

**TDMs No.** 20007 - 05

**P05: INCIDENCE RATES OF NEOPLASMS BY ANATOMIC SITE (SYSTEMIC LESIONS ABRIDGED) (a)**

**Date Report Requested:** 09/21/2010

**Test Type:** CHRONIC

Kava kava extract

**Time Report Requested:** 09:10:56

**Route:** GAVAGE

**CAS Number:** 9000-38-8

**First Dose M/F:** 08/18/04 / 08/19/04

**Species/Strain:** RATS/F 344/N

**Lab:** BAT

F2\_R2

**C Number:** C20007  
**Lock Date:** 03/27/2007  
**Cage Range:** ALL  
**Date Range:** ALL  
**Reasons For Removal:** ALL  
**Removal Date Range:** ALL  
**Treatment Groups:** Include ALL  
**Study Gender:** Both  
**TDMSE Version:** 2.2.0

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FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
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**Disposition Summary**

<b>Animals Initially In Study</b>	<b>50</b>	<b>50</b>	<b>50</b>	<b>50</b>
<b>Early Deaths</b>				
<b>Dosing Accident</b>		<b>1</b>	<b>1</b>	<b>3</b>
<b>Moribund Sacrifice</b>	<b>10</b>	<b>10</b>	<b>13</b>	<b>13</b>
<b>Natural Death</b>	<b>5</b>	<b>4</b>	<b>2</b>	<b>3</b>
<b>Survivors</b>				
<b>Natural Death</b>			<b>1</b>	
<b>Terminal Sacrifice</b>	<b>34</b>	<b>35</b>	<b>33</b>	<b>31</b>
<b>Animals Examined Microscopically</b>	<b>49</b>	<b>50</b>	<b>50</b>	<b>50</b>

## ALIMENTARY SYSTEM

Esophagus	(49)	(50)	(50)	(50)
Intestine Large, Cecum	(49)	(50)	(50)	(50)
Intestine Large, Colon	(49)	(50)	(50)	(50)
Intestine Small, Duodenum	(49)	(50)	(50)	(50)
Intestine Small, Ileum	(49)	(50)	(50)	(50)
Liver	(49)	(50)	(50)	(50)
Cholangioma		1 (2%)		
Fibrosarcoma, Metastatic, Stomach, Glandular			1 (2%)	
Fibrous Histiocytoma, Metastatic, Skeletal Muscle	1 (2%)			1 (2%)
Fibrous Histiocytoma, Metastatic, Skin		1 (2%)		
Hepatocellular Adenoma	1 (2%)	1 (2%)		1 (2%)
Mesentery	(6)	(8)	(7)	(6)
Oral Mucosa	(1)	(1)	(0)	(1)
Squamous Cell Carcinoma				1 (100%)
Squamous Cell Papilloma	1 (100%)			
Pancreas	(49)	(50)	(50)	(50)
Mast Cell Tumor Malignant		1 (2%)		
Acinus, Adenoma	1 (2%)		1 (2%)	
Salivary Glands	(49)	(50)	(50)	(50)
Carcinoma		1 (2%)		
Sarcoma				1 (2%)

a - Number of animals examined microscopically at site and number of animals with lesion

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Schwannoma Malignant			2 (4%)	
Stomach, Forestomach	(49)	(50)	(50)	(50)
Stomach, Glandular	(49)	(50)	(50)	(50)
Carcinoid Tumor Malignant			1 (2%)	
Muscularis, Fibrosarcoma			1 (2%)	
Tooth	(10)	(6)	(9)	(11)

## CARDIOVASCULAR SYSTEM

Blood Vessel	(49)	(50)	(50)	(50)
Heart	(49)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)
Fibrous Histiocytoma, Metastatic, Skin		1 (2%)		

## ENDOCRINE SYSTEM

Adrenal Cortex	(49)	(50)	(50)	(50)
Carcinoma	1 (2%)			
Fibrous Histiocytoma, Metastatic, Skeletal Muscle	1 (2%)			
Adrenal Medulla	(49)	(50)	(50)	(50)
Pheochromocytoma Benign	4 (8%)	8 (16%)	2 (4%)	2 (4%)
Pheochromocytoma Malignant		2 (4%)		
Bilateral, Pheochromocytoma Benign	1 (2%)			
Islets, Pancreatic	(49)	(50)	(50)	(50)
Adenoma	4 (8%)	2 (4%)	1 (2%)	3 (6%)
Adenoma, Multiple			1 (2%)	
Parathyroid Gland	(49)	(50)	(48)	(50)
Adenoma	1 (2%)	1 (2%)		
Pituitary Gland	(49)	(50)	(50)	(50)
Pars Distalis, Adenoma	21 (43%)	20 (40%)	15 (30%)	8 (16%)
Thyroid Gland	(49)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma		1 (2%)	2 (4%)	
C-cell, Adenoma	8 (16%)	8 (16%)	6 (12%)	2 (4%)

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
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C-cell, Carcinoma			2 (4%)	
Follicular Cell, Adenoma	1 (2%)		1 (2%)	
Follicular Cell, Carcinoma			1 (2%)	

## GENERAL BODY SYSTEM

Peritoneum	(0)	(0)	(1)	(0)
Paraganglioma			1 (100%)	
Tissue NOS	(0)	(1)	(0)	(0)
Rhabdomyosarcoma		1 (100%)		

## GENITAL SYSTEM

Coagulating Gland	(2)	(2)	(0)	(0)
Epididymis	(49)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skin		1 (2%)		
Preputial Gland	(49)	(50)	(49)	(50)
Adenoma				1 (2%)
Carcinoma	1 (2%)	1 (2%)		
Schwannoma Malignant		1 (2%)		
Prostate	(49)	(50)	(50)	(50)
Adenoma		1 (2%)	1 (2%)	
Seminal Vesicle	(49)	(50)	(50)	(50)
Testes	(49)	(50)	(50)	(50)
Bilateral, Interstitial Cell, Adenoma	29 (59%)	32 (64%)	40 (80%)	43 (86%)
Interstitial Cell, Adenoma	8 (16%)	12 (24%)	9 (18%)	3 (6%)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(49)	(50)	(50)	(50)
Mast Cell Tumor Malignant		1 (2%)		
Lymph Node	(4)	(3)	(2)	(5)
Deep Cervical, Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (20%)

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Lab: BAT

FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Pancreatic, Mast Cell Tumor Malignant		1 (33%)		
Lymph Node, Mesenteric	(49)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)
Mast Cell Tumor Malignant		1 (2%)		
Spleen	(49)	(50)	(50)	(50)
Mast Cell Tumor Malignant		1 (2%)		
Thymus	(48)	(50)	(50)	(50)
Fibrous Histiocytoma, Metastatic, Skeletal Muscle				1 (2%)

## INTEGUMENTARY SYSTEM

Mammary Gland	(48)	(50)	(50)	(50)
Fibroadenoma		1 (2%)	2 (4%)	3 (6%)
Skin	(49)	(50)	(50)	(50)
Basal Cell Adenoma			2 (4%)	1 (2%)
Dermis, Fibroma	1 (2%)			1 (2%)
Epidermis, Basal Cell Adenoma	2 (4%)			
Epidermis, Keratoacanthoma			1 (2%)	
Epidermis, Squamous Cell Carcinoma			1 (2%)	
Epidermis, Trichoepithelioma			1 (2%)	
Subcutaneous Tissue, Fibroma	6 (12%)	5 (10%)	7 (14%)	1 (2%)
Subcutaneous Tissue, Fibrous Histiocytoma		1 (2%)		
Subcutaneous Tissue, Hemangiosarcoma			1 (2%)	
Subcutaneous Tissue, Lipoma	1 (2%)		1 (2%)	
Subcutaneous Tissue, Liposarcoma	1 (2%)			
Subcutaneous Tissue, Osteosarcoma		1 (2%)	1 (2%)	
Subcutaneous Tissue, Schwannoma			1 (2%)	
Malignant, Metastatic, Salivary Glands				

## MUSCULOSKELETAL SYSTEM

Bone	(49)	(50)	(50)	(50)
Osteosarcoma	1 (2%)	1 (2%)		

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Lab: BAT

FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Skeletal Muscle	(1)	(0)	(1)	(1)
Fibrous Histiocytoma	1 (100%)			1 (100%)
Rhabdomyosarcoma			1 (100%)	

## NERVOUS SYSTEM

Brain	(49)	(50)	(50)	(50)
Meningioma Malignant		1 (2%)		
Spinal Cord	(2)	(0)	(0)	(0)
Glioma Malignant	1 (50%)			

## RESPIRATORY SYSTEM

Lung	(49)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma	1 (2%)		2 (4%)	4 (8%)
Alveolar/Bronchiolar Adenoma, Multiple	1 (2%)			
Alveolar/Bronchiolar Carcinoma	1 (2%)	1 (2%)		
Carcinoma, Metastatic, Salivary Glands		1 (2%)		
Carcinoma, Metastatic, Thyroid Gland			1 (2%)	
Fibrous Histiocytoma, Metastatic, Skeletal Muscle	1 (2%)			1 (2%)
Fibrous Histiocytoma, Metastatic, Skin		1 (2%)		
Neural Crest Tumor, Metastatic, Ear		1 (2%)	1 (2%)	
Osteosarcoma, Metastatic, Skin		1 (2%)	1 (2%)	
Schwannoma Malignant, Metastatic, Salivary Glands			1 (2%)	
Squamous Cell Carcinoma, Metastatic, Skin			1 (2%)	
Mediastinum, Osteosarcoma, Metastatic, Bone	1 (2%)			
Nose	(49)	(50)	(50)	(50)

## SPECIAL SENSES SYSTEM

Ear	(0)	(2)	(1)	(0)
Neural Crest Tumor		2 (100%)	1 (100%)	
Eye	(49)	(50)	(50)	(50)

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Lab: BAT

FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Harderian Gland	(49)	(50)	(50)	(50)
Carcinoma, Metastatic, Oral Mucosa				1 (2%)
Zymbal's Gland	(0)	(0)	(1)	(0)
Carcinoma			1 (100%)	
<b>URINARY SYSTEM</b>				
Kidney	(49)	(50)	(50)	(50)
Nephroblastoma		1 (2%)		
Ureter	(1)	(1)	(0)	(0)
Polyp		1 (100%)		
Urethra	(1)	(0)	(0)	(0)
Urinary Bladder	(49)	(50)	(50)	(50)
<b>SYSTEMIC LESIONS</b>				
Multiple Organ	*(49)	*(50)	*(50)	*(50)
Leukemia Mononuclear	7 (14%)	8 (16%)	7 (14%)	11 (22%)
Lymphoma Malignant	1 (2%)		1 (2%)	1 (2%)
Mesothelioma Malignant	3 (6%)	4 (8%)	1 (2%)	3 (6%)

a - Number of animals examined microscopically at site and number of animals with lesion

\* Number of animals with any tissue examined microscopically

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Lab: BAT

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FISCHER 344 RATS MALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
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**Tumor Summary for Males**

Total Animals with Primary Neoplasms (b)	49	49	50	48
Total Primary Neoplasms	110	125	118	91
Total Animals with Benign Neoplasms	49	48	50	47
Total Benign Neoplasms	92	94	96	73
Total Animals with Malignant Neoplasms	17	23	20	17
Total Malignant Neoplasms	18	29	21	18
Total Animals with Metastatic Neoplasms	2	4	6	2
Total Metastatic Neoplasms	4	7	7	7
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant		2	1	
Total Uncertain Neoplasms		2	1	

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\*\*\* END OF MALE \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors



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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
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**Disposition Summary**

Animals Initially In Study	50	50	50	50
Early Deaths				
Dosing Accident	1	1	2	2
Moribund Sacrifice	12	12	13	6
Natural Death	3	2	11	8
Survivors				
Natural Death		1		
Terminal Sacrifice	34	34	24	34
Animals Examined Microscopically	50	50	50	50

## ALIMENTARY SYSTEM

Esophagus	(50)	(50)	(50)	(50)
Periesophageal Tissue, Lipoma			1 (2%)	
Intestine Large, Cecum	(50)	(50)	(50)	(50)
Intestine Large, Colon	(50)	(50)	(50)	(50)
Liver	(50)	(50)	(50)	(50)
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla		1 (2%)		
Mesentery	(10)	(9)	(7)	(9)
Oral Mucosa	(0)	(1)	(2)	(0)
Squamous Cell Papilloma		1 (100%)	1 (50%)	
Pancreas	(50)	(50)	(50)	(50)
Adenoma, Mixed Cell			1 (2%)	
Acinus, Adenoma			1 (2%)	
Salivary Glands	(50)	(50)	(50)	(50)
Stomach, Forestomach	(50)	(50)	(50)	(50)
Sarcoma, Metastatic, Stomach, Glandular	1 (2%)			
Stomach, Glandular	(50)	(50)	(50)	(50)
Sarcoma	1 (2%)			
Tooth	(5)	(3)	(4)	(2)

## CARDIOVASCULAR SYSTEM

a - Number of animals examined microscopically at site and number of animals with lesion

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Lab: BAT

FISCHER 344 RATS FEMALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Blood Vessel	(50)	(50)	(50)	(50)
Heart	(50)	(50)	(50)	(50)
Fibrosarcoma, Metastatic, Lung	1 (2%)			
Schwannoma Malignant, Metastatic, Lung				1 (2%)

## ENDOCRINE SYSTEM

Adrenal Cortex	(50)	(50)	(50)	(50)
Adenoma		1 (2%)		
Carcinoma		1 (2%)		
Adrenal Medulla	(50)	(50)	(50)	(50)
Pheochromocytoma Benign	3 (6%)	1 (2%)	1 (2%)	1 (2%)
Pheochromocytoma Malignant		1 (2%)		
Islets, Pancreatic	(50)	(50)	(50)	(50)
Adenoma	1 (2%)	1 (2%)		
Parathyroid Gland	(44)	(47)	(44)	(47)
Adenoma				1 (2%)
Pituitary Gland	(50)	(50)	(50)	(50)
Pars Distalis, Adenoma	29 (58%)	20 (40%)	24 (48%)	8 (16%)
Pars Distalis, Carcinoma	1 (2%)			
Thyroid Gland	(50)	(50)	(50)	(50)
Bilateral, C-cell, Adenoma				1 (2%)
C-cell, Adenoma	5 (10%)	6 (12%)	5 (10%)	4 (8%)
Follicular Cell, Adenoma	1 (2%)		1 (2%)	1 (2%)

## GENERAL BODY SYSTEM

None

## GENITAL SYSTEM

Clitoral Gland	(50)	(49)	(50)	(49)
Adenoma	2 (4%)	7 (14%)	3 (6%)	1 (2%)
Carcinoma	1 (2%)	1 (2%)		

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FISCHER 344 RATS FEMALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
Carcinoma, Multiple	1 (2%)			
Ovary	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Lung				1 (2%)
Cystadenoma	1 (2%)			
Granulosa Cell Tumor Benign			1 (2%)	
Uterus	(50)	(50)	(50)	(50)
Carcinosarcoma			1 (2%)	
Polyp Stromal	6 (12%)	9 (18%)	8 (16%)	8 (16%)
Sarcoma Stromal	1 (2%)		1 (2%)	
Bilateral, Polyp Stromal	1 (2%)			
Endometrium, Adenoma				1 (2%)

## HEMATOPOIETIC SYSTEM

Bone Marrow	(50)	(50)	(50)	(50)
Lymph Node	(1)	(3)	(3)	(2)
Mediastinal, Carcinoma, Metastatic, Lung				1 (50%)
Lymph Node, Mesenteric	(50)	(50)	(50)	(50)
Spleen	(50)	(50)	(50)	(50)
Carcinoma, Metastatic, Lung				1 (2%)
Thymus	(50)	(50)	(49)	(48)
Schwannoma Malignant, Metastatic, Lung				1 (2%)
Thymoma Benign		1 (2%)		

## INTEGUMENTARY SYSTEM

Mammary Gland	(50)	(50)	(50)	(50)
Adenoma	2 (4%)	1 (2%)		
Carcinoma	1 (2%)	3 (6%)	1 (2%)	
Fibroadenoma	14 (28%)	17 (34%)	13 (26%)	4 (8%)
Fibroadenoma, Multiple	10 (20%)	7 (14%)	2 (4%)	
Skin	(50)	(50)	(50)	(50)
Subcutaneous Tissue, Fibroma	1 (2%)		1 (2%)	
Subcutaneous Tissue, Lipoma			1 (2%)	
Subcutaneous Tissue, Osteosarcoma			1 (2%)	

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Lab: BAT

FISCHER 344 RATS FEMALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
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## MUSCULOSKELETAL SYSTEM

Bone	(50)	(50)	(50)	(50)
Osteoma			1 (2%)	
Osteosarcoma			1 (2%)	
Osteosarcoma, Metastatic, Skin			1 (2%)	
Skeletal Muscle	(1)	(0)	(1)	(0)
Rhabdomyosarcoma			1 (100%)	

## NERVOUS SYSTEM

Brain	(50)	(50)	(50)	(50)
Granular Cell Tumor Benign				1 (2%)
Peripheral Nerve	(0)	(0)	(1)	(0)
Spinal Cord	(0)	(0)	(1)	(0)

## RESPIRATORY SYSTEM

Lung	(50)	(50)	(50)	(50)
Alveolar/Bronchiolar Adenoma				1 (2%)
Alveolar/Bronchiolar Adenoma, Multiple			1 (2%)	
Alveolar/Bronchiolar Carcinoma				1 (2%)
Carcinoma, Metastatic, Mammary Gland		1 (2%)		
Osteosarcoma, Metastatic, Skin			1 (2%)	
Pheochromocytoma Malignant, Metastatic, Adrenal Medulla		1 (2%)		
Mediastinum, Fibrosarcoma	1 (2%)			
Mediastinum, Schwannoma Malignant				1 (2%)
Nose	(50)	(50)	(50)	(50)
Pleura	(0)	(0)	(0)	(1)
Trachea	(50)	(50)	(50)	(50)

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Lab: BAT

FISCHER 344 RATS FEMALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
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## SPECIAL SENSES SYSTEM

Ear	(1)	(0)	(0)	(1)
Neural Crest Tumor	1 (100%)			1 (100%)
Eye	(50)	(50)	(50)	(50)
Zymbal's Gland	(0)	(0)	(0)	(1)
Adenoma				1 (100%)

## URINARY SYSTEM

Kidney	(50)	(50)	(50)	(50)
Urinary Bladder	(50)	(50)	(50)	(50)

## SYSTEMIC LESIONS

Multiple Organ	*(50)	*(50)	*(50)	*(50)
Adenolipoma	1 (2%)			
Leukemia Mononuclear	5 (10%)	11 (22%)	6 (12%)	9 (18%)
Lymphoma Malignant	1 (2%)			1 (2%)

a - Number of animals examined microscopically at site and number of animals with lesion

\* Number of animals with any tissue examined microscopically

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Species/Strain: RATS/F 344/N

Lab: BAT

FISCHER 344 RATS FEMALE	0.0 G/KG	0.1 G/KG	0.3 G/KG	1.0 G/KG
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**Tumor Summary for Females**

Total Animals with Primary Neoplasms (b)	46	45	44	30
Total Primary Neoplasms	91	89	78	46
Total Animals with Benign Neoplasms	43	41	42	22
Total Benign Neoplasms	76	72	66	33
Total Animals with Malignant Neoplasms	11	16	12	12
Total Malignant Neoplasms	13	17	12	12
Total Animals with Metastatic Neoplasms	2	1	1	2
Total Metastatic Neoplasms	2	3	2	5
Total Animals with Malignant Neoplasms Uncertain Primary Site				
Total Animals with Neoplasms Uncertain- Benign or Malignant	1			1
Total Uncertain Neoplasms	1			1

\*\*\* END OF REPORT \*\*\*

a - Number of animals examined microscopically at site and number of animals with lesion

b - Primary tumors: all tumors except metastatic tumors