

Experiment Number: K07076  
Route: Gavage, IV  
Species/Strain: Mouse/B6C3F1

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)

20 IV Plasma<sup>b</sup>

40 IV Plasma<sup>c</sup>

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

80 IV Plasma<sup>e,n</sup>

k10 (min <sup>-1</sup> )	0.190 ± 0.011	0.15 ± 0.004		
k10 Half-life (min)	3.64 ± 0.21	4.62 ± 0.13		
Cl (L/min/kg)	146 ± 8	104 ± 11		
V1 (L/kg)	768 ± 57	694 ± 89	976 ± 219	712 ± 110
AUC <sub>0-T</sub> (mg*min/L)	148	374	374	1210
AUC <sub>inf_pred</sub> (mg*min/L)	137 ± 7	384 ± 42	374	1210

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Treatment Group (mg/kg)

20 Gavage Plasma<sup>j</sup>

100 Gavage Plasma<sup>k</sup>

400 Gavage Plasma<sup>j</sup>

Cmax_pred (ug/mL)	5.65 ± 0.88	66.4 ± 6.1	342 ± 38
Tmax_pred (min)	2.95 ± 0.78	9.34 ± 0.65	11 ± 2
Cmax_obs (ug/L)	5.37 ± 1.86	75.3 ± 19.8	299 ± 152
Tmax_obs (minute)	2	7	15
k01 (minute <sup>-1</sup> )	0.677 ± 0.299	0.107 ± 0.007	0.200 ± 0.060
k01 Half-life (min)	1.02 ± 0.45	6.48 ± 0.45	3.47 ± 1.04
k10 (minute <sup>-1</sup> )	0.138 ± 0.008	0.107 ± 0.007	0.0326 ± 0.0019
k10 Half-life (min)	5.02 ± 0.28	6.48 ± 0.45	21.3 ± 1.2
Cl <sub>1_F</sub> (mL/min/kg)	325 ± 32	59.3 ± 5.5	26.7 ± 2.8
V <sub>1_F</sub> (L/kg)	2360 ± 300	554 ± 51	820 ± 120
AUC <sub>0-T</sub> (ug mL <sup>-1</sup> min)	60.4	1610	13800
AUC <sub>inf_pred</sub> (mg*min/L)	61.5 ± 6.1	1690 ± 160	15000 ± 1500

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Female

Treatment Group (mg/kg)

10 IV Plasma<sup>f</sup>

20 IV Plasma<sup>g</sup>

40 IV Plasma<sup>h</sup>

40 IV Plasma<sup>i,o</sup>

k10 (min <sup>-1</sup> )	0.280 ± 0.018	0.202 ± 0.008	0.193 ± 0.007	
k10 Half-life (min)	2.47 ± 0.16	3.42 ± 0.13	3.58 ± 0.13	
Cl (L/min/kg)	159 ± 9	144 ± 5	77.2 ± 10.3	
V1 (L/kg)	569 ± 49	710 ± 35	399 ± 64	908 ± 126
AUC_0-T (mg*min/L)	67.4	151	374	374
AUCinf_pred (mg*min/L)	62.7 ± 3.4	139 ± 5	518 ± 69	374

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Female

Treatment Group (mg/kg)

20 Gavage Plasma<sup>j</sup>

100 Gavage Plasma<sup>k</sup>

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

Cmax_pred (ug/mL)	4.25 ± 0.61	57.8 ± 5.1	177 ± 17
Tmax_pred (min)	3.55 ± 0.59	9.25 ± 0.63	
Cmax_obs (ug/L)	5.11 ± 2.12	46.6 ± 12	206 ± 68
Tmax_obs (minute)	4	15	7
k01 (minute <sup>-1</sup> )	0.461 ± 0.144	0.108 ± 0.007	0.664 ± 0.267
k01 Half-life (min)	1.50 ± 0.47	6.41 ± 0.44	1.04 ± 0.42
k10 (minute <sup>-1</sup> )	0.157 ± 0.009	0.108 ± 0.007	
k10 Half-life (min)	4.42 ± 0.26	6.41 ± 0.44	
Cl <sub>1_F</sub> (mL/min/kg)	424 ± 42	68.8 ± 6.4	
V <sub>1_F</sub> (L/kg)	2700 ± 350	637 ± 57	2080 ± 230
AUC <sub>0-T</sub> (ug mL <sup>-1</sup> min)	48.3	1390	10900
AUC <sub>inf_pred</sub> (mg*min/L)	47.2 ± 4.7	1450 ± 130	

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Male

Treatment Group (mg/kg)

20 IV Brain<sup>a</sup>

40 IV Brain<sup>a</sup>

80 IV Brain<sup>a</sup>

	20 IV Brain <sup>a</sup>	40 IV Brain <sup>a</sup>	80 IV Brain <sup>a</sup>
Cmax_obs (mg/L)	32.0 ± 5.7	33.5 ± 11.5	75.2 ± 19.5
Tmax_obs (minute)	6	9	7
Half-life (minute)	5.07	3.68	5.63
AUC_0-T (ug g <sup>-1</sup> min)	620	1280	2410
AUCinf_pred (ug g <sup>-1</sup> min)	620	1290	2410

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Male

Treatment Group (mg/kg)

20 Gavage Brain<sup>a</sup>

100 Gavage Brain<sup>a</sup>

400 Gavage Brain<sup>a</sup>

Cmax_obs (ug/g)	3.35 ± 1.29	41.7 ± 14.3	122 ± 35
Tmax_obs (minute)	8	13	21
Half-life (minute)	4.47	9.20	14.9
AUC_0-T (ug g <sup>-1</sup> min)	41.1	1070	7180
AUCinf_pred (ug g <sup>-1</sup> min)	41.2	1070	7190

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Female

Treatment Group (mg/kg)

10 IV Brain<sup>a</sup>

20 IV Brain<sup>a</sup>

<sup>a</sup>40 IV Brain<sup>a</sup>

Cmax_obs (ug/mL)	13.8 ± 2.0	12.8 ± 0.8	22.0 ± 2.5
Tmax_obs (minute)	6	6	9
Half-life (minute)	4.62	5.81	4.27
AUC_0-T (ug g <sup>-1</sup> min)	344	364	548
AUCinf_pred (ug g <sup>-1</sup> min)	345	364	554

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CAS Number: 96-47-9

Lab: Battelle Columbus

Female

Treatment Group (mg/kg)

20 Gavage Brain<sup>a</sup>

100 Gavage Brain<sup>a</sup>

400 Gavage Brain<sup>a</sup>

Cmax_obs (ug/mL)	4.16 ± 1.41	42.4 ± 16.6	110 ± 38
Tmax_obs (minute)	8	23	13
Half-life (minute)	4.43	7.19	11.7
AUC_0-T (ug g <sup>-1</sup> min)	37.2	1260	7170
AUCinf_pred (ug g <sup>-1</sup> min)	37.2	1260	7180



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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, One-compartment model with first order elimination. C(2min)obs 18.2 SD 4.9, C(2min)pred 17.8 SE 1.1

<sup>c</sup>WinNonlin, Calculated using one-compartment model with bolus input and first-order elimination. 1/Yhat2 weighting was used.

<sup>d</sup>WinNonlin Michaelis-Menten model, Calculated using a Michaelis-Menten one-compartment model (1/Yhat2 weighting). Trapezoidal method was used to calculate AUCs.

<sup>e</sup>WinNonlin Michaelis-Menten model, One-compartment with Michaelis-Menten elimination. Trapezoidal method was used to calculate AUCs.

<sup>f</sup>WinNonlin, One-compartment model with first order elimination. C(2min)obs 10.3 SD 2.2, C(2min)pred 10.0 SE 0.6

<sup>g</sup>WinNonlin, One-compartment model with first order elimination. C(2min)obs 18.5 SD 2.1, C(2min)pred 18.8 SE 0.7

<sup>h</sup>WinNonlin, Calculated using one-compartment model with bolus input and first-order elimination. 1/Yhat2 weighting was used

<sup>i</sup>WinNonlin, Calculated using a Michaelis-Menten one-compartment model (1/Yhat2 weighting). Trapezoidal method was used to calculate AUCs.

<sup>j</sup>WinNonlin, Calculated using a one-compartment model with first order absorption and elimination.

<sup>k</sup>WinNonlin, Calculated using one-compartment model with the same rate constants for first order input and output.

<sup>l</sup>WinNonlin Michaelis-Menten model; Calculated using a Michaelis-Menten one-compartment model.

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EXCEPTIONS

MALE

<sup>m</sup>NCA was used to determine AUC values, no aberrant values, C(2min)obs 36.5 SD 6.5, C(2min)pred 33.5 SE 6.0 Vmax 11.7 SE 12.0 ug/min, Km 79.0 SE 83.1 ug/mL

<sup>n</sup>NCA was used to determine AUC values, C(2min)obs 96.3 SD 13.8, C(2min)pred 98.3 SE 13.7 ug/mL, Vmax 14.9 SE 6.8 ug/min, Km 116 SE 56 ug/mL

FEMALE

<sup>o</sup>NCA was used to determine AUC values, no aberrant values, C(2min)obs 36.9 SD 5.6, C(2min)pred 36.9 SE 64.5 ug/mL, Vmax 5.97 SE 1.90 ug/min, Km 26.9 SE 9.2 ug/mL

<sup>p</sup>NCA was used to determine AUC values, Vmax 2.76 SE 1.14 ug/min, Km 49.0 SE 40.5 ug/MI

ANALYTE

2-Methyltetrahydrofuran

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#### TK PARAMETERS

Cmax = Observed or Predicted Maximum plasma (or tissue) concentration

Tmax = Time at which Cmax predicted or observed occurs

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

k01 = Absorption rate constant, ka

k01 Half-life = Half-life of the absorption process to the central compartment

k10 = Elimination rate constant from the central compartment also ke or kelim

k10 Half-life = Half-life for the elimination process from the central compartment

Cl = Clearance, includes total clearance

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

V1 = Volume of distribution of the central compartment, includes Vd and V volume of distribution, Vz apparent volume of distribution NCA,  
Vapp apparent volume of distribution for intravenous studies

V1<sub>F</sub> = Apparent volume of distribution for the central compartment includes Vd<sub>F</sub>, V<sub>F</sub> for oral groups, and Vc<sub>F</sub>

AUC<sub>0-T</sub> = Area under the plasma concentration versus time curve, AUC, from time ti (initial) to tf (final), AUClast

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

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## TK PARAMETERS PROTOCOL

### ANALYSIS METHOD

Values reported to three significant figures, except for T max. 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. Bodyweight range values are for the Gavage-Phase 2 Repeat animal pool at dosing (20 mg/kg dose group only).

### TK\_INTRA VENOUS PLASMA

#### 20 mg/kg Male

B6C3F1 mice were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 20 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, 25, 30, 40, 50, and 60 minutes.

#### 40 mg/kg Male

B6C3F1 mice 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, 5, 10, 15, 20, 45, 60, 90, and 150 minutes. The 40 mg/kg intravenous plasma values were modeled in two ways (Model 1 one-compartment and two compartment Michaelis-Menten model).

#### 80 mg/kg Male

Male B6C3F1 mice were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 80 mg/kg via a jugular catheter. Blood samples were collected at 10 time points post-administration. Three animals were sampled at each time point. Time points were 2, 5, 10, 15, 20, 25, 30, 45, 60, and 75 minutes.

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#### TK PARAMETERS PROTOCOL (cont'd)

##### 10 mg/kg Female

Female B6C3F1 mice 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. Blood samples were collected at 8 time points post-administration. Three animals were sampled at each time point. Time points were 2, 5, 10, 15, 20, 25, 30, and 40 minutes. AUC(obs.) values were calculated using mean plasma concentration time values and trapezoidal method. Non-compartmental analysis does not calculate a standard error for AUC.

##### 20 mg/kg Female

B6C3F1 mice were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 20 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, 25, 30, 40, 50, and 60 minutes.

##### 40 mg/kg Female

B6C3F1 mice 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, 5, 10, 15, 20, 45, 60, 90, and 150 minutes. The 40 mg/kg intravenous plasma values were modeled in two ways (Model 1 one-compartment and two compartment Michaelis-Menten model).

#### TK\_GAVAGE PLASMA

##### 20 mg/kg Female and Male

B6C3F1 male and female mice were given a single gavage administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 20 mg/kg. Blood samples were collected at 11 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, and 120 minutes. Values reported to three significant figures, except for T max.

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#### TK PARAMETERS PROTOCOL (cont'd)

##### 100 mg/kg Female and Male

B6C3F1 male and female mice 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 8 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 7, 15, 30, 45, 60, 90, and 120 minutes. Values reported to three significant figures, except for T max.

##### 400 mg/kg Female and Male

B6C3F1 male and female mice 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 8 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 7, 15, 45, 60, 90, 120, and 180 minutes. Values reported to three significant figures, except for T max.

#### TK\_INTRAVENOUS BRAIN

##### 20 mg/kg Male

B6C3F1 mice were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 20 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, 25, 30, 40, 50, and 60 minutes.

#### TK\_INTRAVENOUS BRAIN

##### 40 mg/kg Male

B6C3F1 mice 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, 5, 10, 15, 20, 45, 60, 90, and 150 minutes.

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#### TK PARAMETERS PROTOCOL (cont'd)

##### TK\_INTRAVENOUS BRAIN

###### 40 mg/kg Male

B6C3F1 mice 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, 5, 10, 15, 20, 45, 60, 90, and 150 minutes.

###### 80 mg/kg Male

Male B6C3F1 mice were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 80 mg/kg via a jugular catheter. Blood samples were collected at 10 time points post-administration. Three animals were sampled at each time point. Time points were 2, 5, 10, 15, 20, 25, 30, 45, 60, and 75 minutes.

###### 10 mg/kg Female

Female B6C3F1 mice 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. Blood samples were collected at 8 time points post-administration. Three animals were sampled at each time point. Time points were 2, 5, 10, 15, 20, 25, 30, and 40 minutes. AUC(obs.) values were calculated using mean plasma concentration time values and trapezoidal method. Non-compartmental analysis does not calculate a standard error for AUC.

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##### 20 mg/kg Female

B6C3F1 mice were given a single intravenous (IV) administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 20 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, 25, 30, 40, 50, and 60 minutes.

##### 40 mg/kg Female

B6C3F1 mice 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, 5, 10, 15, 20, 45, 60, 90, and 150 minutes.

#### TK\_GAVAGE BRAIN

##### 20 mg/kg Female and Male

B6C3F1 male and female mice were given a single gavage administration of 2-Methyltetrahydrofuran (MTHF) in Milli-Q Water at a dosage of 20 mg/kg. Blood samples were collected at 11 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, and 120 minutes. Values reported to three significant figures, except for T max.

##### 100 mg/kg Female and Male

B6C3F1 male and female mice 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 8 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 7, 15, 30, 45, 60, 90, and 120 minutes. Values reported to three significant figures, except for T max.



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TK PARAMETERS PROTOCOL (cont'd)

400 mg/kg Female and Male

B6C3F1 male and female mice 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 8 time points post-administration. Three animals per species per sex were sampled at each time point. Time points were 2, 7, 15, 45, 60, 90, 120, and 180 minutes. Values reported to three significant figures, except for T max.