

**Study Number:** C16010

**Test Type:** TOX

**Route:** Dosing in Water

**Species/Strain:** Rat/Sprague Dawley

**Study Number:**

**Study Gender:**

**PWG Approval Date:**

**Version:**

**PA44: Urinalysis Data Summary**

**Test Compound:** Nicotine Bitartrate Dihydrate

**CAS Number:** 6019-06-3

C16010

Both

See web page for date of PWG Approval

v1.2.0

**Date Report Requested:** 04/15/2021

**Time Report Requested:** 13:10:47

**Lab:** NTP

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**Male**

**Treatment Groups**

	Phase Day	0 mg/L	1.56 mg/L	3.12 mg/L	6.25 mg/L
<b>URINE CHEMISTRIES</b>					
Creatinine (mg/dL)	SD 90	71.8 ± 5.8 (5) **	73.0 ± 9.0 (5)	73.0 ± 13.2 (5)	101.4 ± 4.8 (5)
Percent of Control			101.7	101.7	141.2
Cotinine Concentration in Urine (ng/mL)	SD 90	1.6 ± 0.1 (5) **	336.7 ± 88.4 (5) **	624.4 ± 84.6 (5) **	1028.4 ± 122.6 (5) **
Percent of Control			21498.1	39872.3	65670.5
Nicotine Concentration/Creatinine (ng/mg)	SD 90	3.3 ± 1.1 (5) **	397.0 ± 95.7 (5) **	926.3 ± 222.8 (5) **	1044.6 ± 121.9 (5) **
Percent of Control			12000.6	27998.4	31571.7
Cotinine Concentration/Creatinine (ng/mg)	SD 90	2.2 ± 0.2 (5) **	456.7 ± 102.1 (5) **	976.4 ± 238.8 (5) **	1006.9 ± 98.0 (5) **
Percent of Control			20532.4	43896.2	45267.8
Nicotine Concentration in Urine (ng/mL)	SD 90	2.4 ± 0.8 (5) **	298.9 ± 88.2 (5) **	599.8 ± 96.8 (5) **	1065.8 ± 137.6 (5) **
Percent of Control			12569.4	25222.9	44819.2

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**Treatment Groups**

	Phase Day	12.5 mg/L	25 mg/L
<b>URINE CHEMISTRIES</b>			
Creatinine (mg/dL)	SD 90	91.6 ± 7.8 (5)	127.0 ± 10.4 (5) **
Percent of Control		127.6	176.9
Cotinine Concentration in Urine (ng/mL)	SD 90	2038.0 ± 393.5 (5) **	5286.0 ± 762.6 (5) **
Percent of Control		130140.5	337547.9
Nicotine Concentration/Creatinine (ng/mg)	SD 90	1999.3 ± 466.7 (5) **	3028.6 ± 501.2 (5) **
Percent of Control		60429.1	91537.4
Cotinine Concentration/Creatinine (ng/mg)	SD 90	2169.0 ± 304.0 (5) **	4237.0 ± 605.5 (5) **
Percent of Control		97508.2	190479.0
Nicotine Concentration in Urine (ng/mL)	SD 90	1935.0 ± 577.6 (5) **	3802.0 ± 658.0 (5) **
Percent of Control		81370.9	159882.3

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		Treatment Groups			
		0 mg/L	1.56 mg/L	3.12 mg/L	6.25 mg/L
Phase Day					
<b>URINE CHEMISTRIES</b>					
Creatinine (mg/dL)	SD 90	53.4 ± 5.1 (5) **	49.4 ± 2.5 (5)	47.2 ± 7.8 (5)	66.4 ± 1.9 (5)
Percent of Control			92.5	88.4	124.3
Cotinine Concentration in Urine (ng/mL)	SD 90	2.5 ± 0.2 (5) **	345.0 ± 36.9 (5) **	736.6 ± 64.9 (5) **	976.0 ± 197.7 (5) **
Percent of Control			14081.6	30065.3	39836.7
Nicotine Concentration/Creatinine (ng/mg)	SD 90	4.0 ± 0.9 (5) **	500.3 ± 46.3 (5) **	1303.1 ± 189.5 (5) **	923.6 ± 238.9 (5) **
Percent of Control			12643.6	32933.2	23340.3
Cotinine Concentration/Creatinine (ng/mg)	SD 90	4.7 ± 0.4 (5) **	705.0 ± 78.2 (5) **	1679.7 ± 196.5 (5) **	1485.5 ± 314.1 (5) **
Percent of Control			14986.6	35706.0	31577.1
Nicotine Concentration in Urine (ng/mL)	SD 90	2.1 ± 0.5 (5) **	246.8 ± 25.9 (5) **	588.2 ± 103.9 (5) **	605.8 ± 151.8 (5) **
Percent of Control			11763.6	28036.2	28875.1

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**Treatment Groups**

	Phase Day	12.5 mg/L	25 mg/L
<b>URINE CHEMISTRIES</b>			
Creatinine (mg/dL)	SD 90	57.8 ± 3.8 (5)	100.6 ± 11.4 (5) **
Percent of Control		108.2	188.4
Cotinine Concentration in Urine (ng/mL)	SD 90	2046.0 ± 298.6 (5) **	5836.0 ± 455.3 (5) **
Percent of Control		83510.2	238204.1
Nicotine Concentration/Creatinine (ng/mg)	SD 90	2237.4 ± 476.3 (5) **	2977.5 ± 335.9 (5) **
Percent of Control		56543.4	75247.5
Cotinine Concentration/Creatinine (ng/mg)	SD 90	3528.2 ± 404.1 (5) **	6014.6 ± 602.7 (5) **
Percent of Control		75000.1	127855.2
Nicotine Concentration in Urine (ng/mL)	SD 90	1339.8 ± 375.0 (5) **	2922.0 ± 357.9 (5) **
Percent of Control		63860.8	139275.5

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#### LEGEND

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Values given as mean  $\pm$  SEM (N) with Percent of Control calculated by (dosed group mean / control group mean) x 100

SD – Study Day

Statistical analysis were performed by Jonckheere (trend) and Shirley or Dunn (pairwise) tests.

No statistical analyses were performed on graded or qualitative endpoints.

Values below the limit of detection (LOD) were substituted with 1/2 the LOD value.

If 80% or more of the values in a dose group were below the LOD, no statistical analysis was performed.

Statistical significance for the control group indicates a significant trend test

Statistical significance for a treatment group indicates a significant pairwise test compared to the vehicle control group

\* Statistically significant at  $P \leq 0.05$

\*\* Statistically significant at  $P \leq 0.01$

**\*\* END OF REPORT \*\***