

Study Number: R12103B

Test Type: Teratology

Route: Oral Gavage

Species/Strain: Rat/Harlan Sprague Dawley

C Number:

Study Gender:

PWG Approval Date

R11: Fetal Defect Summary

Test Compound: Vinpocetine

CAS Number: 42971-09-5

R12103B

Female

See web page for date of PWG Approval

Date Report Requested: 11/13/2019

Time Report Requested: 15:12:13

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	F0 Female			
	Treatment Groups (mg/kg/day)			
	0	5	20	60
All Exams				
No. Fetuses	293	239	261	51
No. Litters	21	19	21	8
Malformation				
Affected fetuses	20 (6.83) ** ##	23 (9.62)	35 (13.41) ** #	15 (29.41) ** ##
Affected litters	12 (57.14)	13 (68.42)	17 (80.95)	4 (50.00)
Variation				
Affected fetuses	42 (14.33) ** ##	44 (18.41)	78 (29.89) ** ##	20 (39.22) ** ##
Affected litters	18 (85.71)	17 (89.47)	18 (85.71)	6 (75.00)
Gross Finding				
Affected fetuses	0 (0.00)	1 (0.42)	1 (0.38)	0 (0.00)
Affected litters	0 (0.00)	1 (5.26)	1 (4.76)	0 (0.00)
External				
No. Fetuses	293	239	261	51
No. Litters	21	19	21	8
Malformation				
Affected fetuses	0 (0.00)	1 (0.42)	4 (1.53) *	0 (0.00)
Affected litters	0 (0.00)	1 (5.26)	4 (19.05)	0 (0.00)

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	F0 Female			
	Treatment Groups (mg/kg/day)			
	0	5	20	60
	Visceral			
No. Fetuses	293	239	261	51
No. Litters	21	19	21	8
Malformation				
Affected fetuses	19 (6.48)	18 (7.53)	23 (8.81)	3 (5.88)
Affected litters	12 (57.14)	12 (63.16)	13 (61.90)	3 (37.50)
Variation				
Affected fetuses	10 (3.41)	15 (6.28)	16 (6.13)	2 (3.92)
Affected litters	7 (33.33)	11 (57.89)	9 (42.86)	2 (25.00)
Gross Finding				
Affected fetuses	0 (0.00)	1 (0.42)	1 (0.38)	0 (0.00)
Affected litters	0 (0.00)	1 (5.26)	1 (4.76)	0 (0.00)
	Head			
No. Fetuses	150	125	134	29
No. Litters	21	19	20	8
Malformation				
Affected fetuses	0 (0.00)	1 (0.80)	0 (0.00)	0 (0.00)
Affected litters	0 (0.00)	1 (5.26)	0 (0.00)	0 (0.00)
Variation				
Affected fetuses	0 (0.00)	0 (0.00)	1 (0.75)	0 (0.00)
Affected litters	0 (0.00)	0 (0.00)	1 (5.00)	0 (0.00)

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	F0 Female			
	Treatment Groups (mg/kg/day)			
	0	5	20	60
Skeletal - Body				
No. Fetuses	293	239	261	47
No. Litters	21	19	21	7
Malformation				
Affected fetuses	2 (0.68) ** ##	6 (2.51)	12 (4.60) **	13 (27.66) ** ##
Affected litters	2 (9.52)	4 (21.05)	4 (19.05)	3 (42.86)
Variation				
Affected fetuses	31 (10.58) ** ##	31 (12.97)	61 (23.37) ** ##	19 (40.43) ** ##
Affected litters	15 (71.43)	10 (52.63)	17 (80.95)	5 (71.43)
Skeletal - Skull				
No. Fetuses	143	114	124	20
No. Litters	21	19	21	5
Variation				
Affected fetuses	1 (0.70)	1 (0.88)	3 (2.42)	0 (0.00)
Affected litters	1 (4.76)	1 (5.26)	3 (14.29)	0 (0.00)

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LEGEND

Upper row denotes number of affected fetuses (%) and lower row the number of affected litters (%)

Trend and pairwise significance levels are determined using one-sided tests.

Statistical analysis for litter data and for fetal data ignoring the litter effects were performed by Cochran-Armitage (trend) and Fisher Exact (pairwise) tests.

* Statistically significant at $P \leq 0.05$

** Statistically significant at $P \leq 0.01$

Statistical analysis for fetal data including litter effects was performed by using a Generalized Linear Mixed Model, where the Dam ID was the random effect for both trend and pairwise analysis.

Statistically significant at $P \leq 0.05$ (litter based analysis)

Statistically significant at $P \leq 0.01$ (litter based analysis)

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

**** END OF REPORT ****