

Study Number: C12010-01
Test Type: TOX
Route: Oral Gavage
Species/Strain: Rat/Harlan Sprague Dawley

PA10 Subchronic: Statistical Analysis of Non-Neoplastic Lesions
Test Compound: Drometrizole
CAS Number: 2440-22-4
Target Version: Actions To Be Taken

Date Report Requested: 06/29/2023
Time Report Requested: 12:52:29
Lab: Battelle

Study Number:

C12010-01

Study Sex:

Male

PWG Approval Date:

See web page for date of PWG Approval

Version:

v1.5.1

Stat Version:

v3.0.2A

Study Version Details:

Actions To Be Taken: Change Nephropathy, Chronic-Progressive to Chronic Progressive Nephropathy (3)

Male					
	Treatment Groups (mg/kg)				
	0	30	100	300	1000
Disposition Summary					
Animals Initially In Study	5	5	5	5	5
Censored					
Early Deaths					
Survivors					
Scheduled Sacrifice, Terminal	5	5	5	5	5
Number Animals Examined Microscopically	5	5	5	5	5
ALIMENTARY SYSTEM					
LIVER	(5)	(5)	(5)	(5)	(5)
HEPATOCYTE; HYPERTROPHY	0 **		2 (40%)	1 (20%)	4 (80%) *
CARDIOVASCULAR SYSTEM					
None					
ENDOCRINE SYSTEM					
None					
GENERAL BODY SYSTEM					
None					
GENITAL SYSTEM					
None					
HEMATOLYMPHOID SYSTEM					
None					
INTEGUMENTARY SYSTEM					
None					

Male					
Treatment Groups (mg/kg)					
	0	30	100	300	1000
MUSCULOSKELETAL SYSTEM					
None					
NERVOUS SYSTEM					
None					
RESPIRATORY SYSTEM					
None					
SPECIAL SENSES SYSTEM					
None					
URINARY SYSTEM					
KIDNEY	(5)	(5)	(5)	(5)	(5)
CHRONIC PROGRESSIVE NEPHROPATHY	2 (40%)	1 (20%)	1 (20%)		2 (40%)

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LEGEND

Censored animals are animals not in one of the other disposition categories that are removed prior to the end of the study. The censored animals are included in the pathology data if microscopic examination of tissues was performed.

In the rows with the tissue names, the number of animals examined for each tissue is shown in parentheses.

In the rows with the lesion names, the number of animals with observation are reported with percent incidence in parentheses. If none of the animals examined have the specific lesion, there is a blank for that dose group for that specific lesion. The exception to this is if statistical significance is found for a lesion and the control group has no animals with the lesion; in that case a 0 is included for the control group on the table for that lesion.

Statistical analysis performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) one-sided tests.

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 ****