

Figure 11 Histopathology of the liver in the males of chronic toxicity study

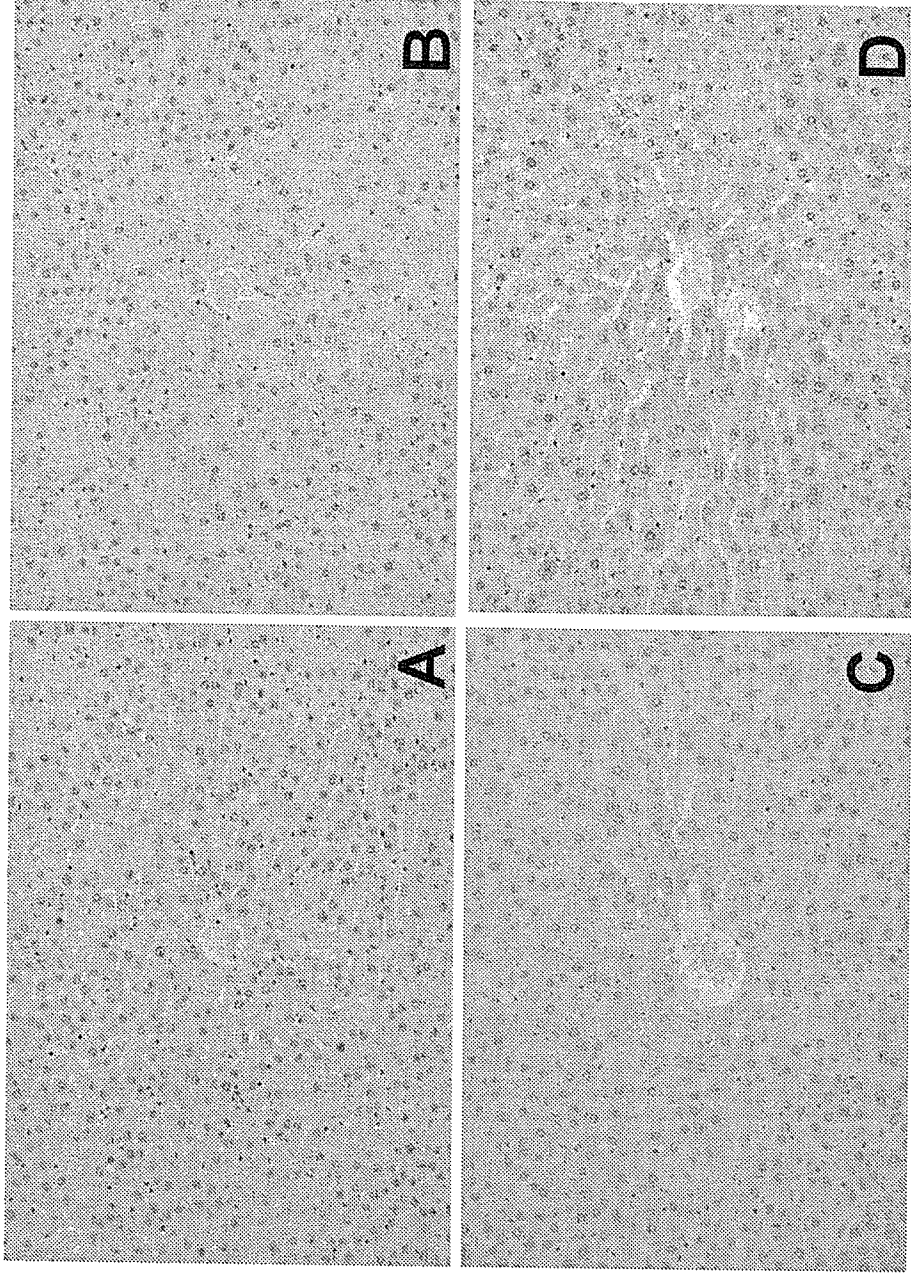


Figure 11 組織写真説明

- A 慢性毒性試験群 12ヶ月間投与対照群 雄 肝臓 異常を認めない. ヘマトキシリン・エオジン染色 x100
- B 慢性毒性試験群 12ヶ月間投与 3%投与群 雄 肝臓 小葉中心肝細胞に軽度な肥大が認められる. しかし、変性あるいは壊死性変化、あるいは炎症性変化などは認められない. ヘマトキシリン・エオジン染色 x100
- C 慢性毒性試験群 12ヶ月間投与対照群 雄 肝臓 小葉中心部にわずかに CYP3A2 抗体陽性部が認められる. CYP3A2 免疫組織化学染色 x100
- D 慢性毒性試験群 12ヶ月間投与 3%投与群 雄 肝臓 小葉中心部の肥大した肝細胞に一致して CYP3A2 抗体陽性部の増加が明らかである. CYP3A2 免疫組織化学染色 x100

Table 1 動物の割付表

群 (略称)	雄 (動物番号)		雌 (動物番号)	
	慢性毒性試験群	がん原性試験群	慢性毒性試験群	がん原性試験群
対照群 (Cont)	101~110	111~160	601~610	611~660
カテキン 0.02%群	201~210	211~260	701~710	711~760
カテキン 0.3%群	301~310	311~360	801~810	811~860
カテキン 1.0%群	401~410	411~460	901~910	911~960
カテキン 3.0%群	501~510	511~560	1001~1010	1011~1060

Table 2

Mortality at termination

Group	No of rats	Number of animals dead and sacrificed when moribund (%)
<b><u>Male</u></b>		
Control	50	18 (36)
0.02%	50	19 (38)
0.3%	50	16 (32)
1%	50	13 (26)
3%	50	11 (22)
<b><u>Females</u></b>		
Control	50	14 (28)
0.02%	50	19 (38)
0.3%	50	14 (28)
1%	50	15 (30)
3%	50	15 (30)

Table 3 Body weights in chronic toxicity study - Males - (g)

Group	(weeks)	-2	-1	0	1	2	3	4	5	6	7	8	9	10
0%	mean	130.4	169.8	194.5	242	283.8	315.2	345.2	369.4	386.3	401.7	412.9	431.3	442.5
(10)	SD	5.34	8.38	10.42	11.17	14.91	15.70	22.70	21.53	23.83	22.85	26.45	27.79	25.83
0.02% Catechin	mean	125.8	166.3	193.8	237.6	277.2	305.1	332.6	356.7	377.8	386.7	401.9	415.3	427.5
(10)	SD	5.79	8.72	10.17	13.95	17.94	21.38	24.61	25.73	25.75	32.06	32.69	32.56	35.69
0.3% Catechin	mean	125.6	164.5	193.1	241.9	284.1	317.2	348.7	369.2	388.8	403.1	420.7	427.1	442.3
(10)	SD	9.98	12.65	17.00	15.85	18.80	19.86	28.53	25.75	26.23	29.47	27.86	33.48	35.81
1.0% Catechin	mean	111.2	165.4	190.5	237.8	280.2	313.6	345.8	369.8	382.6	390.9	412.6	424.5	435.4
(10)	SD	33.69	4.65	5.84	6.71	12.94	15.69	20.58	26.69	24.84	34.14	30.34	30.75	30.53
3.0% Catechin	mean	123.6	166.9	190.1	232.4	271.1	305.7	332.5	357.6	368.4	379.9	381.6	400.3	423.1
(10)	SD	8.57	9.94	14.71	18.29	22.87	29.87	38.45	44.58	47.49	53.87	49.35	56.99	62.85
(weeks)		11	12	13	17	21	25	29	33	37	42	45	49	
Group														
0%	mean	438.9	453.6	462.5	476.1	504.5	522.9	546.3	542.6	556.1	572.0	579.4	575.5	
(10)	SD	34.74	28.82	29.59	37.43	36.69	41.14	46.84	47.90	54.40	56.16	58.04	72.41	
0.02% Catechin	mean	434.6	443	452.4	472.1	496.3	521	546.7	551.1	567.7	583.9	594.3	619.8	
(10)	SD	38.47	38.11	37.48	35.52	37.73	40.52	41.55	42.26	43.36	47.86	37.84	51.32	
0.3% Catechin	mean	448.6	452	462.6	487.8	513.7	540.4	562.1	570.8	596.8	621	625.8	626.2	
(10)	SD	35.14	40.24	42.53	46.48	54.84	66.36	69.54	73.04	95.22	109.32	90.18	92.02	
1.0% Catechin	mean	440.6	444.7	458.8	477	500.7	521.8	538	544.4	556.5	566.5	583.3	594.6	
(10)	SD	32.77	32.97	35.29	36.76	40.01	39.89	42.61	44.64	50.79	52.38	52.71	55.35	
3.0% Catechin	mean	418.8	427.6	442.6	457.4	473.4	495.6	519.2	524.1	544.8	536.6	544	556.5	
(10)	SD	57.65	58.83	72.07	63.79	66.15	74.17	80.44	84.13	85.03	97.35	106.57	107.58	

( ): No. of Animals examined.

Table 4 Body weights in chronic toxicity study - Females -

(g)

(weeks)	-2	-1	0	1	2	3	4	5	6	7	8	9	10	
Group														
0%	Mean	106.9	126.4	148	174	192.5	209.2	220.6	233.3	239.9	246.7	253.4	255.7	260.4
(10)	SD	8.52	7.59	8.86	9.42	9.85	10.18	9.50	10.04	14.88	14.77	14.87	15.55	14.89
0.02% Catechin	Mean	108.8	123.6	147.1	171.1	189.9	205.9	215.1	225	230.7	242.6	244	247.8	247.9
(10)	SD	6.25	4.88	10.03	8.32	10.49	13.18	11.90	14.17	13.19	16.83	19.51	18.71	19.27
0.3% Catechin	Mean	117.8	132	157.6	181.2	198	214.2	222.5	226.9	235.1	244.7	248.3	248.5	247
(10)	SD	2.94	2.16	6.52	6.97	7.87	15.05	9.43	13.09	10.81	12.97	14.88	14.08	15.09
1.0% Catechin	Mean	111.2	126.2	148	175	195.8	208.3	212	223.7	235.5	243.7	245.8	247.7	247
(10)	SD	8.94	7.77	10.28	9.53	13.07	9.81	10.70	12.32	13.03	13.08	14.10	15.66	15.17
3.0% Catechin	Mean	101.6	118.7	140	164.2	189.1	199.3	207.4	217.4	222.8	233.6	237	238	236.4
(10)	SD	6.20	6.63	7.57	10.56	10.73	12.11	11.98	15.26	16.18	17.71	16.92	18.21	17.65

(weeks)	11	12	17	21	25	29	33	37	42	45	49	
Group												
0%	Mean	260.1	265.9	282	293.9	306.6	314.9	316.7	335.5	345.9	355.5	366.6
(10)	SD	19.34	15.42	19.71	17.66	20.52	24.15	26.60	30.73	28.38	34.08	35.97
0.02% Catechin	Mean	253.4	258.4	275	291.9	305.7	311.1	316.6	324.6	338.8	348.9	356.7
(10)	SD	19.82	24.61	23.14	26.84	24.00	32.07	34.97	38.51	48.41	52.71	52.44
0.3% Catechin	Mean	257.6	260	277.2	284.5	295.9	304.8	311.8	319	332.1	340.1	351.5
(10)	SD	16.17	16.27	13.98	21.42	20.56	25.35	24.81	27.01	32.02	35.35	39.29
1.0% Catechin	Mean	253.2	255.9	268.7	278.6	288.6	294.1	319.9	321.9	332.7	341.1	362.7
(10)	SD	17.50	16.83	18.46	19.33	25.21	31.74	35.88	36.88	43.98	49.32	50.34
3.0% Catechin	Mean	239.6	247.7	260.5	270.5	277*	284	294.9*	294.3	303.1	308	310.5*
(10)	SD	18.45	16.73	18.88	22.51	23.55	23.07	22.46	24.64	19.26	20.73	22.62

(:) : No. of Animals examined. \*: Significantly different from 0% (p&lt;0.05)

Table 5 Hematology in chronic toxicity study —Males —

Group	RBC ×10000/mm <sup>3</sup>	WBC Hb / μl	HT g/dl	MCV %	MCH μ3	MCHC pg	%
0% Catechin	Mean	2662.5	15.1	49.4	60.5	18.4	30.5
(8)	SD	1140.10	0.38	1.27	1.77	0.52	0.53
0.02% Catechin	Mean	3500	15.1	48.8	60.2	18.6	31
(10)	SD	1030.64	0.42	2.11	1.32	0.52	0.67
0.3% Catechin	Mean	3500	15.1	48.8	60.2	18.6	31
(10)	SD	1030.64	0.42	2.11	1.32	0.52	0.67
1.0% Catechin	Mean	3350	15.0	48.9	59.6	18.2	30.7
(10)	SD	861.85	0.40	1.41	2.01	0.79	0.48
3.0% Catechin	Mean	793.3	14.8	48.6	61.3	18.6	30.4
(10)	SD	25.46	0.45	1.38	1.89	0.70	1.07

( ): No. of Animals examined.

Table 6 Hematology in Chronic toxicity study --Females --

Group	RBC ×10000/mm <sup>3</sup>	WBC /μl	Hb g/dl	HT	MCV %	MCH μg	MCHC pg	%
Control	Mean	709.2	198	14.3	46.2	65.1	20.2	30.9
(10)	SD	24.04	533.85	0.50	2.66	2.59	0.60	0.97
0.02% Catechin	Mean	693.1	1810.0	13.9	44.9	64.8	20.0	30.8
(10)	SD	22.24	438.30	0.46	1.60	1.48	0.67	0.63
0.3% Catechin	Mean	711.0	2222.2	14.4	46.6	65.4	20.3	30.9
(9) <sup>a</sup>	SD	24.40	742.93	0.57	1.64	0.88	0.50	0.78
1.0% Catechin	Mean	699.0	1700.0	14.2	45.7	65.4	20.2	31.0
(9)	SD	21.64	327.87	0.52	1.89	1.94	0.44	0.71
3.0% Catechin	Mean	691.0	2033.3	14.1	45.9	66.4	20.4	30.7
(9) <sup>a</sup>	SD	19.47	259.81	0.40	1.27	1.88	0.53	0.71

( ): No. of Animals examined.

<sup>a</sup> : Female was the blood sample of one female rat could not available for analysis due to blood coagulation.



Table 7 Blood biochemistry in chronic toxicity study —Males —

Group	TP g/dl	A/G	ALB g/dl	BIL mg/dl	TG mg/dl	TCHO mg/dl	CRE mg/dl	Na mEq/l	K mEq/l	Ca mg/dl	IP mg/dl	AST IU/l	ALT IU/l	ALP IU/l	$\gamma$ -GTP IU/l
0%	Mean	7.0	2.0	4.7	0.1	159	0.4	144.9	4.6	10.6	5.0	155.1	40.1	285.1	2 >
(8)	SD	0.17	0.34	0.29	0.02	52.80	0.04	0.64	0.31	0.23	0.76	36.05	8.84	51.75	
0.02% Catechin	Mean	7.2	1.8	4.6	0.1	189.6	0.4	144.7	4.6	10.8	5.2	148.4	42.1	267.0	2 >
(10)	SD	0.25	0.32	0.28	0.02	87.58	0.06	1.16	0.36	0.13	0.29	34.49	11.79	70.51	
0.3% Catechin	Mean	7.3	1.8	4.6	0.1	224.0	0.3*	145.3	4.4	10.7	5.0	133.7	43.1	268.4	2 >
(10)	SD	0.31	0.31	0.18	0.03	96.76	0.03	1.49	0.32	0.19	0.42	42.75	30.90	94.59	
1.0% Catechin	Mean	7.0	2.0	4.7	0.1	164.7	0.4	145.1	4.5	10.5	5.3	155.7	45.9	308.7	2 >
(10)	SD	0.28	0.19	0.21	0.02	56.19	0.04	0.88	0.28	0.28	0.48	27.13	9.99	47.66	
3.0% Catechin	Mean	6.8	2.1	4.6	0.1	158.6	0.3**	145.4	4.5	10.7	5.6	137.2	54.5	347.6	
(10)	SD	0.25	0.23	0.19	0.02	61.80	0.03	2.12	0.26	0.40	0.49	36.23	28.09	100.97	

( ): No. of Animals examined

\*, \*\*: Significantly different from 0% (p<0.05, p<0.01)

Table 8 Blood biochemistry in chronic toxicity study — Females —

Group	TP g/dl	A/G	ALB g/dl	BIL mg/dl	TG mg/dl	TCHO mg/dl	CRE mg/dl	Na mEq/l	K mEq/l	Ca mg/dl	IP mg/dl	AST IU/l	ALT IU/l	ALP IU/l	$\gamma$ -GTP IU/l
0%	Mean	2.3	5.6	0.1	234.9	110.4	0.4	140.7	4.0	10.5	3.8	140.3	34.1	79.3	2 >
(10)	SD	0.44	0.29	0.05	164.08	30.45	0.04	2.67	0.37	0.37	0.61	31.66	5.34	25.66	
0.02% Catechin	Mean	2.8	5.7	0.1	216.0	108.1	0.4	140.5	4.1	10.5	3.6	133.9	36.3	73.5	2 >
(10)	SD	0.53	0.44	0.05	104.58	16.87	0.04	2.68	0.37	0.32	0.41	35.26	10.86	20.97	
0.3% Catechin	Mean	2.4	5.5	0.1	270.9	107.9	0.4	141.1	4.3	10.4	3.7	134.5	35.4	86.3	2 >
(10)	SD	0.51	0.27	0.03	148.59	28.07	0.04	3.07	0.39	0.35	0.91	30.89	9.36	41.10	
1.0% Catechin	Mean	2.6	5.5	0.1	190.7	103.9	0.4	141.7	4.0	10.5	4.2	133.1	38.1	85.9	2 >
(9)	SD	0.39	0.26	0.03	63.08	32.25	0.05	3.12	0.44	0.42	0.47	27.67	13.53	37.53	
3.0% Catechin	Mean	3.0**	5.7	0.1	153.3	98.5	0.3	142.5	4.3	10.4	3.6	137.9	42.7	92.4	2 >
(10)	SD	0.42	0.35	0.03	83.66	17.36	0.03	3.47	0.25	0.37	0.35	31.88	14.31	11.14	

( ): No. of Animals examined

\*\* : Significantly different from 0% (p<0.01)

Table 9 Differential counts of leukocytes in chronic toxicity study —Males —

Group		Neutrophils					Basophiles	Mono cytes	Others
		Lymphocytes	Stab	Segs	Eosinophils				
0%	Mean	72.0	4.1	22.3	1.0	0	1.6	0	
(8)	SD	8.32	2.95	6.23	1.20	0	1.19	0	
0.02% Catechin	Mean	73.1	3.1	19.7	2	0	2.1	0	
(10)	SD	6.33	1.79	8.25	1.83	0	1.45	0	
0.3% Catechin	Mean	71.8	2	22.1	0.7	0	3.4	0	
(10)	SD	7.91	2.54	7.49	0.82	0	1.51	0	
1.0% Catechin	Mean	67.1	3.2	25.5	1.9	0.1	3.2	0	
(10)	SD	9.83	1.93	6.35	1.60	0.32	1.93	0	
3.0% Catechin	Mean	71.6	3.8	20.9	0.9	0	2.8	0	
(10)	SD	6.33	0.92	7.13	1.10	0	2.39	0	

( ): No. of Animals examined

Table 10 Differential counts of leukocytes in chronic toxicity study — Females —

Group	Lymphocytes	Neutrophils			Eosinophils	Basophiles	Mono cytes	Others
		Stab	Segs	Segs				
0%	Mean	5.2	21.3	2	0	2.9	0	
(10)	SD	3.97	9.45	1.15	0	1.85	0	
0.02% Catechin	Mean	4.3	26.9	2.1	0	3.4	0	
(10)	SD	3.09	9.41	1.20	0	1.26	0	
0.3% Catechin	Mean	1.8*	22.2	1.8	0	3.2	0	
(10)	SD	2.20	8.77	1.62	0	2.04	0	
1.0% Catechin	Mean	4.2	17.4	1.9	0	3.4	0	
(9)	SD	3.31	5.34	2.03	0	1.67	0	
3.0% Catechin	Mean	5	20.2	1.3	0	5.7*	0	
(10)	SD	2.00	5.25	1.49	0	3.09	0	

( ): No. of Animals examined

\*: Significantly different from 0% (p<0.05)

Table 11 Urinalysis in chronic toxicity study —Males —

Group	Urobilinogen	Occult blood	Bilirubin	Keton body	Glucose	Protein	pH	Ascorbic acid	Remarks
0% (8)	— : 8/8	— : 8/8	— : 6/8	— : 8/8	— : 8/8	+: 2/8	6: 3/8	0: 7/8	None
						++: 3/8	7: 3/8	25: 1/8	
						+++: 1/8	8: 2/8		
0.02% Catechin (9)	— : 9/9	— : 9/9	— : 9/9	— : 9/9	— : 9/9	+: 1/9	5: 1/9	0: 9/9	None
						++: 7/9	6: 2/9		
						+++: 1/9	7: 2/9		
							8: 4/9		
0.3% Catechin (9)	— : 9/9	— : 9/9	— : 9/9	— : 9/9	— : 9/9	+: 3/9	5: 2/9	0: 8/9	None
						++: 5/9	6: 2/9	25: 1/9	
						+++: 1/9	7: 4/9		
							8: 1/9		
1.0% Catechin None (7)	— : 7/7	— : 7/7	— : 7/7	— : 7/7	— : 7/7	+: 5/7	5: 1/7	0: 2/7	
						++: 2/7	6: 4/7	25: 5/7	
							7: 2/7		
3.0% Catechin (9)	— : 9/9	— : 9/9	— : 9/9	— : 9/9	— : 9/9	— : 1/9	5: 1/9	0: 1/9	None
						+: 5/9	6: 2/9	25: 5/9	
						++: 3/9	7: 4/9	25/60: 1/9	
							8: 2/9		

( ) : No. of Animals examined

Table 12 Urinalysis in Chronic toxicity study —Females —

Group	Urobilinogen	Occult blood	Bilirubin	Keton body	Glucose	Protein	pH	Ascorbic acid	Remarks
0% None (10)	— : 10/10	— : 9/10	— : 10/10	— : 10/10	— : 10/10	± : 7/10	5: 1/10	0: 1/10	
		+			+	6: 6/10	25: 9/10		
					++:	7: 3/10			
0.02% Catechin (8)	— : 8/8	— : 6/8	— : 8/8	— : 8/8	— : 8/8	— : 1/8	6: 7/8	0: 6/8	None
		+				±: 1/8	8: 1/8	25: 2/8	
						+	3/8		
						++:	3/8		
0.3% Catechin (9)	— : 9/9	— : 9/9	— : 9/9	— : 9/9	— : 9/9	± : 4/9	6: 6/9	0: 7/9	None
						+	4/9	25: 2/9	
						++:	1/9		
1.0% Catechin (8)	— : 8/8	— : 8/8	— : 8/8	— : 8/8	— : 8/8	± : 1/8	6: 4/8	0: 8/8	None
						+	6/8		
						++:	1/8		
3.0% Catechin (9)	— : 9/9	— : 8/9	— : 9/9	— : 8/9	— : 9/9	± : 4/9	6: 4/9	0: 9/9	None
				++:		+	1/9	7: 2/9	
						++:	2/9		

( ) : No. of Animals examined

Table 13 Organ weights in chronic toxicity study —Males —

Absolute weight

Group	Final B. W. (g)	Brain (mg)	Pituitary (mg)	Heart (mg)	Spleen (mg)	Liver (mg)	Adrenals (mg)	Kidneys (mg)	Testis (mg)	Prostate (mg)
0%	Mean	2070.6	13.8	1358.0	834.3	12971.8	60.1	2791.9	3730.6	676.8
(8)	SD	70.47	2.25	85.60	93.23	1236.93	6.85	383.37	235.53	184.03
0.02% Catechin	Mean	2148.6	11.8	1366.0	928.5	14798.1	65.2	2808.8	3938.0	653.0
(10)	SD	46.53	1.62	172.66	103.21	2667.65	13.02	417.57	313.14	141.96
0.3% Catechin	Mean	571	12.0	1393.3	1019.3	14856.8	64.8	2945.8	3460.1	668.8
(10)	SD	71.27	2.16	118.92	154.07	2504.39	7.44	316.11	574.62	138.77
1.0% Catechin	Mean	586	12.4	1387.7	937.9	3387.3	69.6	2921.3	4027.6	639.5
(10)	SD	52.90	1.84	164.06	153.27	1508.17	8.32	474.54	410.94	137.47
3.0% Catechin	Mean	560	12.1	1308	977.7	14289	60	3014.8	3884.1	611.5
(10)	SD	52.90	1.84	164.06	153.27	1508.17	8.32	474.54	410.94	137.47

Table 14 Organ weights in chronic toxicity study —Males —

Group	Relative weight (mg/BWg×100)	Brain	Pituitary	Heart	Spleen	Liver	Adrenals	Kidneys	Testis	Prostate
0%	Mean	360.7	2.4	235.8	145.5	2249.1	10.4	487.1	650.9	117.3
	SD	41.29	0.35	22.32	25.22	229.89	1.31	90.28	89.67	31.92
0.02% Catechin	Mean	356.9	2.0	225.2*	153.4	2435.0	10.8*	463.0	654.5	107.5
	SD	28.72	0.29	15.04	12.19	291.61	1.92	45.34	71.21	21.07
0.3% Catechin	Mean	196.9*	1.2	124.6	84.1	2399.2	6.1*	271.4	366.6	69.5
	SD	187.02	1.08	122.43	75.76	192.96	5.20	236.03	330.49	49.96
1.0% Catechin	Mean	368.4	2.1	236.5	159.8	2283.6	11.9	496.4	689.4	109.1
	SD	32.35	0.31	13.92	20.49	131.24	1.28	47.07	66.34	20.67
3.0% Catechin	Mean	399.1	2.2	236.6	176.4	2566.7*	10.9	541.8	707.8	110.6
	SD	64.71	0.38	29.45	27.48	269.34	2.05	42.90	108.35	21.64

( ): No. of Animals examined

\*: Significantly different from 0% (p<0.05)



Table 15 Organ weights in chronic toxicity study —Female —  
Absolute weight

Group	Final B.W. (g)	Brain (mg)	Pituitary (mg)	Heart (mg)	Spleen (mg)	Liver (mg)	Adrenals (mg)	Kidneys (mg)	Ovaries (mg)	Uterus (mg)
0%	Mean	2011.5	25	978.6	673.9	7474.4	86.9	1969.5	76.9	1320.2
(10)	SD	59.24	7.07	73.76	114.77	1130.63	20.51	178.91	33.31	302.82
0.02% Catechin	Mean	1978.7	24.2	902.6	610.8	7403.1	79.4	1954.7	87.3	1037.5
(10)	SD	56.39	7.08	97.84	98.26	915.07	16.60	171.13	27.64	469.12
0.3% Catechin	Mean	350	22.3	935.9	644.1	7468.9	85.2	1981	73.7	1059.2
(10)	SD	40.34	3.86	58.98	63.09	715.38	12.79	167.66	18.79	273.15
1.0% Catechin	Mean	349.8	20.3	905.8	664.3	7596.2	80.7	1998.8	93.9	1047.8
(9)	SD	54.47	3.32	102.43	88.48	1185.61	15.41	381.89	29.73	420.52
3.0% Catechin	Mean	305.8	18.9	876	667.3	6746.8	76.3	1862.2	90.3	1136.1
(10)	SD	21.58	3.28	78.92	82.44	487.23	5.44	169.20	50.44	445.64

Table 16 Organ weights in chronic toxicity study --Female --  
Relative weight (mg/BWg×100)

Group	Brain	Pituitary	Heart	Spleen	Liver	Adrenals	Kidneys	Ovaries	Uterus
0%	Mean 554.8	6.5	269.3	185.7	2044.5	24.1	541.7	21.3	368.7
	SD 61.74	1.00	28.85	37.74	247.63	6.89	60.99	9.20	119.78
0.02% Catechin	Mean 575.9	7.0**	259.0	174.1	2114.1	22.9	565.4	24.7	301.4
	SD 114.88	2.23	29.83	20.95	178.17	5.52	94.88	6.24	139.59
0.3% Catechin	Mean 550.2	6.5**	269.7	185.7	2148.1	24.5	570.0	21.5	302.9
	SD 111.73	1.36	25.87	23.01	210.31	3.91	53.26	6.79	72.07
1.0% Catechin	Mean 589.9	5.9*	261.9	194.0	2176.7	23.6	573.4	26.6	314.2
	SD 83.01	1.29	32.96	42.41	155.71	6.54	78.23	8.78	161.91
3.0% Catechin	Mean 646.7	6.2*	286.4	219.9	2210.3	25.1	609.1	29.6	371.2
	SD 39.26	1.07	14.72	36.76	148.15	2.57	36.55	16.48	140.34

( ): No. of Animals examined

\*, \*\*: Significantly different from 0% (p<0.05, p<0.01)

Table 17

Final body weights and liver weights at the termination

Group	No of rats	Body weight(g)	Liver weights	
			Absolute (mg)	Relative(a)
<b><u>Male</u></b>				
Control	32	692.32 ± 93.74(b)	21242 ± 4305.7	30.717 ± 5.1845
0.02%	31	680.19 ± 88.480	20691 ± 4037.1	30.524 ± 5.0252
0.3%	34	665.94 ± 104.19	20197 ± 4470.8	30.322 ± 5.2846
1%	37	646.73 ± 84.77	19135 ± 4330.7	29.617 ± 5.5515
3%	39	627.92 ± 71.32	17957 ± 2999.2	28.762 ± 5.0339
<b><u>Females</u></b>				
Control	36	441.81 ± 71.34	12884 ± 3092.5	28.334 ± 7.6226
0.02%	31	438.35 ± 55.84	12252 ± 2398.6	27.981 ± 4.180
0.3%	36	436.86 ± 78.29	13607 ± 3511.5	31.002 ± 4.867
1%	35	447.91 ± 68.80	12529 ± 2492.5	28.021 ± 4.206
3%	35	393.8 ± 50.248	11673 ± 2022.3	29.744 ± 4.136

(a), Liver weight (mg) / body weight (g)

(b), Mean ± SD

Table 18

Summary of histopathology of chronic toxicity study

Tissue Findings	Males						Females						
	Dose (%)	0	0.02	0.3	1	3	10	10	10	0.02	0.3	1	3
Number of rats examined													
10	10	10	10	10	10	10	10	10	10	10	10	10	10
<u>Neoplastic Lesions</u>													
Pituitary Adenoma of anterior lobe	0	0	0	0	0	0	0	0	0	1	1	0	0
Thyroid C-cell adenoma	1	0	2	0	0	0	0	0	0	0	0	0	0
Follicular cell adenoma	0	0	0	0	0	0	1	0	0	0	0	0	0
Spleen Hemangioma	0	0	0	0	1	0	0	0	0	0	0	0	0
Skin Papilloma	0	0	0	0	1	0	0	0	0	0	0	0	0
Testis Leydig cell tumor	0	0	1	0	0	0	0	0	-	-	-	-	-
Uterus Endometrial stromal polyp	-	-	-	-	-	-	-	-	3	1	1	1	0
Ductadenoma	-	-	-	-	-	-	1	0	0	0	0	0	0
<u>Non-neoplastic Lesions</u>													
Liver Centrilobular hypertrophy	0	0	0	0	0	8*	0	0	0	0	0	0	0
of hepatocytes	0	0	2	2	2	2	0	0	3	1	0	4	2
Altered foci, basophilic	0	0	0	0	1	0	0	0	0	0	0	0	0
Altered foci, eosinophilic	0	0	0	0	0	0	0	0	0	0	0	0	0

P\*, Significantly different from the control value (p&lt;0.05)

-, Not examined