406	415	407	402
	Min	391	384	384	391	398	385	400
	Max	423	428	415	407	422	417	413
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	432	430	408	409	395	425	376
	Max	432	430	408	409	395	425	376

NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

(Page 7 of 14)

Study Population: Safety

Parameter: QTcB Interval (msec)

Treatment	Statistic	Screening	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	413	421	415	429	420	419	418	415
	SD	13.2	11.5	6.2	11.1	16.5	3.5	6.1	9.0
	Median	408	422	413	427	419	419	415	410
	Min	403	409	410	419	404	416	414	409
	Max	428	432	422	441	437	423	425	425
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	412	441	415	418	418	422	419	439
	Max	412	441	415	418	418	422	419	439

Reference range is <= 470 (males), <= 490 (females) msec
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

(Page 8 of 14)

Study Population: Safety

Parameter: QTcB Interval (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	428	421	426	422	424	428	421
	SD	15.2	9.2	20.8	16.2	18.0	19.9	9.0
	Median	425	419	415	419	417	432	422
	Min	414	413	413	407	410	406	412
	Max	444	431	450	439	444	445	430
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	424	430	420	424	416	433	435
	Max	424	430	420	424	416	433	435

Reference range is <= 470 (males), <= 490 (females) msec
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

(Page 9 of 14)

Study Population: Safety

Parameter: QTcF Interval (msec)

Treatment	Statistic	Screening	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	413	421	415	421	414	414	416	411
	SD	11.1	7.6	3.5	5.5	8.5	3.2	2.0	4.5
	Median	411	423	417	418	414	413	416	411
	Min	403	413	411	417	406	412	414	406
	Max	425	428	417	427	423	418	418	415
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	408	437	419	418	410	411	418	439
	Max	408	437	419	418	410	411	418	439

Reference range is <= 470 (males), <= 490 (females) msec
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

Study Population: Safety

Parameter: QTcF Interval (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	420	415	416	414	419	418	415
	SD	6.4	1.7	9.5	7.5	8.1	10.8	4.0
	Median	423	414	415	415	415	423	414
	Min	413	414	407	406	413	406	411
	Max	425	417	426	421	428	426	419
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	426	429	416	418	409	429	414
	Max	426	429	416	418	409	429	414

Reference range is <= 470 (males), <= 490 (females) msec
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

(Page 11 of 14)

Study Population: Safety

Parameter: QRS Duration (msec)

Treatment	Statistic	Screening	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	102	102	100	98	99	98	97	97
	SD	6.9	6.5	4.6	7.0	6.1	6.8	6.1	7.5
	Median	106	102	101	97	100	96	96	97
	Min	94	96	95	91	92	93	92	89
	Max	106	109	104	105	104	106	104	104
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	95	100	100	100	101	97	99	102
	Max	95	100	100	100	101	97	99	102

Reference range is <=140 msec
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

(Page 12 of 14)

Study Population: Safety

Parameter: QRS Duration (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	99	100	99	98	101	99	99
	SD	5.3	7.5	7.1	8.2	6.7	6.1	7.5
	Median	97	100	98	96	104	100	99
	Min	95	93	93	91	93	92	92
	Max	105	108	107	107	105	104	107
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	101	103	96	100	98	99	93
	Max	101	103	96	100	98	99	93

Reference range is <=140 msec
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

Study Population: Safety

Parameter: Heart Rate (bpm)

Treatment	Statistic	Screening	Day -1	Day 1 Pre-dose	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3	3
	Mean	59	58	59	66	64	63	61	62
	SD	3.0	3.1	4.0	5.0	7.5	4.7	3.8	5.1
	Median	59	57	58	65	64	61	59	61
	Min	56	55	55	61	56	59	58	58
	Max	62	61	63	71	71	68	65	68
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC	NC
	Min	62	61	56	59	68	70	59	60
	Max	62	61	56	59	68	70	59	60

Reference range is 40-100 BEATS/MIN
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-1   Summary of 12-Lead Electrocardiogram Data

Study Population: Safety

Parameter: Heart Rate (bpm)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	66	65	69	66	63	68	65
	SD	9.8	10.1	11.7	7.9	9.5	10.6	5.1
	Median	60	63	64	63	60	64	66
	Min	60	56	60	60	56	60	59
	Max	77	76	82	75	74	80	69
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	58	60	63	64	66	62	80
	Max	58	60	63	64	66	62	80

Reference range is 40-100 BEATS/MIN
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

(Page 1 of 14)

Study Population: Safety

Parameter: PR Interval (msec)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	184	0	-2	-2	1	0
	SD	45.1	4.9	2.5	4.0	0.6	6.1
	Median	164	2	-2	-1	1	3
	Min	153	-6	-4	-6	1	-7
	Max	236	3	1	2	2	4
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	208	-7	-21	-17	3	6
	Max	208	-7	-21	-17	3	6

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

(Page 2 of 14)

Study Population: Safety

Parameter: PR Interval (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	2	-3	1	1	2	-14	-3
	SD	8.7	10.2	11.8	11.5	10.0	21.2	2.0
	Median	6	1	4	0	2	-4	-3
	Min	-8	-15	-12	-10	-8	-38	-5
	Max	8	4	11	13	12	1	-1
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	9	5	8	0	-6	-11	-13
	Max	9	5	8	0	-6	-11	-13

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

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Study Population: Safety

Parameter: RR Interval (msec)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	1017	-106	-74	-66	-33	-62
	SD	71.5	15.0	86.1	40.8	24.2	5.5
	Median	1031	-98	-98	-72	-29	-59
	Min	940	-123	-145	-104	-59	-68
	Max	1081	-96	22	-23	-11	-58
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	1065	-60	-187	-210	-58	-66
	Max	1065	-60	-187	-210	-58	-66

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

(Page 4 of 14)

Study Population: Safety

Parameter: RR Interval (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	-96	-81	-131	-108	-69	-124	-92
	SD	64.3	69.5	71.7	64.5	84.7	182.1	107.4
	Median	-89	-83	-97	-141	-91	-29	-32
	Min	-164	-149	-213	-150	-140	-334	-216
	Max	-36	-10	-82	-34	25	-9	-28
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	-31	-65	-120	-134	-167	-100	-320
	Max	-31	-65	-120	-134	-167	-100	-320

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

(Page 5 of 14)

Study Population: Safety

Parameter: QT Interval (msec)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	418	-9	-11	-9	-4	-13
	SD	9.7	4.0	11.7	12.4	6.5	0.6
	Median	416	-9	-9	-16	-4	-13
	Min	410	-13	-24	-17	-10	-14
	Max	429	-5	-1	5	3	-13
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	429	-10	-36	-39	-9	10
	Max	429	-10	-36	-39	-9	10

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

(Page 6 of 14)

Study Population: Safety

Parameter: QT Interval (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	-9	-12	-19	-17	-7	-15	-13
	SD	8.5	12.9	6.2	6.2	11.0	26.1	13.8
	Median	-6	-8	-17	-19	-12	-9	-8
	Min	-19	-26	-26	-22	-14	-44	-29
	Max	-3	-1	-14	-10	6	7	-3
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	3	1	-21	-20	-34	-4	-53
	Max	3	1	-21	-20	-34	-4	-53

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

(Page 7 of 14)

Study Population: Safety

Parameter: QTcB Interval (msec)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	415	14	5	4	3	0
	SD	6.2	7.0	10.5	4.2	2.0	3.1
	Median	413	17	6	3	3	-1
	Min	410	6	-6	1	1	-3
	Max	422	19	15	9	5	3
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	415	3	3	7	4	24
	Max	415	3	3	7	4	24

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

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Study Population: Safety

Parameter: QTcB Interval (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	13	6	11	7	9	13	6
	SD	9.0	5.2	14.7	10.0	11.7	18.1	9.3
	Median	12	9	3	6	4	10	2
	Min	4	0	2	-3	0	-4	0
	Max	22	9	28	17	22	32	17
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	9	15	5	9	1	18	20
	Max	9	15	5	9	1	18	20

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

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Study Population: Safety

Parameter: QTcF Interval (msec)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	415	6	-1	-1	1	-4
	SD	3.5	5.1	5.9	6.7	4.0	2.1
	Median	417	7	-3	-4	1	-5
	Min	411	0	-5	-5	-3	-6
	Max	417	10	6	7	5	-2
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	419	-1	-9	-8	-1	20
	Max	419	-1	-9	-8	-1	20

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

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Study Population: Safety

Parameter: QTcF Interval (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	5	0	1	-1	4	3	0
	SD	3.1	3.0	7.0	4.6	6.7	7.4	2.5
	Median	6	0	-2	-2	2	6	0
	Min	2	-3	-4	-5	-2	-5	-3
	Max	8	3	9	4	11	9	2
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	7	10	-3	-1	-10	10	-5
	Max	7	10	-3	-1	-10	10	-5

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

Study Population: Safety

Parameter: QRS Duration (msec)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	100	-2	-1	-2	-3	-3
	SD	4.6	2.9	1.5	3.5	2.5	3.1
	Median	101	-4	-1	-2	-3	-4
	Min	95	-4	-3	-5	-5	-6
	Max	104	1	0	2	0	0
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	100	0	1	-3	-1	2
	Max	100	0	1	-3	-1	2

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

Study Population: Safety

Parameter: QRS Duration (msec)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	-1	0	-1	-2	1	-1	-1
	SD	2.6	3.2	3.2	4.4	3.1	3.8	3.2
	Median	0	-1	-2	-4	0	-3	-2
	Min	-4	-2	-3	-5	-2	-4	-3
	Max	1	4	3	3	4	3	3
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	1	3	-4	0	-2	-1	-7
	Max	1	3	-4	0	-2	-1	-7

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

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Study Population: Safety

Parameter: Heart Rate (bpm)

Treatment	Statistic	Day 1 Pre-dose[a]	Day 1 1 h	Day 1 2 h	Day 1 5 h	Day 2 Pre-dose	Day 3 Pre-dose
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3
	Mean	59	7	5	4	2	4
	SD	4.0	1.0	6.1	2.6	1.0	1.2
	Median	58	7	8	5	2	3
	Min	55	6	-2	1	1	3
	Max	63	8	9	6	3	5
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC
	Min	56	3	12	14	3	4
	Max	56	3	12	14	3	4

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1   Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-2   Summary of Changes from Baseline (Day 1, Predose) in 12-Lead Electrocardiogram Data

Study Population: Safety

Parameter: Heart Rate (bpm)

Treatment	Statistic	Day 4 Pre-dose	Day 5 Pre-dose	Day 5 1 h	Day 5 2 h	Day 5 5 h	Day 6	Follow up
100 mg RDEA594 + allopurinol	N	3	3	3	3	3	3	3
	Mean	7	6	10	7	5	9	6
	SD	6.2	6.1	7.8	5.0	6.5	13.6	7.0
	Median	5	5	6	8	5	2	3
	Min	2	1	5	2	-2	1	1
	Max	14	13	19	12	11	25	14
200 mg RDEA594 + allopurinol	N	1	1	1	1	1	1	1
	Mean	NC	NC	NC	NC	NC	NC	NC
	SD	NC	NC	NC	NC	NC	NC	NC
	Median	NC	NC	NC	NC	NC	NC	NC
	Min	2	4	7	8	10	6	24
	Max	2	4	7	8	10	6	24

[a] Actual value
NC = Not Calculated
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS1 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-3   Frequency of Maximum Increase from Baseline (Day 1, Predose) in 12-Lead QTcB and QTcF Intervals

(Page 1 of 1)

Study Population: Safety

Treatment	Maximum increase in QTcB Interval		Maximum increase in QTcF Interval	
	>30 ms n (%)	>60 ms n (%)	>30 ms n (%)	>60 ms n (%)
100 mg RDEA594 + allopurinol (N=3)	2 (67%)	---	---	---
200 mg RDEA594 + allopurinol (N=1)	---	---	---	---

N = Number of subjects studied
n = Number of subjects
Subjects are counted only once and are presented in the category with the greatest maximum increase
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS2 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

Table 14.3.4-4   Frequency of Maximum 12-Lead QTcB and QTcF Intervals

(Page 1 of 1)

Study Population: Safety

	QTcB Interval				QTcF Interval		
Treatment	>450 ms n (%)	>480 ms n (%)	>500 ms n (%)		>450 ms n (%)	>480 ms n (%)	>500 ms n (%)
100 mg RDEA594 + allopurinol (N=3)	1 (33%)	---	---		---	---	---
200 mg RDEA594 + allopurinol (N=1)	---	---	---		---	---	---

N = Number of subjects studied
n = Number of subjects
Subjects are counted only once and are presented in the category with the highest value
Program Location: P:\1000038\8215451\PHARMACOMETRICS\STATS\CLINICAL\SAS\TECGS2 Program Run: 08APR2011 16:59 PPD
Program Status: FINAL
Reference: Listing 16.2.8-8

APPENDIX 2

16.1 Study Information

16.1.1 Protocol

16.1.2 Sample Case Report Form

16.1.3 List of Independent Ethics Committees or Institutional Review Boards, and Consent Forms

16.1.3.1 List of Independent Ethics Committees or Institutional Review Boards

16.1.3.2 Sample Consent Form

16.1.4 List and Description of Investigators

16.1.5 Signatures of Principal or Coordinating Investigators or Sponsor's Responsible Medical Officer

16.1.6 Listing of Subjects Receiving Test Drugs from Specified Batch

16.1.7 Randomization Scheme

16.1.8 Audit Certificates

16.1.9 Documentation of Statistical Methods

16.1.10 Documentation of Inter-Laboratory Standardization Methods and Quality Assurance Procedures if Used

16.1.11 Publications Based on the Study

16.1.12 Important Publications Referenced in the Report

16.2 Subject Data Listings

16.2.1 Discontinued Subjects

16.2.2 Protocol Deviations

16.2.3 Subjects Excluded from the Analysis

16.2.4 Demographic and Baseline Characteristics Data

16.2.5 Compliance and/or Drug Concentration Data

16.2.5.1 Treatment Details

16.2.5.2 Pharmacokinetic Data

16.2.5.3 Pharmacodynamic Data

16.2.5.4 Pharmacokinetic and Bioanalytical Report

16.2.6 Individual Efficacy Response Data

16.2.7 Adverse Event Listings

16.2.8 Listing of Individual Laboratory Measurements and All Other Safety Measurements by Subject

16.3 Case Report Forms

16.3.1 Case Report Forms for Deaths, Other Serious Adverse Events and Withdrawals for Adverse Events

16.3.2 Other Case Report Forms Submitted

16.4 Individual Subject Data Listings (Not applicable)

16.5 Supportive Information

APPENDIX 3

Subject PPD

Subject Number:	PPD
Age, Sex, Race:	PPD Male, White
Randomized Study Medication:	RDEA594 100 mg PO qd
	PPD
Allopurinol:	Allopurinol 300 mg PO qd
	PPD
Gout Flare Prophylaxis:	Colchicine 0.5 mg PO qd
	PPD
sCr Elevation:	PPD
	(onset to resolution)
Did the sCr Elevation Resolve?	Yes
Maximum sCr Elevation:	≥ 1.5 x Baseline
Was the sCr Elevation Associated With an SAE?	No
Was the sCr Elevation Associated With a TEAE Leading to Randomized Study Medication Discontinuation?	No

Subject PPD was a PPD White male with gout enrolled in Study RDEA594-204 and randomized to **RDEA594 100 mg in combination with allopurinol 300 mg**, which was higher than the protocol specified dose. The subject had a past medical history that was significant for chronic, moderate renal failure that started in PPD and was ongoing at the time of study entry. Relevant concomitant medications that were ongoing at study entry included lisinopril 20 mg qd. The subject had an elevated sCr 36 hours after receiving his final dose of RDEA594 on Day 5, which increased 48 hours after the Day 5 dose, and further increased to ≥ 1.5 x Baseline (defined as the subject's highest sCr value between Day -14 and Day 1) 72 hours after the Day 5 dose. The subject's sCr resolved to ≤ 1.2 x Baseline at the Follow-Up Visit on Day 13.

The Investigator did not report any TEAEs associated with the sCr elevation and the subject completed the study on Day 13.

Medical History

Medical History	Approximate Start Date	Approximate Stop Date
HIGH BLOOD PRESSURE/ARTERIAL HYPERTENSION (IDIOPATHIC)	-----PPD	Ongoing
RETINOPATHIA (HYPERTENSIVE)	-----PPD	Ongoi
ANEMIA (IRON DEFICIENCY)	-----PPD	-----PPD
OBESITY	-----PPD	Ongoi
HYDROPS RIGHT KNEE	-----PPD	-----PPD
ARTHRITIS RIGHT KNEE	-----PPD	-----PPD
ARTHRITIS OF ANKLE AND FOOT BILATERAL	-----PPD	-----PPD
HYPERCHOLESTEROLEMIA	--PPD	Ongoi
MALARIA	--PPD	-----PPD
GOUT	--PPD	Ongoi
PROSTATIC HYPERTROPHY (BENIGN)	--PPD	Ongoing
RENAL FAILURE (CHRONIC, MODERATE) PROTEINURIA AND ALBUMINURIA SINCE 2001	-----PPD	Ongoing
EDEMA (PULMONARY) ACUTE	-----PPD	-----PPD

Renal Laboratory Results

Visit	Date	Chemistry sCr[d] (mg/dL)	GFR (mL/min)	BUN (mmol/L)	K (mmol/L)	Blood	Urinalysis Leukocyte Esterase	Spec Grav	Protein[e] (mg/dL)
Screening	PPD	1.9	46.0	9.28 H	3.70	TRACE	NEGATIVE	1.018	300.00 H
Day -1 (0 hours)	PPD	1.9		10.35 H	3.70	TRACE	NEGATIVE	1.018	300.00 H
6 hours		2.0[a]							
12 hours		1.9							
24 hours		1.8							
Day 1 (predose)	PPD	1.8		8.93 H	4.30	NEGATIVE	NEGATIVE	1.019	300.00 H
Predose mean		1.8							
6 hours		1.8							
12 hours		1.7							
Day 2 (predose)	PPD	1.8							

| | | Chemistry | | | | Urinalysis | | | |
| | | sCr[d] | GFR | BUN | K | | Leukocyte | | Protein[e] |
Visit	Date	(mg/dL)	(mL/min)	(mmol/L)	(mmol/L)	Blood	Esterase	Spec Grav	(mg/dL)
Day 3 (predose)	PPD	1.8							
Day 4 (predose)	PPD	1.8							
Day 5 (predose)	PPD	1.7							
6 hours		1.7							
12 hours		1.7							
24 hours (Day 6)		1.9		10.00 H	3.40 L	NEGATIVE	NEGATIVE	1.021	300.00 H
36 hours		2.1							
48 hours (Day 7)		2.5							
72 hours (Day 8)		3.1[b]		16.07 H	3.40 L	NEGATIVE	NEGATIVE	1.027	300.00 H
Follow-up	PPD	2.2[c]		10.35 H	3.80	SMALL	NEGATIVE	1.014	100.00 H

Abbreviations: BUN, blood u_____; GFR, glomerular filtration rate; K, potassium; sCr, serum creatinine; Spec Grav, specific gravity.

[a] Baseline sCr value, where Baseline is defined as the highest sCr value recorded ≤ 14 days prior to the first dose of randomized study medication.

[b] sCr elevation ≥ 1.5 x Baseline.

[c] Resolution of sCr elevation.

[d] sCr values were obtained from the PD samples.

[e] Protein laboratory assessment performed by dipstick.

Notes: GFR estimate using Cockcroft Gault CrCl based on ideal body weight.