Experiment Number: S0548
Route: IV, Gavage
Species/Strain: Mouse/B6C3F1

Toxicokinetics Data Summary
Compound: Sodium Nitrite / **Analyte:** Nitrite
CAS Number: 7632-00-0

Request Date: 7/11/2023
Request Time: 10:03:16
Lab: Midwest Research Institute

Male

	Treatment Group (mg/kg)		
	20 IV Plasma[a]	**62.5 Gavage Plasma[a]**	**125 Gavage Plasma[a]**
Cmax_pred (ug/mL)	20	34	54
Tmax_pred (min)		6.1	11
k01 Half-life (min)		1.5	2.5
k10 Half-life (min)	14	21	39
V1 (mL)	19	28	51
AUCinf_pred (ug min/mL)	418	1240	3640
F (percent)		95	140

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Female

	Treatment Group (mg/kg)		
	20 IV Plasma[a]	**62.5 Gavage Plasma[a]**	**125 Gavage Plasma[a]**
Cmax_pred (ug/mL)	18	23	52
Tmax_pred (min)		7.2	14
k01 Half-life (min)		1.7	3.3
k10 Half-life (min)	15	26	50
V1 (mL)	16	29	53
AUCinf_pred (ug min/mL)	394	4540	1040
F (percent)		85	180

LEGEND

MODELING SOFTWARE

PCNONLIN

MODELING METHOD & BEST FIT MODEL

[a]PCNONLIN Statistical Consultants, Inc., Lexington, KY, One compartment model

ANALYTE

Nitrite

TK PARAMETERS

Cmax_pred = Observed or Predicted Maximum plasma (or tissue) concentration
Tmax_pred = Time at which Cmax predicted or observed occurs
k01 Half-life = Half-life of the absorption process to the central compartment
k10 Half-life = Half-life of the absorption process to the central compartment
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
AUCinf_pred = Area under the plasma concentration versus time curve, AUC, extrapolated to time equals infinity
F = Bioavailability, absolute bioavailability

TK PARAMETERS PROTOCOL

ANALYSIS METHOD

Blood collection time points for this group are 2, 5, 10, 15, 20, 30, 45, 60, 75, and 90 minutes post-dose.

TK_INTRAVENOUS PLASMA

20 mg/kg Male and Female

A single intravenous dose of 20 mg/kg was given per study via lateral tail vein. Toxicokinetic analyses were performed using the average concentration for each time point. The data were modeled using nonlinear regression analysis (PCNONLIN, Statistical Consultants, Inc., Lexington, KY). The nitrite data was modeled using compartmental models.

ANALYSIS METHOD

Blood collection time points for this group are 2, 5, 10, 15, 30, 45, 60, 90, 120, and 150 minutes post-dose.

TK_GAVAGE PLASMA

62.5 mg/kg Male and Female

A single oral gavage dose of 62.5 mg/kg was given per study. Toxicokinetic analyses were performed using the average concentration for each time point. The data were modeled using nonlinear regression analysis (PCNONLIN, Statistical Consultants, Inc., Lexington, KY). The nitrite data was modeled using compartmental models.

TK PARAMETERS PROTOCOL (cont'd)

ANALYSIS METHOD

Blood collection time points for this group are 2, 5, 10, 15, 30, 60, 90, 120, 180, and 240 minutes post-dose.

TK_GAVAGE PLASMA

125 mg/kg Male and Female

A single oral gavage dose of 125 mg/kg was given per study. Toxicokinetic analyses were performed using the average concentration for each time point. The data were modeled using nonlinear regression analysis (PCNONLIN, Statistical Consultants, Inc., Lexington, KY). The nitrite data was modeled using compartmental models.