



SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

Confidential

PROJECT : TOX-355A
PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 1.03

**SUMMARY OF OBSERVATIONS
(MALES & FEMALES)**

Group & Dosage level (mg / kg B.wt)	Clinical Observations	Necropsy Observations
Control group (Vehicle only) 0 mg/kg B.wt	No toxic signs or symptoms was noticed.	No noteworthy findings
NHH 44 Bt- Cotton seeds 5000 mg/kg B.wt	No treatment related toxic signs or symptoms was noticed.	No noteworthy findings
NHH 44 Non Bt- Cotton seeds 5000 mg/kg B.wt.	No treatment related toxic signs or symptoms was noticed.	No noteworthy findings



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TABLE - 1.04

MEAN PERCENTILE BODY WEIGHT DATA OF RATS

Group No.	Sex	Day 0	Day 7	Day 14	Sex	Day 0	Day 7	Day 14
CONTROL	Male	100.00 ± 0.00	104.18 ± 0.32	107.57 ± 0.42	Female	100.00 ± 0.00	103.91 ± 0.82	107.22 ± 0.94
	Female	100.00 ± 0.00	103.95 ± 0.42	107.44 ± 0.46		103.95 ± 0.36	107.22 ± 0.25	
NHH 44 Bt-COTTON SEEDS	Male	100.00 ± 0.00	103.44 ± 0.91	106.66 ± 1.05	Female	100.00 ± 0.00	103.90 ± 0.56	107.01 ± 0.77
	Female	100.00 ± 0.00	103.44 ± 0.91	106.66 ± 1.05		103.90 ± 0.56	107.01 ± 0.77	



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TABLE – 1.05
WEEKLY PERCENTILE BODY WEIGHT DATA OF RATS
GROUP : CONTROL - Vehicle only

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	100.00	104.49	107.86	1	F	100.00	104.96	108.07
2	M	100.00	104.24	107.27	2	F	100.00	103.35	106.14
3	M	100.00	103.68	107.36	3	F	100.00	102.84	106.25
4	M	100.00	104.09	108.18	4	F	100.00	104.24	107.87
5	M	100.00	104.44	107.22	5	F	100.00	104.19	107.78
Mean ± S.D.		100.00 ± 0.00	104.18 ± 0.32	107.57 ± 0.42	Mean ± S.D.		100.00 ± 0.00	103.91 ± 0.82	107.22 ± 0.94

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TABLE – 1.06
WEEKLY PERCENTILE BODY WEIGHT DATA OF RATS
GROUP : NHH 44 Bt-COTTON SEEDS
DOSE : 5000 mg/kg b.wt.

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	100.00	104.09	107.60	1	F	100.00	103.70	106.79
2	M	100.00	103.42	107.42	2	F	100.00	103.95	107.34
3	M	100.00	104.14	107.69	3	F	100.00	104.54	107.38
4	M	100.00	103.63	106.66	4	F	100.00	103.59	107.18
5	M	100.00	104.49	107.86	5	F	100.00	104.00	107.42
Mean ± S.D.		100.00 ± 0.00	103.95 ± 0.42	107.44 ± 0.46	Mean ± S.D.		100.00 ± 0.00	103.95 ± 0.36	107.22 ± 0.25



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TABLE – 1.07
WEEKLY PERCENTILE BODY WEIGHT DATA OF RATS
GROUP : NHH 44 NON Bt-COTTON SEEDS
DOSE : 5000 mg/kg b.wt.

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	100.00	103.40	106.81	1	F	100.00	104.19	107.18
2	M	100.00	102.79	105.58	2	F	100.00	104.70	108.23
3	M	100.00	104.79	108.38	3	F	100.00	103.42	106.85
4	M	100.00	102.46	106.17	4	F	100.00	103.88	106.66
5	M	100.00	103.48	106.39	5	F	100.00	103.35	106.14
Mean ± S.D.		100.00 ± 0.00	103.44 ± 0.91	106.66 ± 1.05	Mean ± S.D.		100.00 ± 0.00	103.90 ± 0.56	107.01 ± 0.77



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TABLE – 1.08

AVERAGE WEEKLY BODY WEIGHT(in grams) DATA OF RATS

Group No.	Sex	Day 0	Day 7	Day 14	Sex	Day 0	Day 7	Day 14
CONTROL	Male	171.40 ± 7.56	178.60 ± 8.35	184.40 ± 8.29	Female	169.60 ± 7.60	176.20 ± 6.61	181.80 ± 6.57
	Female	174.20 ± 5.63	181.00 ± 5.24	186.40 ± 5.12				
NHH 44 Bt-COTTON SEEDS	Male	171.20 ± 6.83	177.00 ± 7.07	182.60 ± 6.80	Female	171.14 ± 6.58	178.20 ± 7.29	183.80 ± 7.46
	Female	171.60 ± 5.07	178.40 ± 5.59	184.40 ± 6.06				

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TABLE - 1.09**WEEKLY BODY WEIGHT DATA (in gms) OF RATS
GROUP : CONTROL (Vehicle only)**

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	178	186	192	1	F	161	169	174
2	M	165	172	177	2	F	179	185	190
3	M	163	169	175	3	F	176	181	187
4	M	171	178	185	4	F	165	172	178
5	M	180	188	193	5	F	167	174	180
Mean ± S.D.		171.40 ± 7.56	178.60 ± 8.35	184.40 ± 8.29	Mean ± S.D.		169.60 ± 7.60	176.20 ± 6.61	181.80 ± 6.57

M-Male ; F-Female



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TABLE - 1.10

WEEKLY BODY WEIGHT DATA (in gms) OF RATS
GROUP : NHH 44 Bt-COTTON SEEDS
DOSE : 5000 mg /kg b.wt.

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	171	178	184	1	F	162	168	173
2	M	175	181	188	2	F	177	184	190
3	M	169	176	182	3	F	176	184	189
4	M	165	171	176	4	F	167	173	179
5	M	178	186	192	5	F	175	182	188
Mean		171.60	178.40	184.40	Mean		171.14	178.20	183.80
±		±	±	±	±		±	±	±
S.D.		5.07	5.59	6.06	S.D.		6.58	7.29	7.46



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TABLE - 1.11

WEEKLY BODY WEIGHT DATA (in gms) OF RATS
GROUP : NHH 44 NON Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt.

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	176	182	188	1	F	167	174	179
2	M	179	184	189	2	F	170	178	184
3	M	167	175	181	3	F	175	181	187
4	M	162	166	172	4	F	180	187	192
5	M	172	178	183	5	F	179	185	190
Mean ± S.D.		171.20 ± 6.83	177.0 ± 7.07	182.60 ± 6.80	Mean ± S.D.		174.20 ± 5.63	181.00 ± 5.24	186.40 ± 5.12

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TABLE - 2.01**MEAN HAEMATOLOGY DATA OF MALE RATS**

Parameters	Control (Vehicle only)	NHH 44 Bt-Cotton seeds 5000 mg /kg b.wt.	NHH 44 Non Bt-Cotton seeds 5000 mg /kg b.wt.
WBC (X10³)	7.42 ± 0.91	9.96 ± 1.89	7.98 ± 1.48
<u>Differential</u> Lymphocytes %	77.40 ± 3.44	83.20 ± 3.27	80.40 ± 2.51
Neutrophils %	20.80 ± 2.95	15.20 ± 2.49	18.40 ± 2.61
Eosinophils %	1.00 ± 0.71	0.80 ± 0.84	0.80 ± 0.45
Monocytes %	0.80 ± 0.45	0.80 ± 0.45	0.40 ± 0.55
Basophils %	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
R.B.C. (x10⁶) %	7.92 ± 0.43	7.94 ± 0.18	8.32 ± 0.45
Hb (gm %)	14.66 ± 0.60	15.18 ± 0.26	14.96 ± 0.51
Hct %	43.64 ± 2.21	44.96 ± 1.27	44.80 ± 1.58
Platelets (x10⁵)	11.92 ± 1.96	10.22 ± 0.59	11.02 ± 0.86

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TABLE – 2.02**MEAN HAEMATOLOGY DATA OF FEMALE RATS**

Parameters	Control (Vehicle only)	NHH 44 Bt-Cotton seeds 5000 mg /kg b.wt.	NHH 44 Non Bt-Cotton seeds 5000 mg /kg b.wt.
WBC (X10³)	8.07 ± 1.29	8.66 ± 1.13	7.70 ± 1.13
<u>Differential</u> Lymphocytes %	80.40 ± 3.97	85.00 ± 2.55	80.40 ± 2.30
Neutrophils %	18.00 ± 3.54	13.80 ± 2.28	18.00 ± 2.65
Eosinophils %	1.00 ± 0.71	0.60 ± 0.55	0.80 ± 0.45
Monocytes %	0.60 ± 0.55	0.60 ± 0.55	0.80 ± 0.45
Basophils %	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
R.B.C. (x10⁶) %	7.64 ± 0.51	7.94 ± 0.26	7.72 ± 0.48
Hb (gm %)	14.70 ± 0.66	15.24 ± 0.43	14.90 ± 0.58
Hct %	43.22 ± 2.82	44.60 ± 2.26	44.14 ± 1.66
Platelets (x10⁵)	9.06 ± 0.90	10.40 ± 1.27	10.82 ± 0.85



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TABLE - 2.03
HAEMATOLOGY DATA OF RATS
GROUP: Control (Vehicle Only)

DIFFERENTIAL											
Animal No.	Sex	WBC Count (x 10 ³)	L%	N%	E%	M%	B%	RBC Count (x 10 ⁶)	Hb gm %	Hct %	Platelet Count (x 10 ⁵)
1	M	7.2	74.0	23.0	02	01	0.0	8.1	15.4	46.2	10.1
2	M	8.9	83.0	16.0	00	01	0.0	8.5	15.1	45.3	11.2
3	M	7.4	76.0	23.0	01	00	0.0	7.6	14.3	42.0	14.4
4	M	6.4	78.0	20.0	01	01	0.0	7.4	13.9	40.9	10.3
5	M	7.2	76.0	22.0	01	01	0.0	8.0	14.6	43.8	13.6
Mean		7.42	77.40	20.8	01	0.8	0.00	7.92	14.66	43.64	11.92
±		±	±	±	±	±	±	±	±	±	±
S.D		0.91	3.44	2.95	0.71	0.45	0.00	0.43	0.60	2.21	1.96
1	F	7.8	83	16	01	00	0.0	8.3	15.5	46.5	8.2
2	F	7.4	85	13	01	01	0.0	7.7	15.0	43.9	10.4
3	F	10.2	81	19	00	00	0.0	7.0	13.7	39.3	8.8
4	F	6.8	78	20	01	01	0.0	7.3	14.6	41.6	9.5
5	F	7.9	75	22	02	01	0.0	7.9	14.7	44.8	8.4
Mean		8.02	80.4	18.0	01	0.60	0.00	7.64	14.70	43.22	9.06
±		±	±	±	±	±	±	±	±	±	±
S.D		1.29	3.97	3.54	0.71	0.55	0.00	0.51	0.66	2.82	0.90

L = Lymphocytes

N = Neutrophils

E = Eosinophils

M = Monocytes

B = Basophils



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TABLE - 2.04
HAEMATOTOLOGY DATA OF RATS
GROUP: NHH 44 Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt

DIFFERENTIAL											
Animal No.	Sex	WBC Count (x 10 ³)	L%	N%	E%	M%	B%	RBC Count (x 10 ⁶)	Hb gm %	Hct %	Platelet Count (x 10 ⁵)
1	M	7.4	80.0	17.0	02	01	00	8.1	15.4	46.2	10.0
2	M	10.6	88.0	11.0	00	01	00	8.0	14.9	44.7	10.9
3	M	12.4	85.0	15.0	00	00	00	8.1	15.4	46.2	10.8
4	M	10.5	82.0	16.0	01	01	00	7.7	15.3	44.5	9.6
5	M	8.9	81.0	17.0	01	01	00	7.8	14.9	43.2	9.8
Mean		9.96	83.2	15.20	0.80	0.8	0.00	7.94	15.18	44.96	10.22
±		±	±	±	±	±	±	±	±	±	±
S.D		1.89	3.27	2.49	0.84	0.45	0.00	0.18	0.26	1.27	0.59
1	F	8.6	85.0	14.0	01	00	00	8.0	15.4	46.2	8.8
2	F	10.6	85.0	14.0	00	01	00	8.0	15.0	43.6	9.6
3	F	8.4	89.0	10.0	01	00	00	7.8	14.8	42.3	11.4
4	F	7.9	82.0	16.0	01	01	00	8.3	15.9	47.7	10.3
5	F	7.8	84.0	15.0	00	01	00	7.6	15.1	43.2	11.9
Mean		8.66	85	13.98	0.60	0.60	0.00	7.94	15.24	44.60	10.4
±		±	±	±	±	±	±	±	±	±	±
S.D		1.13	2.55	2.28	0.55	0.55	0.00	0.26	0.43	2.26	1.27

L = Lymphocytes N = Neutrophils E = Eosinophils M = Monocytes B = Basophils



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TABLE - 2.05
HAEMATOLOGY DATA OF RATS
GROUP: NHH 44 NON Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt

DIFFERENTIAL											
Animal No.	Sex	WBC Count (x 10 ³)	L%	N%	E%	M%	B%	RBC Count (x 10 ⁶)	Hb gm %	Hct %	Platelet Count (x 10 ⁵)
1	M	8.4	84.0	15.0	00	01	0.0	8.2	14.4	43.2	11.5
2	M	7.1	80.0	19.0	01	00	0.0	8.2	14.7	44.1	10.8
3	M	10.4	77.0	22.0	01	00	0.0	7.9	14.7	43.7	11.5
4	M	7.1	81.0	17.0	01	01	0.0	9.1	15.5	46.5	9.6
5	M	6.9	80.0	19.0	01	00	0.0	8.2	15.5	46.5	11.7
Mean ± S.D		7.98 ± 1.48	80.4 ± 2.51	18.4 ± 2.61	0.8 ± 0.45	0.40 ± 0.55	0.00 ± 0.00	8.32 ± 0.45	14.96 ± 0.51	44.8 ± 1.58	11.02 ± 0.86
1	F	6.8	81	17	01	01	0.0	7.8	15.5	45.0	10.3
2	F	9.2	78	21	00	01	0.0	8.3	15.2	45.6	12.2
3	F	7.2	80	19	01	00	0.0	7.5	14.7	44.4	10.9
4	F	8.6	84	14	01	01	0.0	7.2	14.0	41.3	10.7
5	F	6.7	79	19	01	01	0.0	7.9	15.1	44.4	10.0
Mean ± S.D		7.7 ± 1.13	80.4 ± 2.30	18.0 ± 2.65	0.80 ± 0.45	0.8 ± 0.45	0.00 ± 0.00	7.72 ± 0.48	14.9 ± 0.58	44.14 ± 1.66	10.82 ± 0.85

L = Lymphocytes

N = Neutrophils

E = Eosinophils

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TABLE - 3.01
MEAN BIOCHEMISTRY DATA ON MALE RATS

Parameters	Control (Vehicle only)	NHH 44 Bt-Cotton seeds 5000 mg /kg b.wt.	NHH 44 Non Bt-Cotton seeds 5000 mg /kg b.wt.
Urea (mg %)	72.44 ± 5.94	48.40 ± 12.68	66.46 ± 16.15
Glucose (mg %)	166 ± 19.13	161.60 ± 11.99	147.20 ± 25.96
Total Protein (gm %)	7.36 ± 0.58	7.52 ± 1.28	9.38 ± 1.50
S.G.P.T (I.U)	57.42 ± 12.05	55.78 ± 10.07	56.40 ± 10.47
S.G.O.T (I.U)	129.06 ± 17.78	127.98 ± 19.65	162.24 ± 16.47
Albumin (gm %)	3.96 ± 0.22	3.84 ± 0.60	4.62 ± 0.85
SAP (I.U)	149.2 ± 32.06	160.00 ± 39.53	145.6 ± 24.46
Cholestrol (mg %)	47.4 ± 9.74	51.40 ± 12.92	76.20 ± 22.21

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TABLE - 3.02**MEAN BIOCHEMISTRY DATA ON FEMALE RATS**

Parameters	Control (Vehicle only)	NHH 44 Bt-Cotton seeds 5000 mg /kg b.wt.	NHH 44 Non Bt-Cotton seeds 5000 mg /kg b.wt.
Urea (mg %)	72.12 ± 13.32	52.92 ± 18.18	35.70 ± 4.42
Glucose (mg %)	156.60 ± 12.12	159.60 ± 5.68	158.20 ± 17.40
Total Protein (gm %)	7.44 ± 0.36	8.10 ± 1.95	7.06 ± 0.46
S.G.P.T (I.U)	48.58 ± 8.12	49.22 ± 6.96	36.88 ± 2.69
S.G.O.T (I.U)	129.7 ± 17.53	137.88 ± 21.35	112.14 ± 8.10
Albumin (gm %)	3.92 ± 0.08	4.34 ± 0.59	3.74 ± 0.42
SAP (I.U)	141.40 ± 30.40	119.80 ± 20.61	114.80 ± 17.54
Cholesterol (mg %)	48.00 ± 6.44	67.80 ± 16.77	61.80 ± 12.32



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TABLE - 3.03
BIOCHEMISTRY DATA OF RATS (VEHICLE ONLY)
GROUP : CONTROL

Animal No.	Sex	Urea (mg %)	Glucose (mg %)	Total Protein (gm%)	S .G.P.T I.U.	S.G.O.T I.U.	Cholestrol (mg%)	Albumin (gm%)	SAP I.U.
1	M	73.0	164	7.9	78.3	142.2	48	4.0	173
2	M	72.5	191	6.8	54.1	110.6	34	3.9	122
3	M	69.3	175	6.7	56.0	137.6	42	4.3	179
4	M	65.7	161	7.9	50.1	145.8	58	3.7	164
5	M	81.7	139	7.5	48.6	109.1	55	3.9	108
Mean		72.44	166	7.36	57.42	129.06	47.4	3.96	149.2
±		±	±	±	±	±	±	±	±
S.D		5.94	19.13	0.58	12.05	17.78	9.74	0.22	32.06
1	F	66.4	167	7.5	51.0	104.2	50	4.0	192
2	F	55.0	169	7.6	40.7	146.6	45	3.9	115
3	F	89.9	145	6.8	58.4	138.8	41	3.8	123
4	F	79.9	159	7.7	39.7	119.2	58	3.9	132
5	F	69.4	143	7.6	53.1	139.7	46	4.0	145
Mean		72.12	156.6	7.44	48.58	129.7	48	3.92	141.4
±		±	±	±	±	±	±	±	±
S.D		13.32	12.12	0.36	8.12	17.53	6.44	0.08	30.40



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TABLE - 3.04
BIOCHEMISTRY DATA OF RATS
GROUP: NHH 44 Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt

Animal No.	Sex	Urea (mg %)	Glucose (mg %)	Total Protein (gm%)	S .G.P.T I.U.	S.G.O.T I.U.	Cholestrol (mg%)	Albumin (gm%)	SAP I.U.
1	M	77.0	173	10.9	58.4	172.6	92	5.2	150
2	M	46.7	176	8.0	43.8	167.4	50	3.9	182
3	M	66.9	127	10.6	72.1	153.2	104	5.7	149
4	M	55.0	140	7.6	51.0	138.4	60	3.7	118
5	M	86.7	120	9.8	56.7	179.6	75	4.6	129
Mean		66.46	147.2	9.38	56.4	162.24	76.2	4.62	145.6
±		±	±	±	±	±	±	±	±
S.D		16.15	25.96	1.50	10.47	16.47	22.21	0.85	24.46
1	F	36.9	162	7.2	43.1	134.2	52	3.7	103
2	F	69.3	157	10.4	56.8	168.8	89	4.8	153
3	F	34.7	158	6.5	40.7	110.9	54	4.1	116
4	F	74.2	168	10.0	53.5	145.7	82	5.1	124
5	F	49.5	153	6.4	52.0	129.8	62	4.0	103
Mean		52.92	159.6	8.1	49.22	137.88	67.8	4.34	119.8
±		±	±	±	±	±	±	±	±
S.D		18.18	5.68	1.95	6.96	21.35	16.77	0.59	20.61

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PROJECT : TOX-355A
PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 3.05
BIOCHEMISTRY DATA OF RATS
GROUP: NHH 44 NON Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt

Animal No.	Sex	Urea (mg %)	Glucose (mg %)	Total Protein (gm%)	S .G.P.T I.U.	S.G.O.T I.U.	Cholestrol (mg%)	Albumin (gm%)	SAP I.U.
1	M	44.3	156	7.6	70.7	145.2	50	3.6	196
2	M	70.6	151	9.7	61.6	140.9	74	4.9	101
3	M	38.7	179	7.0	50.8	110.5	44	3.6	155
4	M	45.7	153	6.7	48.4	140.3	43	3.4	197
5	M	42.7	169	6.6	47.4	103.0	46	3.7	151
Mean		48.4	161.6	7.52	55.78	127.98	51.4	3.84	160
±		±	±	±	±	±	±	±	±
S.D		12.68	11.99	1.28	10.07	19.65	12.92	0.60	39.53
1	F	30.4	177	7.1	33.6	106.0	71	4.0	114
2	F	37.5	141	6.3	39.6	122.3	44	3.0	119
3	F	35.9	177	7.1	38.3	103.8	74	4.0	88
4	F	32.8	148	7.3	34.4	109.7	65	3.8	137
5	F	41.9	148	7.5	38.5	118.9	55	3.9	116
Mean		35.7	158.2	7.06	36.88	112.14	61.8	3.74	114.8
±		±	±	±	±	±	±	±	±
S.D		4.42	17.40	0.46	2.69	8.10	12.32	0.42	17.54

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PROJECT : TOX-355A
PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 4.01**MEAN PERCENTILE ORGAN WEIGHT DATA OF MALE RATS**

Dosage Group	Mean body wt. (gm)	Lung (gm)	Liver (gm)	Kidney (gm)	Testis (gm)	Adrenal (gm)	Heart (gm)	Spleen (gm)	Brains (gm)
Control (Vehicle only)	184.4 ± 8.29	0.94 ± 0.21	3.99 ± 0.38	1.02 ± 0.12	1.56 ± 0.23	0.05 ± 0.01	0.49 ± 0.12	0.38 ± 0.07	1.03 ± 0.19
NHH 44 Bt-Cotton seeds 5000 mg/kg b.wt	86.2 ± 3.77	1.08 ± 0.05	4.61 ± 0.47	1.00 ± 0.11	1.43 ± 0.12	0.03 ± 0.01	0.38 ± 0.05	0.32 ± 0.05	1.00 ± 0.12
NHH 44 Non Bt-Cotton seeds 5000 mg/kg b.wt	182.6 ± 6.80	0.79 ± 0.11	4.14 ± 0.62	0.92 ± 0.05	1.19 ± 0.27	0.03 ± 0.01	0.49 ± 0.12	0.38 ± 0.07	1.03 ± 0.19



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PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 4.02

MEAN PERCENTILE ORGAN WEIGHT DATA OF FEMALE RATS

Dosage Group	Mean body wt. (gm)	Lung (gm)	Liver (gm)	Kidney (gm)	Ovary (gm)	Uterus (gm)	Adrenal (gm)	Heart (gm)	Spleen (gm)	Brains (gm)
Control (Vehicle only)	181.80 ± 6.57	0.89 ± 0.17	3.55 ± 0.33	0.89 ± 0.07	0.13 ± 0.03	0.22 ± 0.03	0.07 ± 0.01	0.43 ± 0.03	0.37 ± 0.02	0.97 ± 0.08
NHH 44 Bt-Cotton seeds 5000 mg/kg b.wt	183.80 ± 7.46	0.75 ± 0.02	3.79 ± 0.53	0.85 ± 0.06	0.06 ± 0.02	0.23 ± 0.09	0.04 ± 0.01	0.33 ± 0.03	0.38 ± 0.09	0.91 ± 0.15
NHH 44 Non Bt-Cotton seeds 5000 mg/kg b.wt	178.2 ± 3.77	0.73 ± 0.02	4.21 ± 0.06	0.79 ± 0.01	0.07 ± 0.01	0.12 ± 0.02	0.04 ± 0.01	0.41 ± 0.01	0.25 ± 0.02	1.02 ± 0.01

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STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 4.03**AVERAGE ORGAN WEIGHT DATA OF MALE RATS**

Dosage Group	Mean body wt. (gm)	Lung (gm)	Liver (gm)	Kidney (gm)	Testis (gm)	Adrenal (gm)	Heart (gm)	Spleen (gm)	Brains (gm)
Control (Vehicle only)	184.4 ± 8.29	1.74 ± 0.43	7.34 ± 0.46	1.88 ± 0.23	2.86 ± 0.34	0.09 ± 0.01	0.91 ± 0.24	0.41 ± 0.08	1.88 ± 0.29
NHH 44 Bt-Cotton seeds 5000 mg/kg b.wt	184.4 ± 6.06	2.00 ± 0.11	8.48 ± 0.61	1.84 ± 0.16	2.64 ± 0.26	0.05 ± 0.02	0.70 ± 0.07	0.60 ± 0.07	1.84 ± 0.19
NHH 44 Non Bt-Cotton seeds 5000 mg/kg b.wt	182.6 ± 6.80	1.44 ± 0.22	7.59 ± 1.40	1.68 ± 0.15	2.17 ± 0.51	0.05 ± 0.02	0.71 ± 0.11	0.62 ± 0.12	1.76 ± 0.24



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STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 4.04

AVERAGE ORGAN WEIGHT DATA OF FEMALE RATS

Dosage Group	Mean body wt. (gm)	Lung (gm)	Liver (gm)	Kidney (gm)	Ovary (gm)	Uterus (gm)	Adrenal (gm)	Heart (gm)	Spleen (gm)	Brains (gm)
Control (Vehicle only)	181.80 ± 6.57	1.61 ± 0.33	6.46 ± 0.81	1.65 ± 0.13	0.23 ± 0.05	0.40 ± 0.05	0.13 ± 0.02	0.78 ± 0.05	0.66 ± 0.05	1.77 ± 0.11
NHH 44 Bt-Cotton seeds 5000 mg/kg b.wt	183.80 ± 7.46	1.37 ± 0.07	6.97 ± 0.95	1.56 ± 0.10	0.12 ± 0.05	0.41 ± 0.15	0.07 ± 0.02	0.61 ± 0.04	0.69 ± 0.17	1.66 ± 0.21
NHH 44 Non Bt-Cotton seeds 5000 mg/kg b.wt	186.40 ± 5.13	1.40 ± 0.19	5.92 ± 0.86	1.33 ± 0.12	0.14 ± 0.04	0.38 ± 0.13	0.09 ± 0.01	0.65 ± 0.10	0.54 ± 0.16	1.81 ± 0.19

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PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 4.05
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF MALE RATS
GROUP: CONTROL (VEHICLE ONLY)

Animal No	Sex	Body Weight in gms	LUNG		LIVER		KIDNEY		GONADS		ADRENAL		HEART		SPLEEN		BRAIN	
			Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt
1	M	192	1.37	0.71	7.06	3.68	1.59	0.83	2.31	1.20	0.07	0.04	0.66	0.34	0.53	0.28	1.58	0.82
2	M	177	1.48	0.84	6.95	3.93	1.76	0.99	3.12	1.76	0.1	0.06	0.79	0.45	0.62	0.35	2.08	1.18
3	M	175	1.44	0.82	8.12	4.64	1.9	1.09	3.06	1.75	0.08	0.05	0.81	0.46	0.74	0.42	2.02	1.15
4	M	185	2.18	1.18	7.21	3.90	1.92	1.04	2.74	1.48	0.1	0.05	1.02	0.55	0.87	0.47	2.16	1.17
5	M	193	2.23	1.16	2.23	3.80	2.21	1.15	3.08	1.60	0.09	0.05	1.26	0.65	0.74	0.38	1.56	0.81
Mean ± S.D.		184.4 ± 8.29	1.74 ± 0.43	0.94 ± 0.21	7.34 ± 0.46	3.99 ± 0.38	1.88 ± 0.23	1.02 ± 0.12	2.86 ± 0.34	1.56 ± 0.23	0.09 ± 0.01	0.05 ± 0.01	0.91 ± 0.24	0.49 ± 0.12	0.70 ± 0.13	0.38 ± 0.07	1.88 ± 0.29	1.03 ± 0.19



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PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 4.06
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF MALE RATS
NHH 44 Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt.

Animal No	Sex	Body Weight in gms	LUNG		LIVER		KIDNEY		GONADS		ADRENAL		HEART		SPLEEN		BRAIN	
			Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt
1	M	184	2.12	1.15	7.9	4.29	1.74	0.95	2.37	1.29	0.08	0.04	0.62	0.34	0.52	0.28	1.78	0.97
2	M	188	2.04	1.09	8.53	4.54	1.85	0.98	2.87	1.53	0.05	0.03	0.74	0.39	0.67	0.36	1.74	0.93
3	M	182	1.84	1.01	8.73	4.80	2.08	1.14	2.82	1.55	0.06	0.03	0.72	0.40	0.59	0.32	2.18	1.20
4	M	176	1.95	1.11	9.36	5.32	1.89	1.07	2.33	1.32	0.04	0.02	0.79	0.45	0.67	0.38	1.79	1.02
5	M	192	2.04	1.06	7.9	4.11	1.65	0.86	2.8	1.46	0.04	0.02	0.63	0.33	0.53	0.28	1.72	0.90
Mean ± S.D.		184.40 ± 6.07	2.00 ± 0.11	1.08 ± 0.05	8.48 ± 0.61	4.61 ± 0.47	1.84 ± 0.16	1.00 ± 0.11	2.64 ± 0.26	1.43 ± 0.12	0.05 ± 0.02	0.03 ± 0.01	0.70 ± 0.07	0.38 ± 0.05	0.60 ± 0.07	0.32 ± 0.05	1.84 ± 0.19	1.00 ± 0.12



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PROJECT : TOX-355A
PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE- 4.07
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF MALE RATS
NHH 44 NON Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt.

Animal No	Sex	Body Weight in gms	LUNG		LIVER		KIDNEY		GONADS		ADRENAL		HEART		SPLEEN		BRAIN	
			Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt
1	M	188	1.58	0.84	8.55	4.55	1.86	0.99	2.45	1.30	0.05	0.03	0.74	0.39	0.72	0.38	1.9	1.01
2	M	189	1.52	0.80	9.38	4.96	1.74	0.92	2.65	1.40	0.03	0.02	0.86	0.46	0.73	0.39	1.89	1.00
3	M	181	1.66	0.92	7.12	3.93	1.59	0.88	1.32	0.73	0.07	0.04	0.61	0.34	0.66	0.36	1.73	0.96
4	M	172	1.31	0.76	5.79	3.37	1.48	0.86	2.31	1.34	0.03	0.02	0.58	0.34	0.5	0.29	1.35	0.78
5	M	183	1.12	0.61	7.13	3.90	1.73	0.95	2.1	1.15	0.05	0.03	0.74	0.40	0.48	0.26	1.91	1.04
Mean ± S.D.		182.60 ± 6.80	1.44 ± 0.22	0.79 ± 0.11	7.59 ± 1.40	4.14 ± 0.62	1.68 ± 0.15	0.92 ± 0.05	2.17 ± 0.51	1.19 ± 0.27	0.05 ± 0.02	0.03 ± 0.01	0.71 ± 0.11	0.39 ± 0.05	0.62 ± 0.12	0.34 ± 0.06	1.76 ± 0.24	0.96 ± 0.10



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PROJECT : TOX-355A
PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 4.08
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF FEMALE RATS
GROUP : CONTROL (VEHICLE ONLY)

Animal No	Sex	Body Weight in gms	LUNG		LIVER		KIDNEY		OVARY		UTREUS		ADRENAL		HEART		SPLEEN		BRAIN	
			Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt	Wt.in gm	% Body wt
1	F	174	1.34	0.77	6.06	3.48	1.75	1.01	0.18	0.10	0.35	0.20	0.11	0.06	0.78	0.45	0.58	0.33	1.72	0.99
2	F	190	1.35	0.71	7.83	4.12	1.66	0.87	0.19	0.10	0.4	0.21	0.15	0.08	0.71	0.37	0.71	0.37	1.67	0.88
3	F	187	2.03	1.09	6.49	3.47	1.62	0.87	0.28	0.15	0.43	0.23	0.12	0.06	0.85	0.45	0.66	0.35	1.72	0.92
4	F	178	1.43	0.80	5.79	3.25	1.46	0.82	0.21	0.12	0.34	0.19	0.15	0.08	0.78	0.44	0.66	0.37	1.76	0.99
5	F	180	1.9	1.06	6.13	3.41	1.78	0.99	0.29	0.16	0.46	0.26	0.14	0.08	0.8	0.44	0.71	0.39	1.96	1.09
Mean ± S.D.		181.80 ± 6.57	1.61 ± 0.33	0.89 ± 0.17	6.46 ± 0.81	3.55 ± 0.33	1.65 ± 0.13	0.89 ± 0.07	0.23 ± 0.05	0.13 ± 0.03	0.40 ± 0.05	0.22 ± 0.03	0.13 ± 0.02	0.07 ± 0.01	0.78 ± 0.05	0.43 ± 0.03	0.66 ± 0.05	0.37 ± 0.02	1.77 ± 0.11	0.97 ± 0.08



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PROJECT : TOX-355A
PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 4.09
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF FEMALE RATS
NHH 44 Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt..

Animal No	Sex	Body Weight in gms	LUNG		LIVER		KIDNEY		OVARY		UTREUS		ADRENAL		HEART		SPLEEN		BRAIN	
			Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt
1	F	173	1.27	0.73	6.13	3.54	1.47	0.85	0.12	0.07	0.63	0.36	0.04	0.02	0.61	0.35	0.63	0.36	1.88	1.09
2	F	190	1.37	0.72	5.77	3.04	1.46	0.77	0.18	0.09	0.28	0.15	0.07	0.04	0.58	0.31	0.45	0.24	1.63	0.86
3	F	189	1.45	0.77	7.47	3.95	1.69	0.89	0.13	0.07	0.27	0.14	0.05	0.03	0.58	0.31	0.85	0.45	1.35	0.71
4	F	179	1.37	0.77	7.92	4.42	1.58	0.88	0.05	0.03	0.41	0.23	0.08	0.04	0.62	0.35	0.66	0.37	1.83	1.02
5	F	188	1.4	0.74	7.55	4.02	1.61	0.86	0.12	0.06	0.48	0.26	0.09	0.05	0.68	0.36	0.87	0.46	1.62	0.86
Mean ± S.D.		183.80 ± 7.46	1.37 ± 0.07	0.75 ± 0.02	6.97 ± 0.95	3.79 ± 0.53	1.56 ± 0.10	0.85 ± 0.06	0.12 ± 0.05	0.06 ± 0.02	0.41 ± 0.15	0.23 ± 0.09	0.07 ± 0.02	0.04 ± 0.01	0.61 ± 0.04	0.33 ± 0.03	0.69 ± 0.17	0.38 ± 0.09	1.66 ± 0.21	0.91 ± 0.15



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PROJECT : TOX-355A
 PRODUCT : NHH 44 Bt-COTTON SEEDS
 STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
 REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 4.10
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF FEMALE RATS
NHH 44 NON Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt.

Animal No	Sex	Body Weight in gms	LUNG		LIVER		KIDNEY		OVARY		UTREUS		ADRENAL		HEART		SPLEEN		BRAIN	
			Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt	Wt. in gm	% Body wt
1	F	179	1.15	0.64	5.41	3.02	1.24	0.69	0.12	0.07	0.37	0.21	0.11	0.06	0.64	0.36	0.43	0.24	1.66	0.93
2	F	184	1.26	0.68	4.91	2.67	1.23	0.67	0.15	0.08	0.2	0.11	0.08	0.04	0.48	0.26	0.49	0.27	1.75	0.95
3	F	187	1.48	0.79	7.03	3.76	1.48	0.79	0.16	0.09	0.51	0.27	0.1	0.05	0.73	0.39	0.52	0.28	1.87	1.00
4	F	192	1.52	0.79	6.55	3.41	1.42	0.74	0.19	0.10	0.51	0.27	0.09	0.05	0.73	0.38	0.82	0.43	2.12	1.10
5	F	190	1.59	0.84	5.72	3.01	1.26	0.66	0.1	0.05	0.32	0.17	0.09	0.05	0.66	0.35	0.42	0.22	1.67	0.88
Mean ± S.D.		186.40 ± 5.13	1.40 ± 0.19	0.75 ± 0.08	5.92 ± 0.86	3.17 ± 0.42	1.33 ± 0.12	0.72 ± 0.06	0.14 ± 0.04	0.08 ± 0.02	0.38 ± 0.13	0.20 ± 0.07	0.09 ± 0.01	0.05 ± 0.01	0.65 ± 0.10	0.35 ± 0.16	0.29 ± 0.08	0.25 ± 0.02	1.81 ± 0.19	0.98 ± 0.09

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PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE - 5.01
INTENSITY OF GROSS PATHOLOGICAL LESIONS
GROUP-CONTROL (VEHICLE ONLY) IN RATS

ANIMAL NO.										
ORGAN	MALE RATS					FEMALE RATS				
	1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Liver	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Heart	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gonads	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Spleen	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Kidney	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Brain	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Adrenal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gastrointestinal Tract	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development



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PROJECT : TOX-355A
PRODUCT : NHH 44 Bt-COTTON SEEDS
STUDY : ACUTE ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000041398 DATE : 23.03.2007

TABLE -5.02
INTENSITY OF GROSS PATHOLOGICAL LESIONS
NHH 44 Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt.

ANIMAL NO.										
ORGAN	MALE RATS					FEMALE RATS				
	1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Liver	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Heart	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gonads	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Spleen	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Kidney	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Brain	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Adrenal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gastrointesti -nal Tracts	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

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TABLE -5.03
INTENSITY OF GROSS PATHOLOGICAL LESIONS
NHH 44 NON Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt.

ANIMAL NO.										
ORGAN	MALE RATS					FEMALE RATS				
	1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Liver	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Heart	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gonads	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Spleen	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Kidney	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Brain	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Adrenal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gastrointesti -nal Tracts	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development



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TABLE - 6.01
INTENSITY OF HISTOPATHOLOGICAL LESIONS
GROUP-CONTROL (VEHICLE ONLY) IN RATS

ANIMAL NO.										
	MALE RATS					FEMALE RATS				
ORGAN	1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Liver	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Heart	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gonads	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Spleen	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Kidney	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Brain	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Adrenal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gastrointestinal Tract	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development



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TABLE -6.02
INTENSITY OF HISTOPATHOLOGICAL LESIONS
NHH 44 Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt.

ANIMAL NO.										
ORGAN	MALE RATS					FEMALE RATS				
	1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Liver	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Heart	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gonads	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Spleen	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Kidney	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Brain	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Adrenal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gastrointesti -nal Tracts	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development



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TABLE -6.03
INTENSITY OF HISTOPATHOLOGICAL LESIONS
NHH 44 NON Bt-COTTON SEEDS DOSE : 5000 mg /kg b.wt.

ANIMAL NO.										
ORGAN	MALE RATS					FEMALE RATS				
	1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Liver	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Heart	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gonads	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Spleen	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Kidney	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Brain	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Adrenal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gastrointesti -nal Tracts	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development