Test Type: 14-DAY

Route: GAVAGE Species/Strain: Rat/F 344/N

## P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin **CAS Number:** 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:09

First Dose M/F: NA / NA

Lab: BAT

C96013 C Number:

Not Entered. Lock Date:

Cage Range: ΑII

**Date Range:** ΑII

**Reasons For Removal:** ΑII

**Removal Date Range:** ΑII

**Treatment Groups:** ΑII

**Study Gender:** Both

**PWG Approval Date NONE** 

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin CAS Number: 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:09

First Dose M/F: NA / NA

Lab: BAT

Male RAT
FIRST TERMINAL SACRIFICE AT 28 DAYS
INDIVIDUAL SURVIVAL TIMES (DAYS)

	IND	IVIDUAL SURVIVAL TIMES (DAY	S)	
DOSE = 0 UG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 5 UG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 50 UG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 5000 UG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin

**CAS Number:** 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:09

First Dose M/F: NA / NA

Lab: BAT

Male RAT **FIRST TERMINAL SACRIFICE AT 28 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)** 

DOSE = 50,000 UG/KG

TOTAL 10

**UNCENSORED DEATHS 0** 

CENSORED DEATHS 0

**TERMINAL 10** 

**UNCENSORED DEATH DAYS** 

none

**CENSORED DEATH DAYS** 

DOSE = 200,000 UG/KG

TOTAL 10

**UNCENSORED DEATHS 0** 

**CENSORED DEATHS 0** 

**TERMINAL 10** 

**UNCENSORED DEATH DAYS** 

none

**CENSORED DEATH DAYS** 

none

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin CAS Number: 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:09

First Dose M/F: NA / NA

Lab: BAT

Male RAT FIRST TERMINAL SACRIFICE AT 28 DAYS

#### KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE					TIME	(DAYS)				
	3	6	9	12	15	18	21	24	27	28(A)
0 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
5 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
50 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
5000 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
50,000 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
200,000 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 14-DAY Route: GAVAGE

Species/Strain: Rat/F 344/N

## P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin **CAS Number:** 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:09

First Dose M/F: NA / NA

Lab: BAT

# Male RAT FIRST TERMINAL SACRIFICE AT 28 DAYS

DOSE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%	
(KAPLAN-MEIER)					
SIGNIFICANCE (B)					
(LIFE TABLE)					
MEAN DAY OF NATURAL DEATHS (C)					
(STANDARD ERROR)	(.)	(.)	(.)	(.)	
MEAN LIFE SPAN (D)	28.0	28.0	28.0	28.0	
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Test Type: 14-DAY

Species/Strain: Rat/F 344/N

Route: GAVAGE

### P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin CAS Number: 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:09

First Dose M/F: NA / NA

Lab: BAT

#### Male RAT FIRST TERMINAL SACRIFICE AT 28 DAYS

DOSE	50,000 UG/KG	200,000 UG/KG
SURVIVAL AT END OF STUDY	100.0%	100.0%
(KAPLAN-MEIER)		
SIGNIFICANCE (B)		
(LIFE TABLE)		
MEAN DAY OF NATURAL DEATHS (C)		
(STANDARD ERROR)	(.)	(.)
MEAN LIFE SPAN (D)	28.0	28.0
(STANDARD ERROR)	(0.0)	(0.0)

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin CAS Number: 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:10

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

# Female RAT FIRST TERMINAL SACRIFICE AT 28 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

	עאו וווע	IVIDUAL SURVIVAL TIMES (DAT	<u> </u>	
DOSE = 0 UG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 5 UG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 50 UG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				
DOSE = 5000 UG/KG				
TOTAL 10	UNCENSORED DEATHS 0	CENSORED DEATHS 0	TERMINAL 10	
UNCENSORED DEATH DAYS				
none				
CENSORED DEATH DAYS				
none				

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin CAS Number: 73-31-4

Date Report Requested: 10/23/2014
Time Report Requested: 08:30:10

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

Female RAT FIRST TERMINAL SACRIFICE AT 28 DAYS INDIVIDUAL SURVIVAL TIMES (DAYS)

DOSE = 50,000 UG/KG

TOTAL 10

**UNCENSORED DEATHS 0** 

**CENSORED DEATHS 0** 

**TERMINAL 10** 

**UNCENSORED DEATH DAYS** none

CENSORED DEATH DAYS

none

DOSE = 200,000 UG/KG

TOTAL 10

**UNCENSORED DEATHS 0** 

**CENSORED DEATHS 0** 

**TERMINAL 10** 

**UNCENSORED DEATH DAYS** 

none

**CENSORED DEATH DAYS** 

none

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin CAS Number: 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:10

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

# Female RAT FIRST TERMINAL SACRIFICE AT 28 DAYS

#### KAPLAN-MEIER SURVIVAL PROBABILITY ESTIMATES (%)

DOSE					TIME	(DAYS)				
	3	6	9	12	15	18	21	24	27	28(A)
0 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
5 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
50 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
5000 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
50,000 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0
200.000 UG/KG	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0	100.0

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin CAS Number: 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:10

First Dose M/F: NA / NA

Lab: BAT

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

#### Female RAT FIRST TERMINAL SACRIFICE AT 28 DAYS

DOSE	0 UG/KG	5 UG/KG	50 UG/KG	5000 UG/KG	
SURVIVAL AT END OF STUDY	100.0%	100.0%	100.0%	100.0%	
(KAPLAN-MEIER)					
SIGNIFICANCE (B)					
(LIFE TABLE)					
MEAN DAY OF NATURAL DEATHS (C)					
(STANDARD ERROR)	(.)	(.)	(.)	(.)	
MEAN LIFE SPAN (D)	28.0	28.0	28.0	28.0	
(STANDARD ERROR)	(0.0)	(0.0)	(0.0)	(0.0)	

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

Species/Strain: Rat/F 344/N

Test Type: 14-DAY

Route: GAVAGE

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin CAS Number: 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:10

First Dose M/F: NA / NA

Lab: BAT

Female RAT FIRST TERMINAL SACRIFICE AT 28 DAYS

DOSE	50,000 UG/KG	200,000 UG/KG
SURVIVAL AT END OF STUDY	100.0%	100.0%
(KAPLAN-MEIER)		
SIGNIFICANCE (B)		
(LIFE TABLE)		
MEAN DAY OF NATURAL DEATHS (C)		
(STANDARD ERROR)	(.)	(.)
MEAN LIFE SPAN (D)	28.0	28.0
(STANDARD ERROR)	(0.0)	(0.0)

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)

**Test Type:** 14-DAY **Route:** GAVAGE

Species/Strain: Rat/F 344/N

P11: STATISTICAL ANALYSIS OF SURVIVAL DATA

Test Compound: Melatonin CAS Number: 73-31-4

Date Report Requested: 10/23/2014 Time Report Requested: 08:30:10

First Dose M/F: NA / NA

Lab: BAT

\*\* END OF REPORT \*\*

<sup>(</sup>A) FIRST TERMINAL SACRIFICE

<sup>(</sup>B) THE FIRST ENTRY IS THE TREND TEST (TARONE, 1975) RESULT. SUBSEQUENT ENTRIES ARE THE RESULTS OF PAIRWISE TESTS (COX, 1972). NEGATIVE TRENDS ARE INDICATED BY "N".

<sup>(</sup>C) MEAN OF ALL UNCENSORED DEATHS PRIOR TO TERMINAL SACRIFICE

<sup>(</sup>D) MEAN OF ALL DEATHS (UNCENSORED, CENSORED, TERMINAL SACRIFICE)