Experiment Number: 96013-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
Test Compound: Melatonin
CAS Number: 73-31-4

Date Report Requested: 10/16/2014
Time Report Requested: 23:57:31
First Dose M/F: NA / NA
Lab: BAT

C Number: C96013
Lock Date: 02/28/2003
Cage Range: All
Date Range: All
Reasons For Removal: All
Removal Date Range: All
Treatment Groups: All
Study Gender: Both
PWG Approval Date: NONE
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**Alimentary System**

- **Esophagus:** + + + + + + + + + + 10
- **Intestine Large, Cecum:** + + + + + + + + + + 10
- **Intestine Large, Colon:** + + + + + + + + + + 10
- **Intestine Large, Rectum:** + + + + + + + + + + 10
- **Intestine Small, Duodenum:** + + + + + + + + + + 10
- **Intestine Small, Ileum:** + + + + + + + + + + 10
- **Intestine Small, Jejunum:** + + + + + + + + + + 10
- **Liver:** + + + + + + + + + + 10
  - **Hepatodiaphragmatic Nodule:** X 1
  - **Inflammation, Chronic:** 1 1 1 3 1.0
- **Pancreas:** + + + + + + + + + + 10
- **Salivary Glands:** + + + + + + + + + + 10
- **Stomach, Fore stomach:** + + + + + + + + + + 10
- **Stomach, Glandular:** + + + + + + + + + + 10

**Cardiovascular System**

- **Blood Vessel:** + + + + + + + + + + 10
- **Heart:** + + + + + + + + + + 10
  - **Cardiomyopathy:** 1 1 1 1 1 1 1 1 1 1 9 1.0

**Endocrine System**

- **Adrenal Cortex:** + + + + + + + + + + 10

---

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ ..Tissue examined microscopically  
M ..Missing tissue  
1-4 ..Lesion qualified as:  
1) Minimal  3) Moderate  
2) Mild  4) Marked  
X ..Lesion present  
A ..Autolysis precludes evaluation  
I ..Insufficient tissue  
BLANK ..Not examined microscopically
## Experiment Number:
96013-03

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90-DAY

## Route:
GAVAGE

## Species/Strain:
Rat/F 344/N

## Test Compound:
Melatonin

## CAS Number:
73-31-4

## Date Report Requested:
10/16/2014

## Time Report Requested:
23:57:31

## Lab:
BAT

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### P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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### *TOTALS

- Adrenal Medulla: 10
- Islets, Pancreatic: 10
- Parathyroid Gland: 10
- Pituitary Gland: 10
- Thyroid Gland: 10

### General Body System

- NONE

### Genital System

- Epididymis: 10
- Preputial Gland: 10
- Prostate: 10
- Seminal Vesicle: 10
- Testes: 10

### Hematopoietic System

- Bone Marrow: 10
- Lymph Node, Mandibular: 0
- Lymph Node, Mesenteric: 10
- Spleen: 10
- Thymus: 10

### Integumentary System

- Mammary Gland: 10

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### Mammary Gland
- + + + + + + + + + + + + + 10

### Skin
- + + + + + + + + + + + + + 10

### Musculoskeletal System
- Bone + + + + + + + + + + + + + 10

### Nervous System
- Brain + + + + + + + + + + + + + 10

### Respiratory System
- Lung + + + + + + + + + + + + + 10
  - Alveolar Epith, Hyperplasia, Focal 1 1.0
  - Inflammation, Chronic 1 1 1 1 1 1 1 1 8 1.0
- Nose + + + + + + + + + + + + + 10
- Trachea + + + + + + + + + + + + + 10

### Special Senses System
- Eye + + + + + + + + + + + + + 10

### Harderian Gland
- Inflammation, Chronic 1 1.0
- Pigmentation 2 2 2.0

### Urinary System
- Kidney + + + + + + + + + + + + + 10
- Mineralization 1 1 2 1.0

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**Lab:** BAT

### F 344/N Rat Male  
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* TOTALS

F 344/N Rat Male
5 UG/KG

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*TOTALS

Alimentary System

Liver
+ + 2
Hepatodiaphragmatic Nodule
X  X  2

Cardiovascular System

NONE

Endocrine System

Thyroid Gland
+ + + + + + + + 10

General Body System

NONE

Genital System

NONE

Hematopoietic System

NONE

Integumentary System

NONE

Musculoskeletal System

NONE

Nervous System

NONE

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Lab: BAT

Respiratory System
NONE

Special Senses System
Eye
+ + + + + + + + + + 10
Harderian Gland
+ + + + + + + + + + 10

Urinary System
NONE

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F 344/N Rat Male
50 UG/KG

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*TOTALS

Alimentary System
NONE

Cardiovascular System
NONE

Endocrine System
Thyroid Gland
+ + + + + + + + + + 10

General Body System
NONE

Genital System
NONE

Hematopoietic System
NONE

Integumentary System
NONE

Musculoskeletal System
NONE

Nervous System
NONE

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
1-4 ..Lesion qualified as:
X ..Lesion present
A ..Autolysis precludes evaluation
1) Minimal 3) Moderate
I ..Insufficient tissue
BLANK ..Not examined microscopically
2) Mild 4) Marked

Page 8
Experiment Number: 96013-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
Test Compound: Melatonin
CAS Number: 73-31-4

Date Report Requested: 10/16/2014
First Dose M/F: NA / NA
Lab: BAT

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F 344/N Rat Male
50 UG/KG

ANIMAL ID
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4

Respiratory System
NONE

Special Senses System

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Urinary System
NONE

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
X ..Lesion present
A ..Autolysis precludes evaluation
I ..Insufficient tissue
BLANK ..Not examined microscopically
1-4 ..Lesion qualified as:
1) Minimal  3) Moderate
2) Mild  4) Marked
### P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

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#### Alimentary System

- **Liver:** 
  - Tissue examined microscopically: +
  - Lesion present: X
  - Lesion qualified as: 1

#### Cardiovascular System

- **Thyroid Gland:**
  - Tissue examined microscopically: +
  - Lesion present: +
  - Lesion qualified as: 1

#### General Body System

- **NONE**

#### Endocrine System

- **NONE**

#### Genital System

- **NONE**

#### Hematopoietic System

- **NONE**

#### Integumentary System

- **NONE**

#### Musculoskeletal System

- **NONE**

#### Nervous System

- **NONE**

### Notes

- Tissue examined microscopically: +
- Lesion present: X
- Lesion qualified as: 1 or 4
- Missing tissue: M
- Autolysis precludes evaluation: A
- Insufficient tissue: I
- Not examined microscopically: BLANK

---

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
X ..Lesion present
1-4 ..Lesion qualified as:
1) Minimal  2) Mild  3) Moderate  4) Marked
**Experiment Number:** 96013-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

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

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 23:57:32  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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<th>Special Senses System</th>
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| Eye | + | + | + | + | + | + | + | + | + | 10 |
| Harderian Gland | + | + | + | + | + | + | + | + | + | 10 |
| Inflammation, Chronic | 1 | 1 | 1 | 3 | 1.0 |
| Pigmentation | 2 | 2 | 2 | 2 | 5 | 2.0 |

| Urinary System | NONE |

---

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ ..Tissue examined microscopically  
M ..Missing tissue  
1-4 ..Lesion qualified as:  
1) Minimal  2) Mild  3) Moderate  4) Marked  
X ..Lesion present  
A ..Autolysis precludes evaluation  
I ..Insufficient tissue  
BLANK ..Not examined microscopically
Experiment Number: 96013-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

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

Date Report Requested: 10/16/2014
First Dose M/F: NA / NA
Lab: BAT

### P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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<th>Hepatodiaphragmatic Nodule</th>
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*TOTALS

### Alimentary System

- **Liver**: + 1
- **Hepatodiaphragmatic Nodule**: X 1
- **Inflammation, Chronic**: 1 1.0

### Cardiovascular System

**NONE**

### Endocrine System

- **Thyroid Gland**: + + + + + + + + 10

### General Body System

**NONE**

### Genital System

**NONE**

### Hematopoietic System

**NONE**

### Integumentary System

**NONE**

### Musculoskeletal System

**NONE**

---

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
X ..Lesion present
A ..Autolysis precludes evaluation
I ..Insufficient tissue
BLANK ..Not examined microscopically
1-4 ..Lesion qualified as:
1) Minimal  3) Moderate
2) Mild  4) Marked
Experiment Number: 96013-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

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

Date Report Requested: 10/16/2014
First Dose M/F: NA / NA
Lab: BAT

---

**Nervous System**
- NONE

**Respiratory System**
- NONE

**Special Senses System**

Eye | Cornea, Inflammation | Harderian Gland | Pigmentation
--- | --- | --- | ---
+ | + | + | + | + | + | + | + | 10 | 2 | 1 | 2.0

**Urinary System**
- NONE

---

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
A ..Autolysis precludes evaluation
1-4 ..Lesion qualified as:
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I ..Insufficient tissue
BLANK ..Not examined microscopically
**Experiment Number:** 96013-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N  

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**  
**Test Compound:** Melatonin  
**CAS Number:** 73-31-4  

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 23:57:32  
**First Dose M/F:** NA / NA  
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**ALIMENTARY SYSTEM**

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**CARDIOVASCULAR SYSTEM**

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* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ ..Tissue examined microscopically  
M ..Missing tissue  
1-4 ..Lesion qualified as:  
X ..Lesion present  
A ..Autolysis precludes evaluation  
I ..Insufficient tissue  
BLANK ..Not examined microscopically  
1) Minimal  2) Mild  3) Moderate  4) Marked
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**F 344/N Rat Male**

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

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**General Body System**

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**Genital System**

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*Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade

+ Tissue examined microscopically  
M Missing tissue  
A Autolysis precludes evaluation  
1-4 Lesion qualified as:

1) Minimal  3) Moderate

2) Mild  4) Marked
**Experiment Number:** 96013-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N  
**Test Compound:** Melatonin  
**CAS Number:** 73-31-4  
**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 23:57:32  
**First Dose M/F:** NA / NA  
**Lab:** BAT

**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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**ANIMAL ID**

| Skin | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Musculoskeletal System | 10 |

| Bone | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Nervous System | 10 |

| Brain | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Respiratory System | 10 |

| Lung | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Inflammation, Chronic | 1 | 1 | 1.0 |
| Metaplasia, Osseous | 1 | 1.0 |
| Nose | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Trachea | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |

**Special Senses System**

| Eye | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Harderian Gland | 10 |

| Inflammation, Chronic | 1 | 1.0 |
| Pigmentation | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 | 2 |
| Urinary System | 10 |

| Kidney | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + | + |
| Mineralization | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| Nephropathy | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |

**Notes:**

- **Total animals with tissue examined microscopically:** Total animals with lesion and mean severity grade
- **Tissue examined microscopically:** M ..Missing tissue
- **Lesion present:** + ..Total animals with lesion and mean severity grade
- **Autolysis precludes evaluation:** A ..Autolysis precludes evaluation
- **Insufficient tissue:** I ..Insufficient tissue
- **Not examined microscopically:** BLANK ..Not examined microscopically

*1-4 ..Lesion qualified as:
1) Minimal  2) Mild  3) Moderate  4) Marked
Experiment Number: 96013-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

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F 344/N Rat Male
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*TOTALS

| Urinary Bladder | + | + | + | + | + | + | + | + | + | + |

***END OF MALE DATA***

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
X ..Lesion present
A ..Autolysis precludes evaluation
I ..Insufficient tissue
BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:
1) Minimal  2) Mild  3) Moderate  4) Marked
**Experiment Number:** 96013-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N  
**Test Compound:** Melatonin  
**CAS Number:** 73-31-4  
**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 23:57:32  
**First Dose M/F:** NA / NA  
**Lab:** BAT

### P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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**Alimentary System**

- **Esophagus:**
  - + + + + + + + + + + 10
- **Intestine Large, Cecum:**
  - + + + + + + + + + + 10
- **Intestine Large, Colon:**
  - + + + + + + + + + + 10
- **Intestine Large, Rectum:**
  - + + + + + + + + + + 10
- **Intestine Small, Duodenum:**
  - + + + + + + + + + + 10
- **Intestine Small, Ileum:**
  - + + + + + + + + + + 10
- **Intestine Small, Jejunum:**
  - + + + + + + + + + + 10
- **Liver:**
  - + + + + + + + + + + 10
- **Hepatodiaphragmatic Nodule:**
  - X 1
- **Inflammation, Chronic:**
  - 1 1 1 1 1 1 1 1 8 1.0
- **Pancreas:**
  - + + + + + + + + + + 10
- **Acinus, Atrophy:**
  - 2 1 2.0
- **Salivary Glands:**
  - + + + + + + + + + + 10
- **Stomach, Foregut:**
  - + + + + + + + + + + 10
- **Stomach, Glandular:**
  - + + + + + + + + + + 10

**Cardiovascular System**

- **Blood Vessel:**
  - + + + + + + + + + + 10
- **Heart:**
  - + + + + + + + + + + 10
- **Cardiomyopathy:**
  - 1 1 1 1 1 1 1 7 1.0
- **Myocardium, Mineralization:**
  - 2 1 2.0

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ ..Tissue examined microscopically  
M ..Missing tissue  
1-4 ..Lesion qualified as:
X ..Lesion present  
A ..Autolysis precludes evaluation  
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Experiment Number: 96013-03
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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
Test Compound: Melatonin
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Date Report Requested: 10/16/2014
First Dose M/F: NA / NA
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Endocrine System

Adrenal Cortex + + + + + + + + + + + + 10
Adrenal Medulla + + + + + + + + + + + + 10
Islets, Pancreatic + + + + + + + + + + + + 10
Parathyroid Gland + + + M + + + + + + 9
Pituitary Gland + + + + + + + + + + + + 10
Thyroid Gland + + + + + + + + + + + + 10

General Body System

NONE

Genital System

Clitoral Gland + + + + + + + + + + + + 10
Ovary + + + + + + + + + + + + 10
Cyst X 1
Uterus + + + + + + + + + + + + 10
Dilatation 2 2 1 3 1.7
Metaplasia, Squamous 1 1 2 1.0

Hematopoietic System

Bone Marrow + + + + + + + + + + + + 10
Inflammation, Chronic 1 1 1.0
Lymph Node, Mandibular M M M M M M M M 0
Lymph Node, Mesenteric + + + + + + + + + + + + 10

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
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I ..Insufficient tissue
M ..Missing tissue
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1-4 ..Lesion qualified as:
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**Experiment Number**: 96013-03  
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<th>F 344/N Rat Female</th>
<th>ANIMAL ID</th>
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<td>1 1 1 1 1 1</td>
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<td>4 4 4 4 4 4</td>
<td>5 5 5 5 5 5</td>
<td>2 3 4 5 6 7</td>
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</table>

| *TOTALS | Lymph Node, Mesenteric | + + + + + + + + + + | 10 |
| | Spleen | + + + + + + + + + + | 10 |
| | Thymus | + + + + + + + + + + | 10 |

**Integumentary System**

- Mammary Gland: + + + + + + + + + + | 10 |
- Skin: + + + + + + + + + + | 10 |
- Lip, Inflammation, Chronic Active: 3 | 1 | 3.0 |
- Lip, Ulcer: 3 | 1 | 3.0 |

**Musculoskeletal System**

- Bone: + + + + + + + + + + | 10 |

**Nervous System**

- Brain: + + + + + + + + + + | 10 |
- Cranial Nerve, Degeneration: 2 | 1 | 2.0 |
- Pineal Gland, Infiltration Cellular, Lymphocytic: 1 | 1 | 1.0 |

**Respiratory System**

- Lung: + + + + + + + + + + | 10 |
- Inflammation, Chronic: 1 | 1 | 1.0 |
- Nose: + + + + + + + + + + | 10 |
- Trachea: + + + + + + + + + + | 10 |

*..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+..Tissue examined microscopically
M..Missing tissue
X..Lesion present
A..Autolysis precludes evaluation
I..Insufficient tissue
BLANK..Not examined microscopically

1-4..Lesion qualified as:
1) Minimal
2) Mild
3) Moderate
4) Marked
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**Special Senses System**

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<td>+ + + + + +</td>
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<tr>
<td>Harderian Gland</td>
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<td>+ + + + + +</td>
<td>+ + + + + +</td>
<td>+ + + + + +</td>
<td>+ + + + + +</td>
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<tr>
<td>Inflammation, Chronic</td>
<td>1 1 1</td>
<td>3 1.0</td>
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<tr>
<td>Pigmentation</td>
<td>2 1 2.0</td>
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**Urinary System**

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<td>Infarct</td>
<td>1 1 1 1 1 1</td>
<td>5 1.0</td>
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* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
A ..Autolysis precludes evaluation
1-4 ..Lesion qualified as:
1) Minimal
2) Mild
3) Moderate
4) Marked

Page 21
Experiment Number: 96013-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
Test Compound: Melatonin
CAS Number: 73-31-4

Date Report Requested: 10/16/2014
First Dose M/F: NA / NA
Lab: BAT

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* TOTALS

Alimentary System

<table>
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<tr>
<th></th>
<th>+</th>
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</table>
Liver        |   |   |
Hepatodiaphragmatic Nodule | X | 1 |

Cardiovascular System

NONE

Endocrine System

<table>
<thead>
<tr>
<th></th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>10</th>
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</table>
Thyroid Gland |   |   |   |   |   |   |   |   |   |   |   |

General Body System

NONE

Genital System

<table>
<thead>
<tr>
<th></th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>+</th>
<th>10</th>
</tr>
</thead>
</table>
Ovary        |   |   |   |   |   |   |   |   |   |   |   |
Mineralization | 1 |   |   | 1 | 1.0 |
Uterus       | + | + | + | + | + | + | + | + | + | + | 10 |
Dilatation   |   |   |   |   |   |   |   |   |   |   |   |

Hematopoietic System

NONE

Integumentary System

NONE

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
A ..Autolysis precludes evaluation
X ..Lesion present
I ..Insufficient tissue
BLANK ..Not examined microscopically
1-4 ..Lesion qualified as:
1) Minimal
2) Mild
3) Moderate
4) Marked
Experiment Number: 96013-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
Test Compound: Melatonin
CAS Number: 73-31-4

Date Report Requested: 10/16/2014
Time Report Requested: 23:57:33
First Dose M/F: NA / NA
Lab: BAT

**Musculoskeletal System**
NONE

**Nervous System**
NONE

**Respiratory System**
NONE

**Special Senses System**

<table>
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<tr>
<th>Eye</th>
<th>+</th>
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<th>+</th>
<th>+</th>
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<th>+</th>
<th>+</th>
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<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
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<td>Pigmentation</td>
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<td>2</td>
<td>2</td>
<td>3</td>
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</table>

**Urinary System**
NONE

---

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
1-4 ..Lesion qualified as:
X ..Lesion present
A ..Autolysis precludes evaluation
1) Minimal 3) Moderate
I ..Insufficient tissue
BLANK ..Not examined microscopically
2) Mild 4) Marked
P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

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

DAY ON TEST

| DAY | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |
| 0   | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 9   | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 | 9 |
| 4   | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 | 4 |

ANIMAL ID

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</table>

*TOTALS

**Alimentary System**

- Liver: + + 2
- Hepatodiaphragmatic Nodule: X X 2
- Inflammation, Chronic: 1 1 1.0

**Cardiovascular System**

NONE

**Endocrine System**

Thyroid Gland

**General Body System**

NONE

**Genital System**

- Ovary: + + + + + + + + + + + + 10
- Uterus: + + + + + + + + + + + + 10
- Dilatation: 1 2 2 3 1.7

**Hematopoietic System**

NONE

**Integumentary System**

NONE

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
X ..Lesion present
A ..Autolysis precludes evaluation
I ..Insufficient tissue
BLANK ..Not examined microscopically
1-4 ..Lesion qualified as:
1) Minimal 2) Mild
3) Moderate 4) Marked
Experiment Number: 96013-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
Test Compound: Melatonin
CAS Number: 73-31-4

Date Report Requested: 10/16/2014
Time Report Requested: 23:57:33
First Dose M/F: NA / NA
Lab: BAT

D8Y ON TEST

F 344/N Rat Female
50 UG/KG

ANIMAL ID

| 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

*TOTALS

Musculoskeletal System
NONE

Nervous System
NONE

Respiratory System
NONE

Special Senses System

Eye

Harderian Gland

Pigmentation

2
2
2
2

Urinary System
NONE

*Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
Tissue examined microscopically
Missing tissue
Lesion present
Autolysis precludes evaluation
Insufficient tissue
Not examined microscopically
1-4 Lesion qualified as:
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P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL
Test Compound: Melatonin
CAS Number: 73-31-4

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F 344/N Rat Female
5000 UG/KG

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*TOTALS

Alimentary System

- Liver: + + 2
- Hepatodiaphragmatic Nodule: X X 2

Cardiovascular System

NONE

Endocrine System

- Thyroid Gland: + + + + + + + + + + 10

General Body System

NONE

Genital System

- Ovary: + + + + + + + + + + 10
- Uterus: + + + + + + + + + + 10
- Dilatation: 1 1 1 3 1.0

Hematopoietic System

NONE

Integumentary System

NONE

Musculoskeletal System

NONE

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
X ..Lesion present
A ..Autolysis precludes evaluation
I ..Insufficient tissue
BLANK ..Not examined microscopically

1-4 ..Lesion qualified as:
1) Minimal
2) Mild
3) Moderate
4) Marked

Page 26
Experiment Number: 96013-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

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

Date Report Requested: 10/16/2014
Time Report Requested: 23:57:33
First Dose M/F: NA / NA
Lab: BAT

P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL

Nervous System
NONE

Respiratory System
NONE

Special Senses System

Eye + + + + + + + + + + 10
Harderian Gland + + + + + + + + + + 10
Pigmentation

Urinary System
NONE

ANIMAL ID

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*TOTALS

NONE

F 344/N Rat Female
5000 UG/KG

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
1-4 ..Lesion qualified as:
X ..Lesion present
A ..Autolysis precludes evaluation
I ..Insufficient tissue
BLANK ..Not examined microscopically
1) Minimal
2) Mild
3) Moderate
4) Marked

Page 27
**Experiment Number:** 96013-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N  

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

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 23:57:33  
**First Dose M/F:** NA / NA  
**Lab:** BAT  

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**F 344/N Rat Female**  
**50,000 UG/KG**  

**ANIMAL ID**  
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**Alimentary System**

- Liver: + 1
- Hepatodiaphragmatic Nodule: X 1

**Cardiovascular System**

NONE

**Endocrine System**

- Thyroid Gland: + + + + + + + + + 10

**General Body System**

NONE

**Genital System**

- Ovary: + + + + + + + + + 10
- Uterus: + + + + + + + + + 10
- Dilatation: 1 1 2 1.0

**Hematopoietic System**

NONE

**Integumentary System**

NONE

**Musculoskeletal System**

---

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ ..Tissue examined microscopically  
M ..Missing tissue  
X ..Lesion present  
A ..Autolysis precludes evaluation  
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### Experiment Number: 96013-03
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

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

**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 23:57:33  
**First Dose M/F:** NA / NA  
**Lab:** BAT

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**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

**F 344/N Rat Female**  
**50,000 UG/KG**

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* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ ..Tissue examined microscopically  
M ..Missing tissue  
X ..Lesion present  
A ..Autolysis precludes evaluation  
I ..Insufficient tissue  
BLANK ..Not examined microscopically  
1-4 ..Lesion qualified as:  
1) Minimal  
2) Mild  
3) Moderate  
4) Marked

---

Page 29
**Experiment Number:** 96013-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N

**Test Compound:** Melatonin  
**CAS Number:** 73-31-4  
**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 23:57:33  
**First Dose M/F:** NA / NA  
**Lab:** BAT

### Alimentary System

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### Cardiovascular System

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* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ ..Tissue examined microscopically  
M ..Missing tissue  
1-4 ..Lesion qualified as:  
1) Minimal  
2) Mild  
3) Moderate  
4) Marked  
X ..Lesion present  
A ..Autolysis precludes evaluation  
I ..Insufficient tissue  
BLANK ..Not examined microscopically
**Experiment Number:** 96013-03  
**Test Type:** 90-DAY  
**Route:** GAVAGE  
**Species/Strain:** Rat/F 344/N  
**Test Compound:** Melatonin  
**CAS Number:** 73-31-4  
**Date Report Requested:** 10/16/2014  
**Time Report Requested:** 23:57:33  
**First Dose M/F:** NA / NA  
**Lab:** BAT

### F 344/N Rat Female  
#### 200,000 UG/KG

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**Adrenal Medulla**  
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**Islets, Pancreatic**  
- + + + + + + + + + +  

**Parathyroid Gland**  
- + + M + + + + + + + +  

**Pituitary Gland**  
- + + + + + + + + + +  

**Pars Distalis, Cyst**  
- X  

**Thyroid Gland**  
- + + + + + + + + + +  

**General Body System**

**NONE**

**Genital System**

**Clitoral Gland**  
- + + + + + + + + + +  

**Cyst**  
- 1  

**Ovary**  
- + + + + + + + + + +  

**Uterus**  
- + + + + + + + + + +  

**Hematopoietic System**

**Bone Marrow**  
- + + + + + + + + + +  

**Lymph Node, Mandibular**  
- M M M M M M M M M M M  

**Lymph Node, Mesenteric**  
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**Spleen**  
- + + + + + + + + + +  

**Thymus**  
- + + + + + + + + + +  

**Integumentary System**

**Mammary Gland**  
- + + + + + + + + + +  

---

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade  
+ ..Tissue examined microscopically  
M ..Missing tissue  
1-4 ..Lesion qualified as:  
1) Minimal  
2) Mild  
3) Moderate  
4) Marked  
A ..Autolysis precludes evaluation  
BLANK ..Not examined microscopically  
X ..Lesion present  
I ..Insufficient tissue  

---

Page 31
**P09: NON-NEOPLASTIC LESIONS BY INDIVIDUAL ANIMAL**

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

| DAY ON TEST | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| F 344/N Rat Female | | | | | | | | | | | | | | | | | | | | | | | | | |
| 200,000 UG/KG | | | | | | | | | | | | | | | | | | | | | | | | | |
| ANIMAL ID | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
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|            | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
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**Musculoskeletal System**

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**Nervous System**

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**Special Senses System**

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<th>Tissue Site</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
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<tbody>
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<td>Eye</td>
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<tr>
<td>Retina, Dysplasia</td>
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<td>Harderian Gland</td>
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<td>Pigmentation</td>
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</tr>
<tr>
<td>Kidney</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
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**Urinary System**

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<tbody>
<tr>
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</tr>
</tbody>
</table>

* ..Total animals with tissue examined microscopically; Total animals with lesion and mean severity grade
+ ..Tissue examined microscopically
M ..Missing tissue
X ..Lesion present
A ..Autolysis precludes evaluation
I ..Insufficient tissue
BLANK ..Not examined microscopically
1-4 ..Lesion qualified as:
1) Minimal 2) Mild 3) Moderate 4) Marked
Experiment Number: 96013-03
Test Type: 90-DAY
Route: GAVAGE
Species/Strain: Rat/F 344/N

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

Date Report Requested: 10/16/2014
Time Report Requested: 23:57:33
First Dose M/F: NA / NA
Lab: BAT

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</tbody>
</table>

F 344/N Rat Female
200,000 UG/KG

ANIMAL ID
0 0 0 0 0 0 0 0
0 0 0 0 0 0 0 0
6 6 6 6 6 6 6 6
5 5 5 5 5 5 5 5
1 2 3 4 5 6 7 8

*TOTALS
Infiltration Cellular, Mononuclear CI 1 1 1.0
Mineralization 1 1 1 1 4 1.0
Nephropathy 1 1 2 1.0
Urinary Bladder + + + + + + + + 10

** END OF REPORT **

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+ ..Tissue examined microscopically
X ..Lesion present
I ..Insufficient tissue
M ..Missing tissue
A ..Autoysis precludes evaluation
BLANK ..Not examined microscopically
1-4 ..Lesion qualified as:
1) Minimal 2) Mild 3) Moderate 4) Marked