

Experiment Number: K07076

Route: Gavage, IV

Species/Strain: Rats/F344

Toxicokinetics Data Summary

Compound: 2-Methyltetrahydrofuran /Analyte: 2-Methyltetrahydrofuran

CAS Number: 96-47-9

Request Date: 7/12/2023

Request Time: 2:40:16

Lab: Battelle Columbus

Male

Treatment Group (mg/kg)

2.5 IV Plasma<sup>b,j</sup>

10 IV Plasma<sup>c</sup>

40 IV Plasma<sup>d,j</sup>

k10 (min <sup>-1</sup> )	0.0741 ± 0.0077	0.0676 ± 0.0242	
k10 Half-life (min)	9.35 ± 0.97	10.2 ± 3.7	
k12 (min <sup>-1</sup> )	0.05 ± 0.022	0.258 ± 0.234	0.0843 ± 0.0851
k21 (min <sup>-1</sup> )	0.0727 ± 0.0298	0.264 ± 0.08	0.0949 ± 0.0672
Cl (L/min/kg)	40.7 ± 1.9	22 ± 0.9	
V1 (mL/kg)	549 ± 55	325 ± 120	601 ± 166
V2(mL/kg)	378 ± 86	317 ± 97	
AUC <sub>0-T</sub> (ug mL <sup>-1</sup> min)	62.5	475	3830
AUC <sub>inf_pred</sub> (ug mL <sup>-1</sup> min)	61.4 ± 2.9	455 ± 19	3830

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Male

Treatment Group (mg/kg)

10 Gavage Plasma<sup>e</sup>

30 Gavage Plasma<sup>e</sup>

100 Gavage Plasma<sup>f,k</sup>

400 Gavage Plasma<sup>f,l</sup>

	10 Gavage Plasma <sup>e</sup>	30 Gavage Plasma <sup>e</sup>	100 Gavage Plasma <sup>f,k</sup>	400 Gavage Plasma <sup>f,l</sup>
Cmax_pred (ug/mL)	4.89 ± 0.32	21.1 ± 1.8	46.8 ± 4.6	201 ± 15
Tmax_pred (min)	16 ± 1.3	33.1 ± 3.5		
Cmax_obs (ug/L)	4.95 ± 0.98	18.2 ± 1.0	47.6 ± 1.9	228 ± 51
Tmax_obs (minute)	15	15	20	5
k01 (minute <sup>-1</sup> )	0.0945 ± 0.0172	0.0516 ± 0.0146	0.219 ± 0.088	0.691 ± 1.103
k01 Half-life (min)	7.34 ± 1.34	13.4 ± 3.8	3.17 ± 1.28	1.00 ± 1.60
k10 (minute <sup>-1</sup> )	0.0388 ± 0.0025	0.0158 ± 0.0031		
k10 Half-life (min)	17.8 ± 1.2	43.8 ± 8.5		
Cl <sub>1_F</sub> (mL/min/kg)	42.7 ± 2.8	13.3 ± 1		
V <sub>1_F</sub> (L/kg)	1100 ± 130	844 ± 176	499 ± 57	490 ± 39
AUC <sub>0-T</sub> (ug mL <sup>-1</sup> min)			10000	73100
AUC <sub>inf_pred</sub> (mg*min/L)	234 ± 15	2250 ± 180	10000	74300

Experiment Number: K07076

Route: Gavage, IV

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Toxicokinetics Data Summary

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CAS Number: 96-47-9

Request Date: 7/12/2023

Request Time: 2:40:16

Lab: Battelle Columbus

Female

Treatment Group (mg/kg)

2.5 IV Plasma<sup>g</sup>

10 IV Plasma<sup>h</sup>

40 IV Plasma<sup>d,n</sup>

k10 (min <sup>-1</sup> )	0.0829 ± 0.0045	0.0873 ± 0.0222	
k10 Half-life (min)	8.36 ± 0.45	7.94 ± 2.01	
k12 (min <sup>-1</sup> )	0.0112 ± 0.0021	0.299 ± 0.163	0.0534 ± 0.06
K21 (min <sup>-1</sup> )	0.0274 ± 0.0072	0.256 ± 0.041	0.0783 ± 0.075
Cl1 (L/min/kg)	46.9 ± 1.6	26.1 ± 0.8	
V1 (L/kg)	565 ± 40	299 ± 79	565 ± 137
V2 (mL/kg)	231 ± 40	349 ± 59	
AUC <sub>0-T</sub> (mg*min/L)	53.6	402	3110
AUC <sub>inf_pred</sub> (mg*min/L)	53.3 ± 1.8	384 ± 11	3110

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Route: Gavage, IV

Species/Strain: Rats/F344

Toxicokinetics Data Summary

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CAS Number: 96-47-9

Request Date: 7/12/2023

Request Time: 2:40:16

Lab: Battelle Columbus

Female

Treatment Group (mg/kg)

10 Gavage Plasma<sup>e</sup>

30 Gavage Plasma<sup>e</sup>

100 Gavage Plasma<sup>f,o</sup>

400 Gavage Plasma<sup>f,p</sup>

Cmax_pred (ug/mL)	3.52 ± 0.38	21.4 ± 1.4	51.1 ± 4.0	196 ± 18
Tmax_pred (min)	11.3 ± 2.5	23.5 ± 2.0		
Cmax_obs (ug/mL)	4.09 ± 0.76	19.1 ± 2.7	54.3 ± 8.8	237 ± 36
Tmax_obs (minute)	4	20	10.3	4.33
k01 (min <sup>-1</sup> )	0.194 ± 0.081	0.0710 ± 0.0137	0.436 ± 0.333	0.752 ± 0.912
k01 Half-life (min)	3.56 ± 1.49	9.76 ± 1.88	1.59 ± 1.21	0.922 ± 1.117
k10 (min <sup>-1</sup> )	0.0304 ± 0.0068	0.0230 ± 0.0021		
k10 Half-life (min)	22.8 ± 5.1	30.1 ± 2.7		
Cl1_F (mL/min/kg)	61.2 ± 8	18.8 ± 1.2		
V1_F (L/kg)	2010 ± 400	816 ± 106	280 ± 25	301 ± 28
AUC_0-T (ug mL <sup>-1</sup> min)			8540	69300
AUCinf_pred (mg*min/L)	164 ± 21	1600 ± 100	8540	70000

Experiment Number: K07076

Route: Gavage, IV

Species/Strain: Rats/F344

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Lab: Battelle Columbus

Male

Treatment Group (mg/kg)

2.5 IV Brain<sup>a</sup>

10 IV Brain<sup>a</sup>

40 IV Brain<sup>a</sup>

Cmax_obs (mg/L)	2.61 ± 0.55	9.86 ± 0.88	35.1 ± 3.4
Tmax_obs (minute)	7	7	11
Half-life (minute)	16.1	24.3	44.5
AUC_0-T (ug g <sup>-1</sup> min)	69.7	474	2750
AUCinf_pred (ug g <sup>-1</sup> min)	70.6	476	2810

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Male

Treatment Group (mg/kg)

10 Gavage Brain<sup>a</sup>

30 Gavage Brain<sup>a</sup>

100 Gavage Brain<sup>a,m</sup>

400 Gavage Brain<sup>a</sup>

Cmax_obs (ug/g)	3.44 ± 1.10	15.3 ± 1.3	57.4 ± 16.3	165 ± 25
Tmax_obs (minute)	19	28	96	26
Half-life (minute)	18.6	38.9	33.5	124
AUC_0-T (ug g <sup>-1</sup> min)	150	1130	12900	53000
AUCinf_pred (ug g <sup>-1</sup> min)	151	1180	12900	54700

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Route: Gavage, IV

Species/Strain: Rats/F344

Toxicokinetics Data Summary

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CAS Number: 96-47-9

Request Date: 7/12/2023

Request Time: 2:40:16

Lab: Battelle Columbus

Female

Treatment Group (mg/kg)

2.5 IV Brain<sup>a</sup>

10 IV Brain<sup>a</sup>

40 IV Brain<sup>a</sup>

Cmax_obs (ug/mL)	2.05 ± 0.39	8.83 ± 1.83	43.40 ± 6.3
Tmax_obs (minute)	7	9	10
Half-life (minute)	13.5	21.1	30.5
AUC_0-T (ug g <sup>-1</sup> min)	51.0	475	2650
AUCinf_pred (ug g <sup>-1</sup> min)	51.2	476	2660

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Toxicokinetics Data Summary

Request Date: 7/12/2023

Route: Gavage, IV

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Request Time: 2:40:16

Species/Strain: Rats/F344

CAS Number: 96-47-9

Lab: Battelle Columbus

Female

Treatment Group (mg/kg)

10 Gavage Brain<sup>a</sup>

30 Gavage Brain<sup>a</sup>

100 Gavage Brain<sup>a</sup>

400 Gavage Brain<sup>a</sup>

Cmax_obs (ug/mL)	3.32 ± 0.52	11.0 ± 4.1	60.3 ± 6.4	209 ± 24
Tmax_obs (minute)	12	24	12	10
Half-life (minute)	18.2	23.2	31.3	146
AUC_0-T (ug g <sup>-1</sup> min)	139	792	7320	46400
AUCinf_pred (ug g <sup>-1</sup> min)	140	800	7330	47200



Experiment Number: K07076

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## LEGEND

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### MODELING SOFTWARE

WinNonlin Version 4.0 and 5.0.1

### MODELING METHOD & BEST FIT MODEL

<sup>a</sup>WinNonlin, Noncompartmental analysis

<sup>b</sup>WinNonlin, Two-compartment model with first order elimination; C(2min)obs 3.61 SD 0.12, C(2min)pred 3.58 SE 0.22

<sup>c</sup>WinNonlin, Two-compartment model with first order elimination; C(2min)obs 18.8 SD 3.1, C(2min)pred 18.4 SE 1.0

<sup>d</sup>WinNonlin, Two-compartment model with Michaelis-Menten elimination. IV data sets were modeled using WinNonlin library compartmental and Michaelis-Menten (MM) models. In addition, a two-compartment MM model was written and compiled using WinNonlin code for higher IV dosage groups. For the MM model, the WinNonlin output did not include calculations for the AUC. In order to obtain AUC values, the data sets (average concentration versus target time point) were analyzed using NCA. The equations used included:  $K_m = C_0 / \ln [C_0^*/C_0]$  and  $V_{max} = k \cdot V_d \cdot K_m$ . Where  $K_m$  is the Michaelis-Menten (MM) constant ( $\mu\text{g/mL}$ ),  $C_0$  is the concentration ( $\mu\text{g/mL}$ ) at time 0 and (\*) back-extrapolated concentration at time 0,  $V_{max}$  is the maximum velocity or metabolic rate ( $\mu\text{g/min}$ ),  $k$  is the terminal linear slope (1/min), and  $V_d$  is the volume of distribution (mL).

<sup>e</sup>WinNonlin, Calculated based on a one-compartment model with first order input and output

<sup>f</sup>A two-compartment Michaelis-Menten model was written and compiled using WinNonlin code, Two-compartment model with Michaelis-Menten elimination.

<sup>g</sup>WinNonlin, Two-compartment model with first order elimination; C(2min)obs 3.94 SD 0.32, C(2min)pred 3.67 SE 0.22

<sup>h</sup>WinNonlin, Two-compartment model with first order elimination; C(2min)obs 18.3 SD 2.0, C(2min)pred 18.1 SE 0.6

**Experiment Number:** K07076

**Route:** Gavage, IV

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**Toxicokinetics Data Summary**

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EXCEPTIONS

MALE

<sup>i</sup>AUC 0-T is NCA observed AUC

<sup>j</sup>Estimate for V<sub>2</sub> lacked precision and was not sufficiently reliable to report. Non-compartmental analysis does not calculate a

<sup>k</sup>NCA was used to determine AUC values, V<sub>max</sub> 0.162 SE 0.033 ug/min, K<sub>m</sub> 5.87 SE 2.22 ug/mL

<sup>l</sup>NCA was used to determine AUC values, V<sub>max</sub> 0.316 SE 0.078 ug/min, K<sub>m</sub> 10.7 SE 14.1 ug/mL

<sup>m</sup>T<sub>max</sub>-Similar concentrations were observed from 20 to 90 minutes

FEMALE

<sup>n</sup>Estimate for V<sub>2</sub> lacked precision and was not sufficiently reliable to report. Non-compartmental analysis does not calculate a standard error (SE) for AUC 360 min and AUC infinity fitted. C(2min)<sub>obs</sub> is 60.3 SD 11.3, C(2min)<sub>pred</sub> is 62.7 SE 9.6 ug/mL, V<sub>max</sub> is 1.03 SE 0.65 ug/min, K<sub>m</sub> is 19.6 SE 18.4 ug/mL.

<sup>o</sup>NCA was used to determine AUC values, V<sub>max</sub> 0.217 SE 0.031 ug/min, K<sub>m</sub> 7.62 SE 1.53 ug/mL

<sup>p</sup>NCA was used to determine AUC values, V<sub>max</sub> 0.304 SE 0.096 ug/min, K<sub>m</sub> 11.1 SE 19.8 ug/mL

ANALYTE

2-Methyltetrahydrofuran

**Experiment Number:** K07076

**Route:** Gavage, IV

**Species/Strain:** Rats/F344

**Toxicokinetics Data Summary**

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**CAS Number:** 96-47-9

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TK PARAMETERS

C<sub>max</sub> = Observed or Predicted Maximum plasma (or tissue) concentration

T<sub>max</sub> = Time at which C<sub>max</sub> predicted or observed occurs

Half-life =  $\lambda_z$  Half life,  $t_{1/2}$ , the terminal elimination half-life based on non-compartmental analysis

k<sub>01</sub> = Absorption rate constant, k<sub>a</sub>

k<sub>01</sub> Half-life = Half-life of the absorption process to the central compartment

k<sub>10</sub> = Elimination rate constant from the central compartment also k<sub>e</sub> or k<sub>elim</sub>

k<sub>10</sub> Half-life = Half-life for the elimination process from the central compartment

k<sub>12</sub> = Distribution rate constant from first to second compartment

k<sub>21</sub> = Distribution rate constant from second to first compartment

Cl<sub>1</sub> = Clearance, includes total clearance

Cl<sub>1\_F</sub> = Apparent clearance of the central compartment, also Cl<sub>1\_F</sub> for gavage groups in non-compartmental model

V<sub>1</sub> = Volume of distribution of the central compartment, includes V<sub>d</sub> and V volume of distribution, V<sub>z</sub> apparent volume of distribution NCA,  
V<sub>app</sub> apparent volume of distribution for intravenous studies

V<sub>1\_F</sub> = Apparent volume of distribution for the central compartment includes V<sub>d\_F</sub>, V<sub>F</sub> for oral groups, and V<sub>c\_F</sub>

V<sub>2</sub> = Volume of distribution for the peripheral compartment

AUC<sub>0-T</sub> = Area under the plasma concentration versus time curve, AUC, from time t<sub>i</sub> (initial) to t<sub>f</sub> (final), AUC<sub>last</sub>

AUC<sub>inf\_pred</sub> = Area under the plasma concentration versus time curve, AUC, extrapolated to time equals infinity

**Experiment Number:** K07076  
**Route:** Gavage, IV  
**Species/Strain:** Rats/F344

**Toxicokinetics Data Summary**  
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## TK PARAMETERS PROTOCOL

### ANALYSIS METHOD

Plasma and brain MTHF concentrations were measured using a validated headspace capillary gas chromatography method with mass selective detection (GC/MSD) for the low range and a validated headspace capillary GC method with flame ionization detection (FID) for the high range.

### TK\_INTRAVENTOUS BRAIN

#### 2.5 mg/kg Female and Male

Fischer 344 rats were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 2.5 mg/kg via a jugular catheter in males and females. Blood samples were collected at 10 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 5, 10, 15, 20, 30, 45, 60, 75, and 90 minutes.

#### 10 mg/kg Female and Male

Fischer 344 rats were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 10 mg/kg via a jugular catheter in males and females. Blood samples were collected at 10 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 5, 10, 15, 20, 30, 60, 90, 120, and 180 minutes.

#### 40 mg/kg Female and Male

Fischer 344 rats were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 40 mg/kg via a jugular catheter in males and females. Blood samples were collected at 9 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 7, 12, 30, 45, 90, 120, 240, and 360 minutes.

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TK PARAMETERS PROTOCOL (cont'd)

TK\_GAVAGE BRAIN

10 mg/kg Female and Male

Fischer 344 male and female rats were given a single gavage administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 10 mg/kg. Blood samples were collected at 12 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 4, 8, 10, 15, 20, 30, 45, 60, 90, 120, and 150 minutes. Values reported to three significant figures except for T max. Non-compartmental analysis output was used to determine AUC values.

30 mg/kg Female and Male

Fischer 344 male and female rats were given a single gavage administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 30 mg/kg. Blood samples were collected at 12 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 4, 8, 10, 15, 20, 30, 45, 60, 90, 120, and 180 minutes. Values reported to three significant figures except for T max. Non-compartmental analysis output was used to determine AUC values..

100 mg/kg Female and Male

Fischer 344 males and female rats were given a single gavage administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 100 mg/kg. Blood samples were collected at 9 time points post-administration. Three animals per species per sex were sampled at each time point except for 720 minutes which had two male or female animals. Time points were 5, 10, 20, 45, 90, 240, 360, 480, and 720 minutes. Values reported to three significant figures, except for T max. Non-compartmental analysis output was used to determine AUC values. Non-compartmental analysis does not calculate a standard error for AUC values and for TmaxObs.

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**Experiment Number:** K07076

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**Species/Strain:** Rats/F344

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TK PARAMETERS PROTOCOL (cont'd)

400 mg/kg Female and Male

Fischer 344 males and female rats were given a single gavage administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 400 mg/kg. Blood samples were collected at 9 time points post-administration. Three animals per species per sex were sampled at each time point except for 360 minutes which had two male or female animals. Time points were 5, 10, 20, 45, 90, 240, 360, 480, and 720 minutes. Values reported to three significant figures, except for T max. Non-compartmental analysis output was used to determine AUC values. Non-compartmental analysis does not calculate a standard error for AUC values and for TmaxObs.

TK\_INTRAVENTOUS PLASMA

2.5 mg/kg Female and Male

Fischer 344 rats were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 2.5 mg/kg via a jugular catheter in males and females. Blood samples were collected at 10 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 5, 10, 15, 20, 30, 45, 60, 75, and 90 minutes.

10 mg/kg Female and Male

Fischer 344 rats were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 10 mg/kg via a jugular catheter in males and females. Blood samples were collected at 10 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 5, 10, 15, 20, 30, 60, 90, 120, and 180 minutes.

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TK PARAMETERS PROTOCOL (cont'd)

40 mg/kg Female and Male

Fischer 344 rats were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 40 mg/kg via a jugular catheter in males and females. Blood samples were collected at 9 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 7, 12, 30, 45, 90, 120, 240, and 360 minutes.

TK\_GAVAGE PLASMA

10 mg/kg Female and Male

Fischer 344 male and female rats were given a single gavage administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 10 mg/kg. Blood samples were collected at 12 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 4, 8, 10, 15, 20, 30, 45, 60, 90, 120, and 150 minutes. Values reported to three significant figures except for T max. Non-compartmental analysis output was used to determine AUC values.

30 mg/kg Female and Male

Fischer 344 male and female rats were given a single gavage administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 30 mg/kg. Blood samples were collected at 12 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 4, 8, 10, 15, 20, 30, 45, 60, 90, 120, and 180 minutes. Values reported to three significant figures except for T max. Non-compartmental analysis output was used to determine AUC values.

**Experiment Number:** K07076

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TK PARAMETERS PROTOCOL (cont'd)

100 mg/kg Female and Male

Fischer 344 males and female rats were given a single gavage administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 100 mg/kg. Blood samples were collected at 9 time points post-administration. Three animals per species per sex were sampled at each time point except for 720 minutes which had two male or female animals. Time points were 5, 10, 20, 45, 90, 240, 360, 480, and 720 minutes. Values reported to three significant figures, except for T max. Non-compartmental analysis output was used to determine AUC values. Non-compartmental analysis does not calculate a standard error for AUC values and for TmaxObs.

400 mg/kg Female and Male

Fischer 344 males and female rats were given a single gavage administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 100 mg/kg. Blood samples were collected at 9 time points post-administration. Three animals per species per sex were sampled at each time point except for 360 minutes which had two male or female animals. Time points were 5, 10, 20, 45, 90, 240, 360, 480, and 720 minutes. Values reported to three significant figures, except for T max. Non-compartmental analysis output was used to determine AUC values. Non-compartmental analysis does not calculate a standard error for AUC values and for TmaxObs.