

TABLE 11F - continued.

Print No: 0022

Histopathology - group distribution of non-neoplastic findings for 63) ANSALB

Group 1 2 3 4 5
 Compound : Control Control Palonosetron hydrochloride
 Dosage (mg/kg/day): 0 0 15 30/45 60/90

Printed 01-MOV-01
 Page 7

Schedule number: N8H 001A

ORGAN AND FINDING DESCRIPTION	NUMBER	SEX				
		MALE		FEMALE		
		-1-	-2-	-3-	-4-	-5-
M N M O E H - O P - I N T M S I C - A P P R E P R R - - -						
		63	63	63	63	63
PANCREAS	NUMBER EXAMINED:	63	63	63	63	63
--ACINAR CELL HYPERPLASIA, FOCAL		0	1	0	1	1
--ISLET CELL HYPERPLASIA		0	0	1	0	0
--ACINAR CELL HYPERTROPHY, FOCAL		1	0	0	0	0
--ACINAR ATROPHY WITH CHRONIC INFLAMMATION		0	1	0	0	0
--ACINAR CELL DEGRANULATION		0	1	0	0	0
--EDEMA		1	0	1	1	0
--ARTERITIS		0	0	1	0	0
PARATHYROID	NUMBER EXAMINED:	63	60	59	61	59
--HYPERPLASIA		4	2	4	2	1
PITUITARY	NUMBER EXAMINED:	64	63	63	63	63
--DIFFUSE HYPERPLASIA		0	1	0	1	3
--HYPERPLASIA - PARS DISTALIS, FOCAL		5	9	3	7	3
--HYPERPLASIA - PARS INTERMEDIA, FOCAL		0	0	1	1	0
--HAEMORRHAGE		2	1	0	1	0
--DEVELOPMENTAL CYST(S)		0	10	0	3	7
--DUCTULAR ADENOMAS		0	0	0	1	0
--CONGESTION		0	0	0	1	0
RECTUM	NUMBER EXAMINED:	63	63	63	63	63
--SUBMUCOSAL INFLAMMATION		0	0	0	1	0
S. MUSCLE TRICH	NUMBER EXAMINED:	63	63	63	63	63
--MYOFIBER DEGENERATION		0	0	0	0	1
SALIVARY GLANDS	NUMBER EXAMINED:	63	63	63	63	63
--EDEMA		0	1	0	0	0

380

TABLE 11F - continued

Print No 0031

Histopathology - group distribution of non-neoplastic findings for all animals

Group : 1 2 3 4 5
 Compound : Control Control Palonosetron Hydrochloride
 Dose(s) mg/kg/day: 0 0 33 33/63 63/90

Printed 25-NOV-01
 Page 0

Schedule number N5H 001A

..... NUMBER OF ANIMALS AFFECTED

ORGAN AND FINDING DESCRIPTION	SEX GROUP	FEMALE				
		-1-	-2-	-3-	-4-	-5-
	NUMBER	65	65	65	65	65
** FROM PREVIOUS PAGE **						
SALIVARY GLANDS	NUMBER EXAMINED	65	65	65	65	65
--ACTINAR CELL DEGRANULATION		0	0	1	0	1
SCIATIC NERVE	NUMBER EXAMINED	65	65	65	65	65
--INFLAMMATION		0	1	0	0	0
--DEGENERATE FIBRES		3	1	2	1	3
SPINAL C CERV	NUMBER EXAMINED	65	65	65	65	65
--HAEMORRHAGE		1	0	0	0	0
SPLEEN	NUMBER EXAMINED	65	65	65	65	65
--FOCAL HYPERPLASIA OF WHITE PULP		1	0	0	0	0
--STROMAL HYPERPLASIA		0	0	1	1	0
--EXTRAMEDULLARY HAEMOPOIESIS		0	4	0	10	11
--HAEMOHIDROSIS		31	21	26	27	30
--CAPSULAR CYSTS		1	1	0	1	0
--NECROSIS		0	1	0	0	0
--CAPSULAR INFLAMMATION		0	0	0	1	0
STOMACH ()	NUMBER EXAMINED	65	65	65	65	65
--EPITHELIAL HYPERPLASIA - LIMITING RIDGE		2	2	2	0	1
--ROUNDED CYST - LIMITING RIDGE		2	0	1	3	0
--HYPERKERATOSIS - NONGLANDULAR REGION		0	1	0	0	0
--ULCERATION - NONGLANDULAR REGION		0	0	0	0	1
--EROSION - NONGLANDULAR REGION		1	0	0	0	7
--KERATINISED REGION ACANTHOLYSIS		0	0	2	0	1
--EPITHELIAL HYPERPLASIA - NONGLANDULAR REGION		1	0	2	0	1
--SUBMUCOSAL INFLAMMATION - NONGLANDULAR REGION		0	0	1	0	3
--DILATED GLANDS		12	8	10	9	12

381

TABLE 11P - continued.

Histopathology - group distribution of non-neoplastic findings for all animals

Group 1 2 3 4 5
 Compound Control Control Palonosetron Hydrochloride
 Doseage (mg/kg/day): 0 0 15 30/15 60/15

Printed 05-NOV-01
 Page 9

Schedule number N3H 001A

ORGAN AND FINDING DESCRIPTION	SEX GROUP	NUMBER OF ANIMAL AFFECTED					
		MALE		FEMALE			
		-1-	-2-	-3-	-4-	-5-	
STOMACH & J		NUMBER EXAMINED:	65	65	65	65	65
** FROM PREVIOUS PAGE **			0	0	0	0	0
--FIBROSIS IN LAMINA PROPRIA - GLANDULAR REGION			0	1	0	0	0
--GLANDULAR REGION - FOCAL STIMENT			0	0	1	0	0
--MUCOSAL EROSION - GLANDULAR REGION			0	0	2	2	0
--MUCUS CELL HYPERPLASIA			1	2	0	0	0
--ECTOPIC MINGLANDULAR EPITHELIUM IN GLANDULAR MUCOSA FOCAL			2	2	0	1	0
--EPITHELIAL HYPERPLASIA - GLANDULAR REGION			0	0	0	0	1
THYMUS		NUMBER EXAMINED:	64	64	65	64	65
--EPITHELIAL HYPERPLASIA			6	5	4	5	17
--CYSTITIS			23	20	27	27	24
--LYMPHOID ATROPHY			0	0	0	0	1
--HEMORRHAGE			0	0	0	1	0
--SITE ONLY			1	1	0	2	0
THYROID		NUMBER EXAMINED:	65	65	65	65	65
--PARAFOLLICULAR CELL HYPERPLASIA			21	7	10	12	3
--CYSTIC FOLLICULAR CELL HYPERPLASIA			2	0	0	2	0
--FOLLICULAR DILATATION			2	1	2	0	1
--FOLLICULAR CYSTITIS			2	0	1	1	2
--FOLLICULAR CELL HYPERTROPHY			0	0	0	0	1
TONGUE		NUMBER EXAMINED:	65	65	65	65	65
--INFLAMMATION			0	0	0	1	0
URINARY BLADDER		NUMBER EXAMINED:	65	65	65	65	65
--TRANSITIONAL CELL HYPERPLASIA			2	0	0	1	0
--LUMINAL DILATATION			1	0	0	1	0
--INFLAMMATION			0	0	1	0	0

0 0

TABLE IIF - continued

Print No. 00

Histopathology - group distribution of non-neoplastic findings for all animals

Group : 1 2 3 4 5
 Compound : Control Control Palonosetron Hydrochloride
 Dosage (mg/kg/day) : 0 0 15 30/45 60/90

Printed 03-NOV-
 Page 10

Schedule Number: 05H 001

----- NUMBER OF ANIMALS AFFECTED -----

ORGAN AND FINDING DESCRIPTION	NUMBER EXAMINED	SEX: ----- FEMALES -----				
		GROUP: -1-	-2-	-3-	-4-	-5-
***** FROM PREVIOUS PAGE ****						
URINARY BLADDER	NUMBER EXAMINED	65	65	65	65	64
--ARTERITIS		0	1	0	0	0
UTERINE CERVIX	NUMBER EXAMINED	65	65	65	64	65
--MURAL HYPERPLASIA		1	1	2	0	2
--EPITHELIAL HYPERPLASIA		0	0	2	0	2
--BOVIFORM EPITHELIAL CYST(S)		0	0	2	0	0
--EPITHELIAL MUCIFICATION		0	3	0	3	1
--FOCAL HISTIOCYTE ACCUMULATION		0	0	0	0	1
--HYPERPLASIOSIS		0	0	0	1	0
UTERUS	NUMBER EXAMINED	65	65	65	64	65
--ENDOMETRIAL STROMAL HYPERPLASIA		0	1	2	1	2
--ENDOMETRIAL HYPERPLASIA		0	2	2	2	1
--GLANDULAR DILATATION		0	1	2	1	0
--MYOMETRIAL ATROPHY		0	1	0	0	0
--MURAL HEMORRHAGE		0	0	1	0	0
--DILATED		3	11	14	9	5
--LUMINAL HEMORRHAGE		0	2	0	0	0
--ANGIECTASIS		0	2	0	0	0
VAGINA	NUMBER EXAMINED	65	65	65	65	65
--STROMAL HYPERPLASIA		0	0	0	0	1
--MUCUS AND INFLAMMATORY CELLS IN LUMEN		0	2	1	2	2
ADIPOSE TISSUE	NUMBER EXAMINED	0	3	0	3	2
--FOCAL PIGMENTED MACROPHAGES		1	1	0	0	0
--FAT NECROSIS		3	1	1	1	1
--EDEMA		0	0	0	0	1

383

TABLE 117 - continued.

Grant No. 0022

Histopathology - group distribution of non-neoplastic findings for all animals

Group Compound 1 Control 2 Control 3 Polameteron 4 Hydrochloride 5
 Dose (mg/kg/day) 0 0 15 20/41 60/10

Printed: 01-MAY-01
 Page: 11

Schedule number: N25 001A

----- NUMBER OF ANIMALS AFFECTED -----

ORGAN AND FINDING DESCRIPTION	SEX GROUP	FEMALE				
		1	2	3	4	5
ADIPOSE TISSUE	NUMBER EXAMINED	0	3	5	3	2
--CONGESTION		0	0	2	1	0
BILE DUCT	NUMBER EXAMINED	0	1	2	0	1
--LUMINAL DILATATION		0	1	1	0	1
BONE	NUMBER EXAMINED	0	2	1	3	1
--OSTEOLYSIS		0	0	0	1	1
--OSTEOCLAST HYPERPLASIA		0	0	1	0	0
LN AXILLARY	NUMBER EXAMINED	20	20	25	25	27
--SINUS HISTIOCYTOSIS		1	1	1	1	1
--SINUS ERYTHROCYTOSIS/ERYTHROPHAGOCYTOSIS		0	3	7	1	1
--PLASMOCYTOSIS		0	0	0	0	1
--PLASMOCYTOSIS		0	0	0	2	0
--HAEMORRHAGES		0	1	0	0	0
--AGGREGATIONS OF HISTIOCYTES		0	1	0	0	0
--SITE ONLY		0	0	1	0	0
LN BRONCHIAL	NUMBER EXAMINED	1	2	0	0	4
--SINUS ERYTHROCYTOSIS/ERYTHROPHAGOCYTOSIS		0	0	0	0	1
--SITE ONLY		0	0	0	0	1
LN THYMICAL	NUMBER EXAMINED	23	24	21	20	21
--SINUS ERYTHROCYTOSIS/ERYTHROPHAGOCYTOSIS		0	0	1	0	0
--AGGREGATIONS OF HISTIOCYTES		0	0	1	0	0
--SITE ONLY		3	3	3	3	2

384

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