**Experiment Number:** S0548
**Route:** Gavage, IV
**Species/Strain:** Rat/Fischer 344

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

**Date Report Requested:** 12/02/2016
**Time Report Requested:** 11:52:24
**Lab:** Midwest Research Institute

**Male**

| | **Treatment Groups (mg/kg)** | | | | | |
|---|---|---|---|---|---|---|
| | **40 [a, #]** | **40 [b, *]** | **80 [a, #]** | **80 [b, *]** | **20 IV [a, #]** | **20 IV [c, *]** |
| | **Plasma** | | | | | |
| $C_{max}$ | 18.8 percent | 2.5 ug/mL | 40.1 percent | 11 ug/mL | 26.3 percent | 35 ug/mL |
| $T_{max}$ (minute) | 60.0 | 8.8 | 120.0 | 17.0 | 45.0 | |
| $t_{1/2}$ (minute) | 50 | | 75 | | 53 | |
| $t_{1/2(Alpha)}$ (minute) | | | | | | 1.5 |
| $t_{1/2(Beta)}$ (minute) | | | | | | 52.0 |
| $t_{1/2(k01)}$ (minute) | | 79 | | 2.9 | | |
| $t_{1/2(k10)}$ (minute) | | 1.5 | | 144 | | 9.1 |
| $k_{12}$ (min^-1) | | | | | | 0.32 |
| $k_{21}$ (min^-1) | | | | | | 0.081 |
| $V_1$ (mL) | | 15.0 | | 1400.0 | | 91.0 |
| MRT (minute) | 117 | | 171 | | 94 | |
| $AUC_{0-t}$ (percent min) | 2620 | | 10500.0 | | 3260 | |
| $AUC_{inf}$ (ug*min/mL) | | 308.0 | | 2550.0 | | 454.0 |
| F (percent) | | 34.0 | | 140.0 | | |

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| | Female | | | | | |
|---|---|---|---|---|---|---|
| | Treatment Groups (mg/kg) | | | | | |
| | **40 [a, #]** | **40 [b, *]** | **80 [a, #]** | **80 [b, *]** | **20 IV [a, #]** | **20 IV [b, *]** |
| | Plasma | | | | | |
| $C_{max}$ | 31.5 percent | 12 ug/mL | 65.9 percent | 32 ug/mL | 25.8 percent | 11 ug/mL |
| $T_{max}$ (minute) | 60.0 | 13.0 | 120.0 | 28.0 | 45.0 | |
| $t_{1/2}$ (minute) | 73 | | 81 | | 82 | |
| $t_{1/2(k01)}$ (minute) | | 3.7 | | 8.4 | | |
| $t_{1/2(k10)}$ (minute) | | 35 | | 60 | | 49 |
| $V_1$ (mL) | | 140 | | 250 | | 200 |
| MRT (minute) | 125 | | 186 | | 130 | |
| $AUC_{0-t}$ (percent min) | 5480 | | 16400.0 | | 4340 | |
| $AUC_{inf}$ (ug*min/mL) | | 770 | | 3840 | | 796 |
| F (percent) | | 52 | | 130 | | |

LEGEND

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Data are displayed as a mean value

MODELING METHOD & BEST FIT MODEL

[a] PCNONLIN Statistical Consultants, Inc., Lexington, KY; Non compartmental (NCA) model

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

[c] PCNONLIN Statistical Consultants, Inc., Lexington, KY; Two compartmental model

ANALYTE

[#] Methemoglobin

* Nitrite

TK PARAMETERS

$C_{max}$ = Observed or Predicted Maximum plasma (or tissue) concentration

$T_{max}$ = Time at which $C_{max}$ predicted or observed occurs

$t_{½}$ = Lambda$_z$ half-life, $t_{1/2}$, the terminal elimination half-life based on non-compartmental analysis

$t_{½(alpha)}$ = Half-life for the alpha phase

$t_{½(beta)}$ = Half-life for the beta phase

$t_{1/2(k01)}$ = Half-life of the absorption process to the central compartment

$t_{1/2(k10)}$ = Half-life for the elimination process from the central compartment

$k_{12}$ = Distribution rate constant from first to second compartment etc.

$k_{21}$ = Distribution rate constant from second to first compartment etc.

$V_1$ = Volume of distribution of the central compartment, includes $V_d$ and $V_{volume}$ of distribution, $V_z$ apparent volume of distribution NCA, $V_{app}$ apparent volume of distribution for intravenous studies

MRT = Mean residence time

$AUC_{0-t}$ = Area under the plasma concentration versus time curve, AUC, from time $t_i$ (initial) to $t_f$ (final), $AUC_{last}$

$AUC_{inf}$ = Area under the plasma concentration versus time curve, AUC, extrapolated to time equals infinity

F = Bioavailability, absolute bioavailability

** END OF REPORT **