

Experiment Number: F46736

Test Type: Genetic Toxicology - Micronucleus

Route: Gavage

Species/Strain: Mouse/B6C3F1

G04: In Vivo Micronucleus Summary Data

Test Compound: Emtricitabine (FTC)

CAS Number: 143491-57-0

Date Report Requested: 09/21/2018

Time Report Requested: 16:39:33

NTP Study Number:

F46736

Study Duration:

4 Days

Study Methodology:

Flow Cytometry

Male Study Result:

Positive

Female Study Result:

Positive

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Tissue: Blood; Sex: Male; Number of Treatments: 4; Time interval between final treatment and cell sampling: 24 h

Dose (mg/kg)	N	MN PCE/1000		N	MN NCE/1000		% PCE	
		Mean ± SEM	p-Value		Mean ± SEM	p-Value	Mean ± SEM	p-Value
Vehicle Control ¹	5	2.320 ± 0.197		5	1.538 ± 0.023		1.362 ± 0.081	
1000.0	5	2.720 ± 0.283	0.1305	5	1.530 ± 0.026	0.7932	1.352 ± 0.072	0.9448
1500.0	5	3.160 ± 0.312	0.0154 *	5	1.425 ± 0.048	0.8667	1.302 ± 0.081	0.9421
2000.0	5	3.710 ± 0.141	< 0.001 *	5	1.670 ± 0.034	0.0082 *	1.374 ± 0.057	0.9688
Trend p-Value		< 0.001 *			0.1653		0.9466	
Positive Control ²	5	14.770 ± 1.203	< 0.001 *	5	1.803 ± 0.033	< 0.001 *	0.894 ± 0.153	0.0214 *

Trial Summary: Positive

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Tissue: Blood; Sex: Female; Number of Treatments: 4; Time interval between final treatment and cell sampling: 24 h

Dose (mg/kg)	N	MN PCE/1000		N	MN NCE/1000		% PCE	
		Mean ± SEM	p-Value		Mean ± SEM	p-Value	Mean ± SEM	p-Value
Vehicle Control ¹	5	2.250 ± 0.220		5	1.276 ± 0.049		1.098 ± 0.086	
1500.0	5	2.840 ± 0.247	0.0557	5	1.153 ± 0.033	0.8386	1.140 ± 0.154	0.9806
Trend p-Value		0.0559			0.9653		0.9805	
Positive Control ²	5	10.800 ± 0.508	< 0.001 *	5	1.423 ± 0.055	0.0403	0.809 ± 0.062	0.0219 *

Trial Summary: Positive

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Tissue: Blood; Sex: Female; Number of Treatments: 4; Time interval between final treatment and cell sampling: 24 h

Dose (mg/kg)	N	MN PCE/1000		N	MN NCE/1000		% PCE	
		Mean ± SEM	p-Value		Mean ± SEM	p-Value	Mean ± SEM	p-Value
Vehicle Control ¹	5	2.040 ± 0.147		5	1.094 ± 0.033		1.554 ± 0.114	
750.0	5	2.670 ± 0.266	0.0233 *	5	1.119 ± 0.019	0.8895	1.521 ± 0.081	0.9573
1000.0	5	2.900 ± 0.157	0.0054 *	5	1.104 ± 0.043	1.0000	1.555 ± 0.085	0.9958
1500.0	5	3.415 ± 0.232	< 0.001 *	5	1.139 ± 0.019	0.5886	1.248 ± 0.106	0.0439
Trend p-Value		< 0.001 *			0.2724		0.0675	
Positive Control ²	5	15.470 ± 0.498	0.0045 *	5	1.489 ± 0.054	< 0.001 *	0.953 ± 0.135	0.0119 *

Trial Summary: Positive

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LEGEND

MN = micronucleated, PCE = polychromatic erythrocyte, NCE = normochromatic erythrocyte

CAS Number = Chemical Abstracts Service registry number

N = Number of subjects

Values given as Mean or Mean \pm Standard Error Mean

Pairwise comparison with the control group; values are significant at $P \leq 0.025$ by Williams or Dunn's test

Dose-related trend; significant at $P \leq 0.025$ by linear regression or Jonckheere's test

* Statistically significant pairwise or trend test

1: Vehicle Control: Corn Oil

2: 25.0 mg/kg Cyclophosphamide

**** END OF REPORT ****