

Experiment Number: **G10334**

Test Type: **Genetic Toxicology - Bacterial
Mutagenicity**

G06: Ames Summary Data

Test Compound: **Nelfinavir**

CAS Number: **159989-64-7**

Date Report Requested: **08/12/2021**

Time Report Requested: **10:45:38**

NTP Study Number:

G10334

Study Result:

Negative

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CAS Number: 159989-64-7

Strain: TA100

Dose (ug/Plate)	Without S9	Without S9	Without S9	With 10% Rat S9	With 10% Rat S9
Vehicle Control ¹	108 ± 3.3	102 ± 3.2	100 ± 14.3	105 ± 4.2	97 ± 8.3
10.0	114 ± 12.4	101 ± 4.7			
20.0	112 ± 7.3	99 ± 1.9		89 ± 4.3	82 ± 4.7
50.0	108 ± 6.2	93 ± 7.4		91 ± 4.6	84 ± 4.1
125.0	101 ± 9.2	130 ± 2.0		108 ± 5.1	104 ± 12.3
250.0	120 ± 4.8	96 ± 8.2 ^p		96 ± 7.6	95 ± 4.7
500.0	88 ± 11.3 ^p	92 ± 3.3 ^p	71 ± 3.8 ^p	70 ± 9.9	59 ± 4.6 ^p
750.0			49 ± 1.3 ^x		
1000.0					
1500.0			38 ± 4.8 ^x	68 ± 4.9 ^p	69 ± 0.9 ^p
2000.0					
2500.0					
3000.0			32 ± 3.3 ^x		
6000.0			17 ± 9.8 ^x		
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control ²	857 ± 14.7	862 ± 40.8	528 ± 27.8		
Positive Control ³					
Positive Control ⁴				1847 ± 138.6	2181 ± 126.2

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Strain: TA100

Dose (ug/Plate)	With 10% Rat S9	With 10% Rat S9
Vehicle Control ¹	59 ± 5.5	81 ± 4.4
10.0		
20.0		
50.0		
125.0		
250.0		
500.0		36 ± 4.4
750.0		30 ± 2.0
1000.0	58 ± 4.8	
1500.0	47 ± 13.2	33 ± 2.0
2000.0	62 ± 3.8	
2500.0	68 ± 8.0	
3000.0	67 ± 9.1	74 ± 4.5
6000.0		64 ± 10.5 ^p
Trial Summary	Negative	Negative
Positive Control ²		
Positive Control ³	572 ± 35.1	709 ± 35.0
Positive Control ⁴		

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Strain: TA98

Dose (ug/Plate)	Without S9	Without S9	Without S9	With 10% Rat S9	With 10% Rat S9
Vehicle Control ¹	34 ± 4.2	19 ± 4.8	16 ± 3.8	40 ± 5.4	36 ± 1.5
10.0	18 ± 1.3	19 ± 1.2			
20.0	31 ± 3.6	20 ± 4.8		44 ± 0.7	29 ± 4.4
50.0	16 ± 3.8 ^P	18 ± 3.2 ^P		42 ± 4.4	34 ± 5.9
125.0	18 ± 3.2 ^P	21 ± 0.6 ^P		43 ± 2.0	33 ± 4.0
250.0	13 ± 0.9 ^P	15 ± 2.6 ^P		31 ± 0.9	39 ± 8.1
500.0	19 ± 0.6 ^P	20 ± 2.7 ^P	14 ± 1.2 ^P	33 ± 4.1	29 ± 2.3 ^P
750.0			13 ± 1.5 ^P		
1000.0					
1500.0			7 ± 1.5 ^X	25 ± 2.3 ^P	23 ± 2.8 ^P
2000.0					
2500.0					
3000.0			6 ± 0.7 ^X		
6000.0			7 ± 1.2 ^X		
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control ⁵					1082 ± 58.1
Positive Control ⁶				1721 ± 57.6	
Positive Control ⁷	473 ± 25.4	719 ± 13.2	444 ± 2.7		

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G06: Ames Summary Data
Test Compound: Nelfinavir
CAS Number: 159989-64-7

Date Report Requested: 08/12/2021
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Strain: TA98

Dose (ug/Plate)	With 10% Rat S9	With 10% Rat S9
Vehicle Control ¹	24 ± 0.9	26 ± 2.7
10.0		
20.0		
50.0		
125.0		
250.0		
500.0		22 ± 4.5
750.0		30 ± 3.3
1000.0	26 ± 4.6	
1500.0	22 ± 2.2	33 ± 2.7
2000.0	20 ± 0.9	
2500.0	16 ± 2.4	
3000.0	25 ± 3.3	25 ± 3.3 ^p
6000.0		21 ± 0.3 ^p
Trial Summary	Negative	Negative
Positive Control ⁵		
Positive Control ⁶	2290 ± 293.6	1794 ± 95.2
Positive Control ⁷		

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CAS Number: 159989-64-7

Strain: E. coli WP2 uvrA pKM101

Dose (ug/Plate)	Without S9	Without S9	Without S9	With 10% Rat S9	With 10% Rat S9
Vehicle Control ¹	181 ± 9.9	183 ± 13.5	144 ± 31.5	206 ± 8.2	199 ± 8.7
10.0	165 ± 2.0	172 ± 6.7			
20.0	159 ± 9.2	165 ± 2.6		198 ± 3.4	222 ± 19.0
50.0	170 ± 4.6 ^P	129 ± 11.7 ^P		205 ± 0.6	213 ± 10.1
125.0	184 ± 2.9 ^P	134 ± 6.8 ^P		195 ± 9.7	207 ± 3.8
250.0	153 ± 1.0 ^P	156 ± 5.8 ^P		193 ± 5.0	182 ± 3.2
500.0	135 ± 16.2 ^P	147 ± 3.5 ^P	146 ± 9.5 ^P	187 ± 3.4	194 ± 12.7
750.0			140 ± 10.5 ^P		
1000.0					
1500.0			145 ± 1.8 ^P	220 ± 10.7	225 ± 13.0
2000.0					
2500.0					
3000.0			149 ± 5.2 ^P		
6000.0			132 ± 3.7 ^P		
Trial Summary	Negative	Negative	Negative	Negative	Negative
Positive Control ⁸			1716 ± 100.3		
Positive Control ⁹				1431 ± 150.2	1287 ± 50.6
Positive Control ¹⁰	909 ± 20.1	1033 ± 47.8			

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Strain: E. coli WP2 uvrA pKM101

Dose (ug/Plate)	With 10% Rat S9	With 10% Rat S9
Vehicle Control ¹	216 ± 22.0	220 ± 8.5
10.0		
20.0		
50.0		
125.0		
250.0		
500.0		223 ± 7.2
750.0		217 ± 8.5
1000.0	163 ± 13.6	
1500.0	163 ± 3.6	204 ± 13.2
2000.0	204 ± 31.9	
2500.0	206 ± 29.6	
3000.0	149 ± 2.8	213 ± 14.3
6000.0		162 ± 5.2 ^p
Trial Summary	Negative	Negative
Positive Control ⁸		
Positive Control ⁹	1560 ± 33.5	1881 ± 42.9
Positive Control ¹⁰		

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LEGEND

Values given as Mean or Mean \pm Standard Error Mean

The number of samples = 3, unless samples marked toxic or contaminated were excluded from mean and SEM calculations

CAS Number = Chemical Abstracts Service registry number

The S9 fraction refers to the liver unless otherwise indicated

1: Vehicle Control: Dimethyl Sulfoxide

2: 1.0 ug/Plate Sodium Azide

3: 2.0 ug/Plate Other Positive Control

4: 2.5 ug/Plate 2-Aminoanthracene

5: 1.0 ug/Plate 2-Aminoanthracene

6: 2.0 ug/Plate 2-Aminoanthracene

7: 3.0 ug/Plate 2-Nitrofluorene

8: 0.25 ug/Plate Other Positive Control

9: 20.0 ug/Plate 2-Aminoanthracene

10: 100.0 ug/Plate Methyl Methane Sulfonate

p: Precipitate

x: Slight Toxicity and Precipitate

**** END OF REPORT ****