Annexure to Report No. : 000066702
Dt. : 14.11.03

TOXICOLOGY STUDY REPORT

PROJECT NO.	:	TOX / 286
SPONSOR	:	J. K. AGRI – GENETICS, (A DIVISION OF J. K. INDUSTRIES LTD.) 1-10-177, 4TH FLOOR, VARUN TOWERS, BEGUMPET, HYDERABAD – 500016
SUBJECT	:	ACUTE ORAL TOXICITY STUDY IN RATS
PRODUCT	:	CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE (JKC738 Lot No. F 3815) ALONG WITH NON TRANSGENIC COTTON SEED LINE (JKC738 Lot No. F 3815)
MATERIAL DESCRIPTION	:	BROWN COLORED CRUSHED WHOLE SEED
RESULT	:	Under the condition of this study, the given sample of crushed whole seed of transgenic cotton line JKC738 was found to be **non-toxic** to wistar rats, as compared to non- transgenic crushed cotton line JKC738, when it was administered orally as a single dose at maximum dose level of 5000 mg/kg.b.wt.of the test substance.
Total No. of pages :		61

SCIENTIST
PATHOLOGY

DY. DIRECTOR

SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH
(A Unit of Shriram Scientific & Industrial Research Foundation, Delhi)
19, University Road, Delhi - 110 007

SHRIRAM INSTITUTE

CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE ALONG WITH NON TRANSGENIC COTTON SEED ACUTE ORAL TOXICITY STUDY IN RAT

QUALITY ASSURANCE STATEMENT

The work described in this report was performed under my supervision as study director in accordance with Guidelines for toxicity and allergenicity, Evaluation of Transgenic seeds, plants and plant parts (Adoption O.E.C.D guidelines No. 401), Department of Biotechnology, Ministry of Science and Technology, Government of India for non-clinical laboratory studies.

The report provides true and accurate record of results obtained.

M Aggarwal

Asst. Director &
Chief, Toxicology

The following scientific and supervisory personnel were involved in the study :

Dr. Binu Bhat

Dr. Dhirendra Singh

Manoj Kumar

SHRIRAM INSTITUTE

CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE ALONG WITH NON TRANSGENIC COTTON SEED ACUTE ORAL TOXICITY STUDY IN RAT

OBJECTIVE

(a) To determine the acute oral toxicity to the rat of the test substance when administered as a single dose at the maximum dose level of the test substance.

b) To obtain information on the health hazards likely to arise from a short term exposure by the oral route.

EXPERIMENTAL DESIGN

Name of species	:	***Rattus Rattus albanicus***
Strain of the animals	:	Wistar
No. of animals used per dose	:	5 Male, 5 Female
Age of the animals used	:	5 to 8 weeks
Weight range	:	160-180 gms
Acclimatization period	:	7 Days
Route of administration	:	Oral
Vehicle used	:	Groundnut oil

SHRIRAM INSTITUTE

CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE ALONG WITH NON TRANSGENIC COTTON SEED ACUTE ORAL TOXICITY STUDY IN RAT

HUSBANDRY

All animals were caged in a group of 5 according to sex in plastic cages fitted with wire mesh tops and having sterilized paddy husk bedding. Water and standard rat diet were freely available. The room temperature was maintained at 24 ± 2 ^{0}C with 40 - 70 % relative humidity.

The room was ventilated at the rate of approximately 15 air changes per hour. Lighting was controlled to give 12 hours artificial light (8 a.m. - 8 p.m.) each day.

METHOD OF ADMINISTRATION

The animals were fasted for approximately 18 hours before and 4 hours after dosing.

Three groups of 5 male and 5 female rats each were designated for the study. First group was kept as control which was administered with vehicle only. Second group was administered with the non-transgenic crushed cotton seed sample at the dose levels of 2500 and 5000mg/kg. B.wt. Similarly transgenic crushed cotton seed sample were provided to group 3 at the dose levels of 2500 and 5000mg/kg. B.wt respectively.

SHRIRAM INSTITUTE

OBSERVATION

All experimental (test and control) animals were observed for 14 days (Table-1). Observations were made three times on the day of dosing and twice daily thereafter for the remainder of 14 days or until reversible toxic signs or symptoms subsided.

Body weights : Recorded individually, before treatment and at weekly intervals, thereafter mean body weights were calculated.

Signs / symptoms : Recorded daily in terms of clinical manifestation, if any.

Mortalities : If any, subjected to detailed macroscopic Examination.

The following clinical laboratory determinations were made in all the animals of both (test and control) groups after termination of the experiment. All animals were sacrificed and the organs were weighed and subjected to detailed histopathological examinations.

CLINICAL LABORATORY STUDIES

Blood sampling : 3-5 ml of blood was withdrawn by cardiac puncture under light nembutol anaesthesia prior to sacrifice.

SHRIRAM INSTITUTE

CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE ALONG WITH NON TRANSGENIC COTTON SEED ACUTE ORAL TOXICITY STUDY IN RAT

HAEMATOLOGY :

Following haematological estimations were performed on control and treated group of animals using Baker Haematology system 9120^{+} .

Haematocrit (Hct)
Haemoglobin (Hb)
Total Erythrocyte count (TEC)
Platelet count
Total Leucocyte count (TLC)
Differential Leucocyte counts (DLC)
Neutrophils (N)
Lymphocytes (L)
Basophils (B)
Monocyte (M)
Eosinophils (E)

SERUM BIOCHEMISTRY :

Following estimations were performed on control and treated rats using Boehringer Mannheim diagnostic kits :

(a) Blood sugar
(b) Blood urea nitrogen (BUN)
(c) Total protein (TP)
(d) Albumin
(e) Serum glutamic oxalo acetate transaminase (SGOT)
(f) Serum glutamic pyruvic transaminase (SGPT)
(g) Serum alkaline phosphatase (SAP)

SHRIRAM INSTITUTE

CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE ALONG WITH NON TRANSGENIC COTTON SEED ACUTE ORAL TOXICITY STUDY IN RAT

SACRIFICE AND NECROPSY

All the experimental animals were subjected to necropsy, whether they were sacrificed or died during study. All findings not considered normal were recorded.

Histopathology : Microscopic examination of the following tissues from all animals of the control and treated group were carried out :

Stomach	Brain
Ileum	Heart
Liver	Lungs
Spleen	Kidneys (both)
Testis (both) in males	Adrenals (both)
Ovaries (both) in females	Uterus in females

Any other macroscopically abnormal tissue.

BIOSTATISTICAL METHOD USED : Student's T-test

SHRIRAM INSTITUTE

RESULT

Mortality and toxic signs

No mortality was recorded (Table-1) due to effect of test substance. No toxic signs or symptoms (Table-2) were noticed in any test as well as control group of animals.

Mean body weights

No significant differences were observed in the body weight gain / loss pattern (Table 3 -3.11) in both test and control group.

Haematological evaluations

No significant changes were noted among both test and control group of animals with respect to haematological findings (Tables 4-4.06) as all the parameters fall within the accepted limits of normal variations.

Clinical biochemistry evaluations

Serum biochemistry evaluations (Tables 5-5.06) disclosed no significant differences in test and control groups of animals as all the parameters fall with in the accepted limits of normal variations.

Organ Weight

Absolute organ weights and their ratios (Relative organ weights) with body weights are shown in tables 7-7.13. In absence of any significant change in the organ weights, these organs have failed to suggest any specific target organ to the test substance.

SHRIRAM INSTITUTE

Necropsy Finding

Necropsy examination (Tables 8-8.04) did not reveal any macroscopical changes in any of the test (Transgenic group of crushed cotton seed) as well as control groups i.e. administered crushed non-Transgenic cotton seed and vehicle only.

Histopathological Finding

No remarkable histopathological changes (Tables 8.04-8.09) were observed in the animals treated with any transgenic group of crushed cotton seed and non-transgenic crushed cotton seed. These animals were comparable with the animals of control group (vehicle only).

Under the condition of this study, the given samples of 'Crushed whole seed of Transgenic cotton line JKC738 was found to be **non-toxic** to wistar rats, when compared to Non-transgenic crushed cotton line JKC738 as the control, when it was administered orally as a single dose at maximum dose level of 5000 mg/kg.b.wt.of the test substance.

The compound has been tested as per "Guidelines for toxicity and allergenicity, Evaluation of Transgenic seeds, plants and plant parts (Adoption O.E.C.D guidelines No. 401), Department of Biotechnology, Ministry of Science and Technology, Government of India for non- clinical laboratory studies.

SHRIRAM INSTITUTE

CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE
ALONG WITH NON TRANSGENIC COTTON SEED
ACUTE ORAL TOXICITY STUDY IN RAT

TABLE - 1

LD_{50} ASSAY - MORTALITY DATA

Sex & Dosage level gm/rat	Time of Death (Days) 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15	Cumulative Mortality
MALES		
CONTROL- WITHOUT ANY COTTON SEED, i.e. VEHICLE ONLY	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0/5
NON- TRANSGENIC COTTON SEED SAMPLE 2500 mg/kg .B.wt	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0/5
NON- TRANSGENIC COTTON SEED SAMPLE 5000 mg/kg .B.wt	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0/5
TRANSGENIC COTTON SEED SAMPLE 2500 mg/kg .B.wt	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0/5
TRANSGENIC COTTON SEED SAMPLE 5000 mg/kg .B.wt	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0/5
FEMALES		
CONTROL- WITHOUT ANY COTTON SEED, i.e. VEHICLE ONLY	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0/5
NON- TRANSGENIC COTTON SEED SAMPLE 2500 mg/kg .B.wt	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0/5
NON- TRANSGENIC COTTON SEED SAMPLE 5000 mg/kg .B.wt	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0/5
TRANSGENIC COTTON SEED SAMPLE 2500 mg/kg .B.wt	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0/5
TRANSGENIC COTTON SEED SAMPLE 5000 mg/kg .B.wt	0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	0/5

SHRIRAM INSTITUTE

CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE ALONG WITH NON TRANSGENIC COTTON SEED ACUTE ORAL TOXICITY STUDY IN RAT

TABLE-2
SUMMARY OF OBSERVATIONS
(MALES & FEMALES)

Dosage level (gm/rat B.wt)	Clinical Observations	Necropsy Observations
Control (without any cotton seed, given vehicle only)	No toxic signs or symptoms were noted.	No noteworthy findings
Non-transgenic cotton seed (2500 mg/kg. b.wt.)	No treatment related toxic signs or symptoms were noted.	No noteworthy findings
Non-transgenic cotton seed (5000 mg/kg. b.wt.)	No treatment related toxic signs or symptoms were noted.	No noteworthy findings
Transgenic cotton seed (2500 mg/kg. b.wt.)	No treatment related toxic signs or symptoms were noted.	No noteworthy findings
Transgenic cotton seed (5000 mg/kg. b.wt.)	No treatment related toxic signs or symptoms were noted.	No noteworthy findings

TABLE - 3
MEAN PERCENTILE BODY WEIGHT DATA OF RATS

Gp. No.	Sex	Day 0	Day 7	Day 14	Sex	Day 0	Day 7	Day 14
1. Control (vehicle only)	Male	100	103.74	107.78	Female	100	103.34	107.02
2. Non- transgenic crushed cotton seed sample (2500 mg/kg.b.wt)	Male	100	103.36	106.94	Female	100	103.29	107.16
3.Non-Transgenic Crushed cotton seed sample (5000 mg/kg.b.wt)	Male	100	103.77	107.43	Female	100	103.34	106.52
4. Transgenic Crushed cotton seed sample 2500 mg/kg.b.wt)	Male	100	103.78	107.64	Female	100	103.17	106.59
5. Transgenic Crushed cotton seed sample (5000 mg/kg.b.wt)	Male	100	103.67	106.65	Female	100	103.54	107.20

TABLE - 3.01

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	103.27	106.93	1	F	100	103.06	106.37
2	M	100	103.24	106.54	2	F	100	103.47	108.02
3	M	100	104.29	109.14	3	F	100	104.23	107.69
4	M	100	103.68	107.55	4	F	100	103.15	106.98
5	M	100	103.74	108.90	5	F	100	102.82	106.10
	Mean	100	103.74	107.78		Mean	100	103.34	107.02

TABLE - 3.02
WEEKLY PERCENTILE BODY WEIGHT DATA OF RATS
GROUP : NON TRANSGENIC CRUSHED COTTON SEED SAMPLE
DOSE : 2500 mg/kg b.wt.

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	100	102.88	106.26	1	F	100	103.77	108.27
2	M	100	103.78	108.06	2	F	100	103.41	108.02
3	M	100	103.56	106.50	3	F	100	102.48	105.25
4	M	100	103.08	106.83	4	F	100	103.72	107.45
5	M	100	103.58	107.28	5	F	100	102.77	106.82
Mean		100	103.36	106.94	Mean		100	103.29	107.16

TABLE - 3.03

WEEKLY PERCENTILE BODY WEIGHT DATA OF RATS

GROUP : NON TRANSGENIC CRUSHED COTTON SEED SAMPLE

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	103.82	107.76	1	F	100	103.52	106.91
2	M	100	104.54	107.65	2	F	100	102.65	105.86
3	M	100	103.70	107.72	3	F	100	103.33	106.32
4	M	100	104.16	108.38	4	F	100	103.56	106.24
5	M	100	102.72	105.78	5	F	100	103.67	107.29
Mean		100	103.77	107.43	Mean		100	103.34	106.52

TABLE - 3.04

WEEKLY PERCENTILE BODY WEIGHT DATA OF RATS

GROUP : TRANSGENIC CRUSHED COTTON SEED SAMPLE

DOSE : 2500 mg/kg b.wt.

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	100	104.60	107.53	1	F	100	102.96	106.65
2	M	100	103.10	106.48	2	F	100	103.60	107.08
3	M	100	103.80	108..98	3	F	100	103.65	106.70
4	M	100	103.83	107.67	4	F	100	103.57	107.14
5	M	100	103.63	107.58	5	F	100	102.05	105.34
Mean		100	103.78	107.64	Mean		100	103.17	106.59

TABLE - 3.05

WEEKLY PERCENTILE BODY WEIGHT DATA OF RATS

GROUP : TRANSGENIC CRUSHED COTTON SEED SAMPLE

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	103.21	106.91	1	F	100	103.80	107.67
2	M	100	103.49	107.55	2	F	100	103.41	106.82
3	M	100	101.96	106.43	3	F	100	104.19	108.62
4	M	100	102.32	104.88	4	F	100	103.84	107.80
5	M	100	104.39	107.55	5	F	100	102.54	105.25
Mean		100	103.67	106.65	Mean		100	103.54	107.20

TABLE - 3.06 : AVERAGE BODY WEIGHT(GRAMS) DATA OF RATS

Gp. No.	Sex	Day 0	Day 7	Day14	Sex	Day 0	Day 7	Day14
1. Control (Vehicle only)	Male	169.92	176.28	183.14	Female	171.06	176.78	183.08
2 Non-transgenic Crushed cotton seed 5000 mg/kg.b.wt	Male	171.40	177.16	183.34	Female	168.62	174.08	180.70
3 Non-transgenic Crushed cotton seed 5000 mg/kg.b.wt	Male	161.96	174.30	180.44	Female	165.52	171.06	176.32
4. Transgenic Crushed cotton seed 2500 mg/kg.b.wt	Male	169.58	176.00	182.54	Female	164.42	169.64	175.26
5. Transgenic Crushed cotton seed 5000 mg/kg.b.wt	Male	167.12	172.26	178.24	Female	168.24	174.20	180.36

TABLE - 3.07
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	180.30	186.20	192.80	1	F	160.00	164.90	170.20
2	M	178.90	184.70	190.60	2	F	166.90	172.70	180.30
3	M	165.20	172.30	180.30	3	F	167.60	174.70	180.50
4	M	160.20	166.10	172.30	4	F	180.50	186.20	193.10
5	M	165.00	172.10	179.70	5	F	180.30	185.40	191.30
Mean ± S.D.		169.92 ± 9.07	176.28 ± 8.74	183.14 ± 8.46	Mean ± S.D.		171.06 ± 9.02	176.78 ± 9.01	183.08 ± 8.34

TABLE - 3.08
WEEKLY BODY WEIGHT DATA (in gms) OF RATS
GROUP : NON-TRANSGENIC CRUSHED COTTON SEED
DOSE : 2500 mg /kg b.wt.

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	180.40	185.60	191.70	1	F	164.30	170.50	177.90
2	M	161.20	167.30	174.70	2	F	166.90	172.60	180.30
3	M	179.18	186.20	191.50	3	F	169.30	173.50	178.20
4	M	165.40	170.50	176.70	4	F	177.00	183.60	190.20
5	M	170.20	176.30	182.60	5	F	165.60	170.20	176.90
Mean ± S.D.		171.40 ± 8.56	177.16 ± 8.62	183.34 ± 8.13	Mean ± S.D.		168.62 ± 5.03	174.08 ± 5.50	180.70 ± 5.45

TABLE - 3.09
WEEKLY BODY WEIGHT DATA (in gms) OF RATS
GROUP : NON-TRANSGENIC CRUSHED COTTON SEED
DOSE : 5000 mg /kg b.wt.

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	167.50	173.90	180.50	1	F	164.80	170.60	176.20
2	M	167.20	174.80	180.00	2	F	162.00	166.30	171.50
3	M	161.80	167.80	174.30	3	F	180.20	186.20	191.60
4	M	163.40	170.20	177.10	4	F	160.20	165.90	170.20
5	M	179.90	184.80	190.30	5	F	160.40	166.30	172.10
Mean ± S.D.		167.96 ± 7.10	174.30 ± 6.51	180.44 ± 6.04	Mean ± S.D.		165.52 ± 8.41	171.06 ± 8.68	176.32 ± 8.83

TABLE - 3.10
WEEKLY BODY WEIGHT DATA (in gms) OF RATS
GROUP : TRANSGENIC CRUSHED COTTON SEED
DOSE : 2500 mg /kg b.wt.

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day14
1	M	167.20	174.90	179.80	1	F	165.30	170.20	176.30
2	M	180.60	186.20	192.30	2	F	160.90	166.70	172.30
3	M	173.60	180.20	189.20	3	F	167.10	173.20	178.30
4	M	164.20	170.50	176.80	4	F	167.90	173.90	179.90
5	M	162.30	168.20	174.60	5	F	160.90	164.20	169.50
Mean ± S.D.		169.58 ± 7.50	176.00 ± 7.31	182.54 ± 7.79	Mean ± S.D.		164.42 ± 3.34	169.64 ± 4.16	175.26 ± 4.29

TABLE - 3.11

WEEKLY BODY WEIGHT DATA (in gms) OF RATS

GROUP : TRANSGENIC CRUSHED COTTON SEED SAMPLE

DOSE : 5000 mg /kg b.wt.

S.No.	Sex	Day 0	Day 7	Day14	S.No.	Sex	Day 0	Day 7	Day15
1	M	164.90	170.20	176.30	1	F	170.80	177.30	183.90
2	M	160.20	165.80	172.30	2	F	167.10	172.80	178.50
3	M	167.90	171.20	178.70	3	F	162.30	169.10	176.30
4	M	171.90	175.90	180.30	4	F	164.00	170.30	176.80
5	M	170.70	178.20	183.60	5	F	177.00	181.50	186.30
Mean ± S.D.		167.12 ± 4.72	172.26 ± 4.89	178.26 ± 4.24	Mean ± S.D.		168.24 ± 5.87	174.20 ± 5.14	180.36 ± 4.48

TABLE : 4.0 MEAN HAEMATOLOGY DATA OF MALE RATS

Parameters	Control (Vehicle only)	Non-transgenic Crushed cotton seed 2500 mg /kg b.wt.	Non-Transgenic Crushed cotton seed 5000 mg /kg b.wt	Transgenic crushed cotton seed 2500 mg /kg b.wt	Transgenic crushed cotton seed 5000 mg /kg b.wt
WBC ($X10^3$)	7.52 ± 1.90	7.56 ± 1.07	7.90 ± 1.93	6.48 ± 1.16	8.78 ± 1.68
Differential Lymphocytes %	87.60 ± 1.67	87.04 ± 1.82	87.20 ± 1.30	87.20 ± 1.92	88.20 ± 1.92
Neutrophils %	11.00 ± 1.00	11.20 ± 1.30	11.44 ± 0.73	11.80 ± 1.48	10.60 ± 1.14
Eosinophils %	0.40 ± 0.55	0.20 ± 0.45	0.20 ± 0.45	0.20 ± 0.45	0.20 ± 0.45
Monocytes %	1.00 ± 1.73	1.20 ± 1.64	1.20 ± 1.79	0.80 ± 1.30	1.00 ± 1.73
Basophils %	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Protime	11.40 ± 0.55	11.60 ± 0.89	11.60 ± 0.89	11.60 ± 0.55	11.80 ± 0.84
R.B.C. ($x10^6$) %	8.00 ± 0.57	7.59 ± 0.62	7.62 ± 0.45	7.99 ± 0.60	8.73 ± 0.73
Hb (gm %)	14.20 ± 0.68	14.24 ± 0.49	14.08 ± 0.30	14.40 ± 0.75	15.22 ± 0.93
Hct %	41.36 ± 2.70	40.88 ± 3.57	40.68 ± 2.45	41.44 ± 2.69	44.78 ± 3.92
Platelets ($x10^5$)	787.40 ± 124.86	797.80 ± 66.82	772.20 ± 52.85	816.80 ± 91.84	859.20 ± 52.07

TABLE : 4.01 MEAN HAEMATOLOGY DATA OF FEMALE RATS

Parameters	Control (Vehicle only)	Non-transgenic Crushed cotton seed 2500 mg /kg b.wt.	Non-Transgenic Crushed cotton seed 5000 mg /kg b.wt	Transgenic crushed cotton seed 2500 mg /kg b.wt	Transgenic crushed cotton seed 5000 mg /kg b.wt
WBC ($X10^3$)	7.44 ± 2.19	7.56 ± 1.93	7.66 ± 1.50	7.52 ± 1.98	6.75 ± 2.61
Differential Lymphocytes %	86.00 ± 1.48	87.40 ± 1.14	87.80 ± 1.30	86.60 ± 1.14	86.20 ± 1.48
Neutrophils %	11.80 ± 0.84	11.60 ± 0.89	11.20 ± 0.84	12.00 ± 2.23	11.81 ± 1.30
Eosinophils %	0.20 ± 0.45	0.20 ± 0.45	0.20 ± 0.45	0.40 ± 0.55	0.20 ± 0.45
Monocytes %	1..20 ± 1.09	0.80 ± 1.10	0.80 ± 1.09	1.00 ± 1.00	1.80 ± 1.48
Basophils %	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Protime	11.75 ± 0.96	11.80 ± 0.84	11.80 ± 0.84	11.80 ± 0.84	11.60 ± 0.55
R.B.C. ($x10^6$) %	7.29 ± 0.58	7.23 ± 0.39	7.33 ± 0.53	7.04 ± 0.30	7.61 ± 0.60
Hb (gm %)	13.88 ± 0.26	13.78 ± 0.24	13.88 ± 0.19	14.00 ± 0.19	13.40 ± 0.78
Hct %	40.18 ± 2.27	38.54 ± 1.50	39.62 ± 1.27	38.72 ± 2.29	36.34 ± 3.28
Platelets ($x10^5$)	783.60 ± 73.94	748.80 ± 45.80	766.60 ± 72.20	795.00 ± 72.46	865.60 ±

TABLE - 4.02
HAEMATOLOGY DATA OF CONTROL GROUP- RATS TREATED WITH VEHICLE ONLY

			DIFFERENTIAL									
Animal No.	Sex	WBC Count ($x 10^3$)	L%	N%	E%	M%	B%	Protime	RBC Count ($x 10^6$)	Hb Gm %	Hct %	Platelet Count ($x 10^5$)
1	M	8.6	86	10	0	4	0	12.0	8.59	14.40	42.30	873.0
2	M	10.2	90	10	0	0	0	12.0	8.64	15.30	45.60	807.0
3	M	5.8	88	12	0	0	0	11.0	7.66	13.80	40.60	926.0
4	M	5.4	86	12	1	1	0	11.0	7.43	13.60	38.90	612.0
5	M	6.5	88	11	1	0	0	11.0	7.69	13.90	39.40	719.0
Mean ± S.D		7.52 + 1.90	87.60 + 1.67	11.0 + 1.00	0.4 + 0.55	1.00 + 1.73	0.0 + 0.0	11.40 + 0.55	8.00 + 0.57	14.20 + 0.68	41.36 ± 2.70	787.40 ± 124.86
1	F	8.9	87	11	0	2	0	11.0	7.95	14.10	41.80	784.0
2	F	10.3	85	12	1	2	0	12.0	6.84	13.60	38.90	841.0
3	F	7.3	87	13	0	0	0	12.0	6.67	13.60	36.80	697.0
4	F	5.6	86	12	0	2	0	13.0	7.83	14.0	41.30	871.0
5	F	5.1	89	11	0	0	0	11.0	7.14	14.10	42.10	725.0
Mean ± S.D		7.44 ± 2.19	86.80 ± 1.48	11.80 ± 0.84	0.20 ± 0.45	1.20 ± 1.09	0.0 ± 0.00	11.75 ± 0.96	7.29 ± 0.58	13.88 ± 0.26	40.18 ± 2.27	783.60 ± 73.94

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

TABLE - 4.03

HAEMATOLOGY DATA OF NON-TRANSGENIC CRUSHED COTTON SEED

DOSE : 2500 mg /kg b.wt

			DIFFERENTIAL									
Animal No.	**Sex**	**WBC Count ($x 10^3$)**	**L%**	**N%**	**E%**	**M%**	**B%**	**Protime**	**RBC Count ($x 10^6$)**	**Hb gm %**	**Hct %**	**Platelet Count ($x 10^5$)**
1	M	6.80	87.0	12.0	0	1	0	13.0	8.51	14.8	45.2	783.0
2	M	8.90	88.0	10.0	1	1	0	11.0	7.84	14.6	42.6	870.0
3	M	8.50	85.0	11.0	0	4	0	11.0	7.13	14.3	41.9	791.0
4	M	7.10	87.0	13.0	0	0	0	11.0	7.49	13.9	38.3	847.0
5	M	6.50	90.0	10.0	0	0	0	12.0	6.96	13.6	36.4	698.0
Mean ± S.D		7.56 ± 1.07	87.40 ± 1.82	11.20 ± 1.30	0.2 ± 0.45	1.20 ± 1.64	0.0 ± 0.00	11.60 ± 0.89	7.59 ± 0.62	14.24 ± 0.49	40.88 ± 3.51	797.8 ± 66.82
1	F	9.80	89.0	11.0	0	0	0	12.0	7.96	14.0	40.2	784.0
2	F	7.60	86.0	12.0	0	2	0	11.0	6.96	13.8	38.9	698.0
3	F	8.30	87.0	12.0	1	0	0	13.0	6.78	13.6	38.2	871.0
4	F	6.70	89.0	11.0	0	0	0	12.0	7.84	14.1	41.5	782.0
5	F	5.90	88.0	10.0	0	2	0	11.0	7.13	13.9	39.3	698.0
Mean ± S.D		7.66 ± 1.50	87.80 ± 1.30	11.20 ± 0.84	0.2 ± 0.45	0.8 ± 1.09	0.0 ± 0.00	11.80 ± 0.84	7.33 ± 0.53	13.88 ± 0.19	39.62 ± 1.27	766.60 ± 72.20

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

TABLE - 4.04
HAEMATOLOGY DATA OF NON-TRANSGENIC CRUSHED COTTON SEED
DOSE : 5000 mg /kg b.wt

			DIFFERENTIAL									
Animal No.	Sex	WBC Count ($x 10^3$)	L%	N%	E%	M%	B%	Protime	RBC Count ($x 10^6$)	Hb gm %	Hct %	Platelet Count ($x 10^5$)
1	M	10.30	87.0	12.0	1	0	0	13.0	7.89	14.2	42.5	837.0
2	M	8.70	86.0	11.0	0	4	0	11.0	8.13	14.5	43.4	780.0
3	M	8.50	88.0	11.0	0	0	0	12.0	7.72	14.1	41.2	692.0
4	M	5.30	86.0	12.0	0	2	0	11.0	7.41	13.9	38.5	761.0
5	M	6.70	89.0	11.0	0	0	0	11.0	6.97	13.7	37.8	791.0
Mean ± S.D		7.90 ± 1.93	87.20 ± 1.30	11.44 ± 0.73	0.2 ± 0.45	1.20 ± 1.79	0.0 ± 0.00	11.60 ± 0.89	7.62 ± 0.45	14.08 ± 0.30	40.68 ± 2.45	772.10 ± 52.85
1	F	8.70	89.0	11.0	0	0	0	12.0	7.83	14.1	40.9	748.0
2	F	10.20	87.0	11.0	0	2	0	11.0	6.94	13.6	37.9	814.0
3	F	7.40	86.0	13.0	1	0	0	12.0	7.24	13.8	38.5	769.0
4	F	5.70	87.0	11.0	0	2	0	13.0	6.84	13.5	36.8	716.0
5	F	5.80	88.0	12.0	0	0	0	11.0	7.29	13.9	38.6	697.0
Mean ± S.D		7.56 ± 1.93	87.40 ± 1.14	11.60 ± 0.89	0.2 ± 0.45	0.80 ± 1.10	0.0 ± 0.00	11.80 ± 8.84	7.23 ± 0.39	13.78 ± 0.24	38.54 ± 1.50	748.80 ± 45.88

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

TABLE - 4.05
HAEMATOLOGY DATA OF TRANSGENIC CRUSHED COTTON SEED
DOSE : 2500 mg /kg b.wt

			DIFFERENTIAL									
Animal No.	Sex	WBC Count ($x 10^3$)	L%	N%	E%	M%	B%	Protime	RBC Count ($x 10^6$)	Hb gm %	Hct %	Platelet Count ($x 10^5$)
1	M	8.40	85.0	12.0	0	3.0	0	12.0	8.57	14.50	42.30	823.0
2	M	6.40	89.0	10.0	0	0.0	0	12.0	8.69	15.50	45.40	807.0
3	M	5.50	87.0	12.0	0	1.0	0	11.0	7.61	13.80	39.60	791.0
4	M	5.60	86.0	14.0	0	0.0	0	12.0	7.39	13.60	38.40	959.0
5	M	6.50	88.0	11.0	1	0.0	0	11.0	7.68	14.60	41.50	704.0
Mean ± S.D		6.48 ± 1.16	87.2 ± 1.92	11.80 ± 1.48	0.2 ± 0.45	0.8 ± 1.30	0.0 ± 0.00	11.60 ± 0.55	7.99 + 0.60	14.40 ± 0.75	41.44 ± 2.69	816.80 ± 91.85
1	F	4.20	88.0	9.0	1	2	0	12.0	6.69	14.10	35.20	896.0
2	F	8.10	87.0	13.0	0	0	0	13.0	7.36	14.20	39.10	858.0
3	F	9.30	85.0	15.0	0	0	0	11.0	7.31	13.80	38.80	699.0
4	F	7.40	86.0	12.0	0	2	0	11.0	6.78	14.10	41.60	791.0
5	F	8.60	87.0	11.0	1	1	0	12.0	7.08	13.80	38.90	670.0
Mean ± S.D		7.52 ± 1.98	86.60 ± 1.14	12.0 ± 0.2.23	0.4 ± 0.55	1.00 ± 1.00	0.0 ± 0.00	11.80 ± 0.84	7.04 ± 0.30	14.00 ± 0.19	38.72 ± 2.28	795.0 ± 72.46

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

TABLE - 4.06
HAEMATOLOGY DATA OF RATS OF TRANSGENIC CRUSHED COTTON SEED SAMPLE
DOSE : 5000 mg /kg b.wt

DIFFERENTIAL												
Animal No.	Sex	WBC Count ($x 10^3$)	L%	N%	E%	M%	B%	Protime	RBC Count ($x 10^6$)	Hb gm %	Hct %	Platelet Count ($x 10^5$)
1	M	10.90	89.0	11.0	0	0	0	12.0	9.77	16.2	48.3	906.0
2	M	9.20	87.0	12.0	0	1	0	13.0	7.84	14.0	39.0	817.0
3	M	6.20	91.0	9.0	0	0	0	11.0	9.10	16.1	48.6	790.0
4	M	8.70	88.0	11.0	1	0	0	11.0	8.46	15.0	43.9	891.0
5	M	8.90	86.0	10.0	0	4	0	12.0	8.50	14.8	44.1	892.0
Mean ± S.D		8.78 ± 1.68	88.2 ± 1.42	10.60 ± 1.14	0.2 ± 0.45	1.0 ± 1.73	0.0 ± 0.00	11.80 ± 0.84	8.73 ± 0.73	15.22 ± 0.93	44.78 ± 3.92	859.20 ± 52.07
1	F	5.60	86.0	13.0	0	1	0	12.0	6.97	13.5	36.9	787.0
2	F	5.30	84.0	11.0	1	4	0	11.0	8.04	14.5	41.3	929.0
3	F	11.20	87.0	13.0	0	0	0	12.0	6.84	13.7	36.8	860.0
4	F	7.40	86.0	12.0	0	2	0	11.0	6.57	12.7	33.3	857.0
5	F	7.40	88.0	10.0	2	2	0	12.0	6.61	12.6	33.4	895.0
Mean ± S.D		6.75 ± 2.61	86.20 ± 1.48	11.80 ± 1.30	0.2 ± 0.45	1.80 ± 1.48	0.0 ± 0.00	11.60 ± 0.55	7.01 ± 0.60	13.40 ± 0.78	36.34 ± 3.28	865.60 ± 52.84

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

SHRIRAM INSTITUTE

CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE ALONG WITH NON TRANSGENIC COTTON SEED LINE ACUTE ORAL TOXICITY STUDY IN RATS

TABLE - 5.0 MEAN BIOCHEMISTRY DATA ON MALE RATS

Parameters	Control Group (Vehicle only)	Non-transgenic Crushed cotton seed sample 2500 mg /kg b.wt.	Non-transgenic Crushed cotton seed sample 5000 mg /kg b.wt	Transgenic Crushed cotton seed sample 2500 mg /kg b.wt.	Transgenic Crushed cotton seed sample 5000 mg /kg b.wt.
Glucose (mg %)	88.80 ± 4.76	86.40 ± 6.19	88.60 ± 4.39	87.20 ± 5.17	86.20 ± 5.89
BUN (mg %)	26.04 ± 4.08	26.36 ± 3.53	26.88 ± 3.36	27.82 ± 3.98	29.10 ± 2.50
Total Protein (gm %)	6.59 ± 0.42	6.39 ± 0.0.65	6.647 ± 0.225	6.386 ± 0.102	6.512 ± 0.301
S.G.P.T (I.U)	31.07 ± 5.63	33.43 ± 7.17	30.73 ± 6.77	32.00 ± 6.20	32.73 ± 3.44
S.G.O.T (I.U)	31.49 ± 3.07	38.29 ± 3.61	33.54 ± 5.23	33.98 ± 6.71	37.32 ± 5.82
Albumin (I.U)	3.85 ± 0.14	3.98 ± 0.14	3.95 ± 0.15	3.83 ± 0.26	3.93 ± 0.11
SAP (U/L)	92.28 ± 3.67	91.37 ± 10.50	93.84 ± 7.63	93.94 ± 7.47	91.58 ± 6.42

TABLE - 5.01 MEAN BIOCHEMISTRY DATA ON FEMALE RATS

Parameters	Control Group (Vehicle only)	Non-transgenic Crushed cotton seed sample 2500 mg /kg b.wt.	Non-transgenic Crushed cotton seed sample 5000 mg /kg b.wt	Transgenic Crushed cotton seed sample 2500 mg /kg b.wt.	Transgenic Crushed cotton seed sample 5000 mg /kg b.wt.
Glucose (mg %)	85.20 ± 7.12	86.00 ± 5.00	88.60 ± 6.88	89.00 ± 7.50	88.50 ± 7.26
BUN (mg %)	27.14 ± 2.94	27.66 ± 1.33	27.70 ± 3.15	25.96 ± 2.20	27.83 ± 3.30
Total Protein (gm %)	6.62 ± 0.44	6.466 ± 0.402	6.420 ± 0.266	6.344 ± 0.126	6.237 ± 0.125
S.G.P.T (I.U)	30.81 ± 2.54	34.71 ± 5.53	33.82 ± 2.77	32.86 ± 7.91	34.49 ± 6.16
S.G.O.T (I.U)	32.48 ± 2.64	34.86 ± 5.14	36.85 ± 2.43	31.83 ± 5.88	34.76 ± 7.28
Albumin (I.U)	3.89 ± 0.09	3.93 ± 0.10	3.95 ± 0.131	3.97 ± 0.144	3.90 ± 0.18
SAP (U/L)	91.22 ± 5.86	91.36 ± 6.01	93.62 ± 5.73	88.44 ± 9.05	91.90 ± 4.29

TABLE - 5.02
BIOCHEMISTRY DATA OF CONTROL GROUP – RATS GIVEN VEHICLE ONLY

Animal No.	Sex	BUN (mg %)	Glucose (mg %)	Total Protein (gm%)	S .G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	SAP U/L
1	M	29.9	88	7.052	26.93	29.57	3.83	89.3
2	M	26.4	93	6.988	32.80	30.23	4.02	96.8
3	M	30.1	81	6.544	39.28	28.60	3.70	92.0
4	M	22.9	92	6.089	24.83	36.20	3.98	95.1
5	M	21.0	90	6.321	31.49	32.85	3.74	88.2
Mean ± S.D		26.06 ± 4.08	88.8 ± 4.76	6.599 ± 0.42	31.07 ± 5.63	31.49 ± 3.07	3.85 ± 0.14	92.28 ± 3.67
1	M	24.0	97	7.65	30.47	35.33	4.01	99.3
2	M	28.6	84	6.433	32.51	30.27	3.79	87.5
3	M	23.9	85	7.089	29.85	31.69	3.82	93.1
4	M	29.5	82	6.085	27.30	35.23	3.86	83.9
5	M	29.7	78	6.433	33.90	29.90	3.96	92.3
Mean ± S.D		27.14 ± 2.94	25.2 ± 7.12	6.621 ± 0.44	30.81 ± 2.54	32.48 ± 2.64	3.89 ± 0.09	91.22 ± 5.86

TABLE - 5.03
BIOCHEMISTRY DATA OF NON TRANSGENIC CRUSHED COTTON SEED GROUP OF RATS
DOSE : 2500 mg /kg b.wt.

Animal No.	Sex	BUN (mg %)	Glucose (mg %)	Total Protein (gm%)	S .G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	SAP U/L
1	M	22.9	87	6.326	24.45	34.21	4.12	78.5
2	M	24.6	90	6.479	31.84	42.43	4.08	87.2
3	M	31.0	78	6.441	41.44	40.75	3.75	82.7
4	M	29.2	83	6.345	39.95	34.91	3.96	98.8
5	M	24.1	94	6.364	29.47	39.14	4.01	101.0
Mean ± S.D		26.36 ± 3.53	86.4 ± 6.19	6.391 ± 0.065	33.43 ± 7.17	38.29 ± 3.61	3.98 ± 0.14	91.37 ± 10.5r0
1	M	28.4	91	6.096	26.82	42.62	3.92	98.5
2	M	26.8	83	6.802	32.37	33.92	4.02	92.3
3	M	29.3	87	6.230	36.20	36.02	3.85	94.8
4	M	25.9	90	6.993	41.75	28.50	3.82	82.9
5	M	27.9	79	6.211	36.39	33.23	4.05	88.3
33.32 ±		27.66 ± 1.33	86.0 ± 5.00	6.466 ± 0.402	34.71 ± 5.53	34.86 ± 5.14	3.93 ± 0.10	91.36 ± 6.01

TABLE - 5.04
BIOCHEMISTRY DATA OF NON TRANSGENIC CRUSHED COTTON SEED GROUP OF RATS
DOSE : 5000 mg /kg b.wt.

Animal No.	Sex	BUN (mg %)	Glucose (mg %)	Total Protein (gm%)	S .G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	SAP U/L
1	M	26.8	95	6.993	34.26	27.45	3.03	81.6
2	M	28.6	83	6.725	18.76	31.51	4.12	95.2
3	M	22.2	90	6.572	34.93	40.44	3.96	96.3
4	M	25.6	88	6.399	33.63	37.14	3.76	102.5
5	M	31.2	87	6.546	32.06	31.05	4.08	93.6
Mean ± S.D		26.88 ± 3.36	88.60 ± 4.39	6.647 ± 0.225	30.73 ± 6.77	33.54 ± 5.23	3.95 ± 0.15	93.84 ± 7.63
1	M	26.4	79	6.484	35.98	35.30	4.02	100.8
2	M	29.3	97	6.725	36.52	40.46	3.91	93.3
3	M	32.0	88	6.019	34.75	38.15	3.76	97.2
4	M	23.6	93	6.326	30.15	35.81	4.11	90.9
5	M	27.2	86	6.546	31.75	34.51	3.98	85.9
Mean ± S.D		27.70 ± 3.15	88.60 ± 6.88	6.420 ± 0.266	33.82 ± 2.77	36.85 ± 2.43	3.95 ± 0.13	93.62 ± 5.73

TABLE - 5.05
BIOCHEMISTRY DATA OF TRANSGENIC CRUSHED COTTON SEED GROUP OF RATS
DOSE : 2500 mg /kg b.wt.

Animal No.	Sex	BUN (mg %)	Glucose (mg %)	Total Protein (gm%)	S .G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	SAP U/L
1	M	26.5	83.0	6.312	31.44	34.31	4.11	87.30
2	M	32.1	96.0	6.522	29.88	28.29	4.00	98.20
3	M	24.6	84.0	6.417	31.55	35.51	3.58	102.7
4	M	23.9	87.0	6.260	42.04	44.20	3.53	96.40
5	M	32.0	86.0	6.412	25.07	27.57	3.94	85.10
Mean ± S.D		27.82 ± 3.98	87.2 ± 5.17	6.386 ± 0.102	32.00 ± 6.20	33.98 ± 6.71	3.83 ± 0.26	93.94 ± 7.47
1	M	26.3	91.0	6.417	45.60	25.72	3.89	89.30
2	M	22.7	95.0	6.207	24.80	37.43	3.87	97.00
3	M	27.0	78.0	6.260	33.53	35.33	4.15	75.30
4	M	28.6	85.0	6.522	28.15	25.18	4.11	84.20
5	M	25.2	96.0	6.312	32.22	35.27	3.85	96.40
33.32 ±		25.96 ± 2.20	89.0 ± 7.52	6.344 ± 0.126	32.86 ± 7.91	31.83 ± 5.88	3.97 ± 0.144	88.44 ± 9.05

TABLE - 5.06

BIOCHEMISTRY DATA OF TRANSGENIC CRUSHED COTTON SEED GROUP OF RATS

DOSE : 5000 mg /kg b.wt.

Animal No.	Sex	BUN (mg %)	Glucose (mg %)	Total Protein (gm%)	S .G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	SAP U/L
1	M	30.60	84.00	6.207	38.39	28.18	3.82	87.8
2	M	32.00	95.00	6.955	32.75	38.25	3.87	82.5
3	M	27.50	83.00	6.417	29.50	44.32	3.89	95.4
4	M	29.60	80.00	6.312	32.45	37.08	4.11	93.6
5	M	25.70	89.00	6.668	30.55	38.75	3.98	98.6
Mean ± S.D	Mean ± S.D	29.10 ± 2.50	86.20 ± 5.89	6.512 ± 0.301	32.73 ± 3.44	37.32 ± 5.82	3.93 ± 0.11	91.58 ± 6.42
1	M	31.50	96.00	6.312	29.74	28.63	4.08	97.1
2	M	31.00	84.00	6.102	41.33	26.38	3.71	91.3
3	M	22.30	90.00	6.102	32.48	35.50	4.05	93.7
4	M	27.20	95.00	6.312	40.61	43.73	3.95	85.4
5	M	27.70	79.00	6.359	30.27	39.57	3.71	92.0
33.32 ±		27.83 ± 3.30	88.50 ± 7.26	6.237 ± 0.125	34.49 ± 6.16	34.76 ± 7.28	3.90 ± 0.18	91.90 ± 4.27

TABLE - 7
MEAN PERCENTILE ORGAN WEIGHT DATA OF MALE RATS

Organs	DOSAGE LEVEL				
	Control (Vehicle only)	Non-transgenic crushed cotton seed sample 2500 mg/kg b.wt.	Non-transgenic Crushed cotton seed sample 5000 mg/kg b.wt.	Transgenic Crushed cotton seed sample 2500 mg/kg b.wt.	Transgenic Crushed cotton seed sample 5000 mg/kg b.wt.
Lung	0.76 ± 0.07	0.82 ± 0.08	0.88 ± 0.08	0.82 ± 0.06	0.80 ± 0.09
Liver	3.04 ± 0.46	3.56 ± 0.19	3.83 ± 0.76	3.90 ± 0.33	3.49 ± 0.36
Kidney	0.78 ± 0.12	0.91 ± 0.08	0.81 ± 0.06	1.01 ± 0.07	0.73 ± 0.06
Testis	1.30 ± 0.13	1.42 ± 0.155	1.31 ± 0.14	1.53 ± 0.13	1.26 ± 0.08
Adrenal	0.04 ± 0.006	0.03 ± 0.004	0.04 ± 0.003	0.024 ± 0.008	0.02 ± 0.006
Heart	0.38 ± 0.06	0.43 ± 0.05	0.41 ± 0.04	0.51 ± 0.05	0.37 ± 0.04
Spleen	0.36 ± 0.07	0.38 ± 0.06	0.32 ± 0.05	0.46 ± 0.05	0.30 ± 0.07
Brain	0.87±0.086	1.06±0.09	0.88±0.11	1.05 ± 0.03	0.98 ± 0.04

TABLE - 7.01

MEAN PERCENTILE ORGAN WEIGHT DATA OF FEMALE RATS

	DOSAGE LEVEL				
Organs	Control (Vehicle only)	Non-transgenic crushed cotton seed sample 2500 mg/kg b.wt	Non-transgenic Crushed cotton seed sample 5000 mg/kg b.wt.	Transgenic Crushed cotton seed sample 2500 mg/kg b.wt.	Transgenic Crushed cotton seed sample 5000 mg/kg b.wt.
Lung	0.80 ± 0.20	0.79 ± 0.10	0.83 ± 0.09	0.86 ± 0.17	0.73 ± 0.065
Liver	2.61 ± 0.36	3.16 ± 0.42	3.27 ± 0.198	3.51 ± 0.63	3.50 ± 0.30
Kidney	0.75 ± 0.12	0.74 ± 0.12	0.75 ± 0.06	0.72 ± 0.034	0.78 ± 0.09
Gonads	0.05 ± 0.02	0.05 ± 0.01	0.07 ± 0.006	0.04 ± 0.004	0.05 ± 0.003
Adrenal	0.04 ± 0.005	0.03 ± 0.03	0.03 ± 0.004	0.04 ± 0.002	0.02 ± 0.005
Heart	0.40 ± 0.07	0.36 ± 0.015	0.38 ± 0.023	0.40 ± 0.05	0.32 ± 0.03
Uterus	0.32± 0.12	0.20 ± 0.03	0.25 ± 0.08	0.23 ± 0.04	0.17 ± 0.02
Spleen	0.39 ± 0.12	0.45 ± 0.08	0.41 ± 0.05	0.39 ± 0.08	0.38 ± 0.07
Brain	1.05 ± 0.06	0.89 ± 0.07	0.99 ± 0.05	0.92 ± 0.08	0.88 ± 0.16

TABLE - 7.02
AVERAGE ORGAN WEIGHT DATA OF MALE RATS

Dosage Group	Mean body wt. (gm)	Lung (gm)	Liver (gm)	Kidney (gm)	Gonads (gm)	Adrenal (gm)	Heart (gm)	Spleen (gm)	Brains (gm)
Control (Vehicle only)	183.20 ± 8.43	1.38 ± 0.15	5.58 ± 0.93	1.42 ± 0.23	2.39 ± 0.24	0.064 ± 0.01	0.70 ± 0.15	0.66 ± 0.14	1.60 ± 0.13
Non-transgenic Crushed Cotton seed 2500 mg/kg b.wt	183.34 ± 8.13	1.50 ± 0.15	6.53 ± 0.14	1.67 ± 0.12	2.60 ± 0.24	0.06 ± 0.007	0.79 ± 0.09	0.71 ± 0.08	1.96 ± 0.12
Non-transgenic Crushed Cotton seed 5000 mg/kg b.wt	180.44 ± 6.04	1.58 ± 0.10	6.92 ± 0.17	1.45 ± 0.07	2.38 ± 0.32	0.07 ± 0.005	0.75 ± 0.08	0.60 ± 0.12	1.60 ± 0.11
Transgenic crushed cotton seed Sample 2500 mg/kg b.wt	182.54 ± 7.80	1.51 ± 0.16	7.10 ± 0.74	1.85 ± 0.18	2.81 ± 0.26	0.04 ± 0.016	0.94 ± 0.13	0.84 ± 0.11	1.92 ± 0.11
Transgenic Crushed Cotton seed Sample 5000 mg/kg b.wt	178.24 ± 4.25	1.44 ± 0.15	6.22 ± 0.57	1.31 ± 0.07	2.24 ± 0.12	0.04 ± 0.01	0.67 ± 0.04	0.54 ± 0.39	1.75 ± 0.08

TABLE - 7.03
AVERAGE ORGAN WEIGHT DATA OF FEMALE RATS

Dosage Group	Mean body wt. (gm)	Lung (gm)	Liver (gm)	Kidney (gm)	Gonads (gm)	Uterus (gm)	Adrenal (gm)	Heart (gm)	Spleen (gm)	Brains (gm)
Control (Vehicle only)	183.08 ± 9.33	1.48 ± 0.41	4.83 ± 0.78	1.39 ± 0.26	0.096 ± 0.02	0.59 ± 0.20	0.066 ± 0.009	0.74 ± 0.13	0.72 ± 0.25	1.93 ± 0.14
Non-transgenic Crushed Cotton seed 2500 mg/kg b.wt	180.70 ± 5.45	1.43 ± 0.18	5.70 ± 0.63	1.35 ± 0.18	0.096 ± 0.02	0.37 ± 0.05	0.056 ± 0.005	0.66 ± 0.015	0.81 ± 0.14	1.63 ± 0.11
Non-transgenic Crushed Cotton seed 5000 mg/kg b.wt	176.32 ± 8.83	1.48 ± 0.24	5.78 ± 0.46	1.32 ± 0.07	0.13 ± 0.007	0.42 ± 0.17	0.06 ± 0.008	0.68 ± 0.04	0.73 ± 0.12	1.75 ± 0.08
Transgenic crushed cotton seed Sample 2500 mg/kg b.wt	175.20 ± 4.27	1.52 ± 0.29	6.15 ± 0.99	1.26 ± 0.06	0.072 ± 0.008	0.40 ± 0.07	0.06 ± 0.005	0.70 ± 0.07	0.70 ± 0.14	1.62 ± 0.11
Transgenic Crushed Cotton seed Sample 5000 mg/kg b.wt	180.40 ± 4.48	1.32 ± 0.13	6.30 ± 0.50	1.46 ± 0.16	0.094 ± 0.005	0.32 ± 0.04	0.04 ± 0.01	0.59 ± 0.06	0.68 ± 0.11	1.60 ± 2.28

TABLE - 7.04
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF CONTROL GROUP OF MALE RATS (VEHICLE ONLY)

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Gonads		Adrenal		Heart		Spleen		Brain	
			Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. In Gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt
1	M	192.8	1.37	0.71	6.00	3.11	1.47	0.76	2.21	1.14	0.05	0.03	0.78	0.40	0.53	0.27	1.48	0.76
2	M	190.6	1.66	0.87	6.74	3.53	1.66	0.87	2.78	1.45	0.08	0.04	0.91	0.47	0.86	0.45	1.66	0.87
3	M	180.3	1.29	0.71	5.04	2.79	1.32	0.73	2.32	1.28	0.06	0.03	0.58	0.32	0.74	0.41	1.81	1.00
4	M	172.3	1.31	0.76	5.84	3.38	1.59	0.92	2.47	1.43	0.06	0.04	0.65	0.37	0.60	0.35	1.55	0.70
5	M	179.7	1.31	0.73	4.32	2.39	1.08	0.60	2.17	1.20	0.07	0.04	0.57	0.32	0.56	0.31	1.54	0.85
Mean ± S.D.		183.2 ± 8.43	1.388 ± 0.154	0.756 ± 0.66	5.58 ± 0.93	3.04 ± 0.46	1.44 ± 0.23	0.77 ± 0.13	2.39 ± 0.24	1.30 ± 0.13	0.06 ± .01	0.03 ± 0.006	0.69 ± 0.15	0.33 ± 0.06	0.66 ± .14	0.36 ± 0.07	1.60 ± 0.13	0.87 ± 0.09

SHRIRAM INSTITUTE

CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE ALONG WITH NON TRANSGENIC COTTON SEED LINE
ACUTE ORAL TOXICITY STUDY IN RATS

TABLE - 7.05

ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC CRUSHED COTTON SEED OF MALE RATS

DOSE : 2500 mg /kg b.wt.

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Gonads		Adrenal		Heart		Spleen		Brain	
			Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. In Gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt
1	M	191.7	1.37	0.71	6.68	3.48	1.67	0.87	2.40	1.25	0.06	0.03	0.93	0.48	0.59	0.30	2.03	1.05
2	M	174.2	1.31	0.75	6.57	3.77	1.54	0.88	2.36	1.35	0.06	0.03	0.74	0.42	0.77	0.44	2.07	1.18
3	M	191.5	1.59	0.83	6.29	3.28	1.58	0.82	2.69	1.40	0.05	0.03	0.71	0.37	0.70	0.36	1.94	1.01
4	M	196.7	1.59	0.89	6.24	3.71	1.75	0.99	2.96	1.67	0.06	0.03	0.84	0.47	0.78	0.44	2.01	1.23
5	M	182.6	1.65	0.90	6.55	3.58	1.83	1.00	2.59	1.42	0.07	0.04	0.73	0.40	0.72	0.89	1.76	0.96
Mean		183.34	1.50	0.82	6.53	3.56	1.67	0.91	2.60	1.42	0.06	0.03	0.79	0.43	0.71	0.38	1.96	1.06
±		±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±
S.D.		8.13	0.15	0.08	0.14	0.19	0.12	0.08	0.74	0.16	0.007	0.004	0.09	0.05	0.08	0.06	0.12	0.09

SHRIRAM INSTITUTE

CRUSHED WHOLE SEED OF TRANSGENIC COTTON LINE ALONG WITH NON TRANSGENIC COTTON SEED LINE

ACUTE ORAL TOXICITY STUDY IN RATS

TABLE - 7.06

ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC CRUSHED COTTON SEED OF MALE RATS

DOSE : 5000 mg /kg b.wt.

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Gonads		Adrenal		Heart		Spleen		Brain	
			Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. In Gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt
1	M	180.5	1.46	0.80	6.68	3.70	1.47	0.81	2.49	1.38	0.06	0.03	0.87	0.48	0.54	0.30	1.56	0.86
2	M	180.0	1.62	0.90	6.79	3.77	1.37	0.76	2.00	1.11	0.06	0.03	0.71	0.39	0.56	0.31	1.71	0.95
3	M	174.3	1.71	0.98	7.10	4.07	1.54	0.88	2.20	1.26	0.07	0.04	0.73	0.42	0.46	0.26	1.53	0.87
4	M	177.1	1.63	0.92	6.97	3.93	1.51	0.85	2.36	1.33	0.07	0.04	0.67	0.38	0.66	0.37	1.47	0.83
5	M	190.3	1.50	0.79	7.05	3.70	1.39	0.73	2.85	1.49	0.07	0.04	0.77	0.40	0.72	0.38	1.71	0.89
Mean ± S.D.		180.44 ± 6.04	1.58 ± 0.10	0.88 ± 0.08	6.92 ± 0.17	3.83 ± 0.76	1.45 ± 0.07	0.81 ± 0.06	2.38 ± 0.32	1.31 ± 0.14	0.07 ± 0.005	0.04 ± 0.004	0.75 ± 0.08	0.41 ± 0.04	0.60 ± 0.12	0.32 ± 0.05	1.60 ± 0.11	0.88 ± 0.05

TABLE - 7.07

ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF TRANSGENIC CRUSHED COTTON SEED OF MALE RATS

DOSE : 2500 mg /kg b.wt.

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Gonads		Adrenal		Heart		Spleen		Brain	
			Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. In Gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt
1	M	179.8	1.30	0.72	6.26	3.48	1.83	1.01	2.51	1.39	0.05	0.03	0.80	0.44	0.70	0.39	1.96	1.09
2	M	192.3	1.72	0.89	7.89	4.10	2.15	1.11	3.20	1.66	0.07	0.04	1.09	0.56	1.00	0.52	2.05	1.06
3	M	189.2	1.62	0.85	7.48	3.95	1.82	0.96	2.68	1.41	0.03	0.02	1.06	0.56	0.84	0.44	2.00	1.05
4	M	176.8	1.51	0.85	7.62	4.30	1.83	1.03	2.94	1.66	0.04	0.02	0.85	0.48	0.89	0.50	1.83	1.03
5	M	174.6	1.42	0.81	6.42	3.67	1.65	0.94	2.74	1.56	0.03	0.02	0.89	0.50	0.78	0.45	1.78	1.02
Mean ± S.D.		182.54 ± 7.80	1.51 ± 0.16	0.82 ± 0.06	7.10 ± 0.74	3.90 ± 0.33	1.85 ± 0.18	1.01 ± 0.07	2.81 ± 0.26	1.53 ± 0.13	0.04 ± 0.002	0.02 ± 0.008	0.94 ± 0.13	0.51 ± 0.05	0.84 ± 0.11	0.46 ± 0.05	1.92 ± 0.11	1.05 ± 0.03

TABLE - 7.08
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF TRANSGENIC CRUSHED COTTON SEED OF MALE RATS
DOSE : 5000 mg /kg b.wt.

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Gonads		Adrenal		Heart		Spleen		Brain	
			Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. In Gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. In Gms	% Body wt	Wt. in gms	% Body wt
1	M	176.3	1.28	0.72	5.51	3.12	1.27	0.72	2.03	1.15	0.02	0.01	0.65	0.37	0.37	0.21	1.77	1.00
2	M	172.3	1.58	0.91	6.83	3.96	1.41	0.81	2.32	1.35	0.04	0.02	0.71	0.41	0.58	0.33	1.67	0.96
3	M	178.7	1.57	0.88	6.76	3.78	1.38	0.77	2.36	1.32	0.03	0.02	0.61	0.34	0.65	0.36	1.68	0.94
4	M	180.3	1.49	0.82	5.85	3.24	1.27	0.70	2.26	1.25	0.05	0.03	0.71	0.39	0.44	0.24	1.86	1.03
5	M	183.6	1.26	0.68	6.16	3.35	1.24	0.67	2.24	1.22	0.04	0.02	0.67	0.36	0.66	0.36	1.76	0.96
Mean ± S.D.		178.24 ± 4.25	1.44 ± 0.16	0.80 ± 0.10	6.22 ± 0.57	3.49 ± 0.36	1.31 ± 0.07	0.73 ± 0.06	2.24 ± 0.12	1.26 ± 0.08	0.04 ± 0.01	0.02 ± 0.006	0.67 ± 0.04	0.37 ± 0.04	054 ± 0.39	0.30 ± 0.07	1.75 ± 0.08	0.98 ± 0.04

TABLE - 7.09
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF CONTROL GROUP OF FEMALE RATS (VEHICLE ONLY)

Animal No	Sex	Body Wt. in gms	Lung		Liver		Kidney		Gonads		Adrenal		Heart		Uterus		Spleen		Brain	
			Wt. in gms	% Body wt	Wt. In Gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt
1	F	170.2	1.17	0.68	4.24	2.43	1.11	0.65	0.10	0.06	0.06	0.04	0.66	0.38	0.85	0.50	0.59	0.35	1.74	1.02
2	F	180.5	1.79	0.99	5.34	2.96	165	0.91	0.14	0.08	0.07	0.04	0.93	0.51	0.36	0.20	0.64	0.35	2.10	1.16
3	F	180.5	1.16	0.64	4.40	2.43	1.18	0.65	0.08	0.04	0.08	0.04	0.73	0.40	0.43	0.24	0.57	0.31	1.88	1.04
4	F	193.1	2.06	1.06	5.97	3.05	1.68	0.87	0.09	0.05	0.06	0.03	0.79	0.41	0.72	0.37	1.18	0.61	2.03	1.05
5	F	191.3	1.26	0.66	4.23	2.21	1.32	0.69	0.07	0.04	0.06	0.03	0.58	0.30	0.59	0.30	0.63	0.33	1.91	0.99
Mean ± S.D.		183.08 ± 9.33	1.48 ± 0.41	0.81 ± 0.20	4.83 ± 0.78	2.61 ± 0.36	1.39 ± 0.26	0.75 ± 0.12	0.10 ± 0.02	0.05 ± 0.02	0.07 ± 0.009	0.04 ± 0.005	0.74 ± 0.13	0.40 ± 0.08	0.59 ± 0.20	0.32 ± 0.12	0.72 ± 0.25	0.39 ± 0.12	1.93 ± 0.14	1.05 ± 0.06

TABLE - 7.10

ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC CRUSHED COTTON SEED SAMPLE OF FEMALE RATS

DOSE : 2500 mg/kg b.wt.

Animal No	Sex	Body Wt. in gms	Lung		Liver		Kidney		Gonads		Adrenal		Heart		Uterus		Spleen		Brain	
			Wt. in gms	% Body wt	Wt. In Gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt
1	F	177.9	1.72	0.96	6.46	3.63	1.65	0.92	0.13	0.07	0.06	0.03	0.66	0.38	0.39	0.22	0.82	0.46	1.70	0.95
2	F	180.3	1.22	0.67	5.35	2.96	1.16	0.64	0.08	0.04	0.05	0.03	0.93	0.51	0.33	0.18	1.01	0.56	1.58	0.87
3	F	178.2	1.44	0.80	6.17	3.46	1.36	0.76	0.10	0.06	0.06	0.03	0.73	0.40	0.42	0.23	0.63	0.35	1.45	0.81
4	F	190.2	1.44	0.75	4.88	2.56	1.23	0.64	0.08	0.04	0.05	0.03	0.79	0.41	0.42	0.22	1.86	0.45	1.66	0.87
5	F	176.9	1.33	0.75	5.66	3.21	1.35	0.76	0.09	0.05	0.06	0.03	0.58	0.30	0.31	0.17	0.73	0.41	1.75	0.98
Mean ± S.D.		180.7 ± 5.45	1.43 ± 0.18	0.79 ± 0.10	5.70 ± 0.63	3.16 ± 0.42	1.35 ± 0.18	0.74 ± 0.12	0.10 ± 0.02	0.05 ± 0.01	0.06 ± 0.005	0.03 ± 0.003	0.74 ± 0.13	0.40 ± 0.08	0.37 ± 0.05	0.20 ± 0.03	0.81 ± 0.14	0.45 ± 0.08	1.63 ± 0.11	0.89 ± 0.07

TABLE - 7.11

ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC CRUSHED COTTON SEED SAMPLE OF FEMALE RATS

DOSE : 5000 mg/kg b.wt.

Animal No	Sex	Body wt. in gms	Lung		Liver		Kidney		Gonads		Adrenal		Heart		Uterus		Spleen		Brain	
			Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. In Gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt
1	F	176.2	1.97	0.77	6.26	3.55	1.26	0.71	0.13	0.07	0.06	0.03	0.77	0.42	0.67	0.38	073	0.41	1.82	1.03
2	F	171.5	1.35	0.78	5.16	3.00	1.26	0.73	0.12	0.07	0.05	0.03	0.53	0.30	0.21	0.23	0.56	0.32	1.65	0.96
3	F	191.6	1.91	0.99	6.21	3.24	1.32	0.69	0.13	0.07	0.06	0.03	0.65	0.36	0.34	0.17	0.89	0.46	1.78	0.93
4	F	170.2	1.37	0.80	5.52	3.24	1.43	0.84	0.13	0.08	0.05	0.03	0.57	0.31	0.48	0.28	0.74	0.43	1.67	0.98
5	F	172.1	1.41	0.82	5.74	3.33	1.35	0.78	0.14	0.08	0.07	0.04	0.58	0.33	0.38	0.22	0.74	0.43	1.81	1.05
Mean ± S.D.		176.32 ± 8.83	1.48 ± 0.24	0.83 ± 0.09	5.78 ± 0.46	3.27 ± 0.19	1.32 ± 0.07	0.75 ± 0.06	0.13 ± 0.007	0.07 ± 0.006	0.06 ± 0.008	0.03 ± 0.004	0.62 ± 0.04	0.34 ± 0.05	0.42 ± 0.17	0.25 ± 0.08	0.73 ± 0.12	0.41 ± 0.05	1.75 ± 0.08	0.99 ± 0.05

TABLE - 7.12
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF TRANSGENIC CRUSHED COTTON SEED SAMPLE OF FEMALE RATS
DOSE : 2500 mg/kg b.wt.

Animal No	Sex	Body wt. in gms	Lung		Liver		Kidney		Gonads		Adrenal		Heart		Uterus		Spleen		Brain	
			Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt
1	F	176.0	1.34	0.76	5.16	2.93	1.28	0.72	0.06	0.03	0.06	0.03	0.78	0.44	0.31	0.18	0.45	0.25	1.74	0.98
2	F	172.3	1.82	1.05	6.50	3.77	1.34	0.77	0.07	0.04	0.06	0.03	0.64	0.37	0.46	0.27	0.77	0.44	1.55	0.89
3	F	178.3	1.82	1.02	6.56	3.67	1.23	0.69	0.08	0.04	0.07	0.04	0.68	0.38	0.38	0.21	0.74	0.41	1.61	0.90
4	F	179.9	1.19	0.66	5.11	2.84	1.24	0.69	0.08	0.04	0.06	0.03	0.63	0.35	0.48	0.27	0.73	0.40	1.48	0.82
5	F	169.5	1.42	0.83	7.40	4.36	1.19	0.70	0.07	0.04	0.06	0.03	0.78	0.46	0.39	0.23	0.77	0.45	1.72	1.01
Mean ± S.D.		179.80 ± 2.77	1.52 ± 0.29	0.86 ± 0.17	6.15 ± 0.99	3.51 ± 0.63	1.26 ± 0.06	0.72 ± 0.03	0.07 ± 0.008	0.04 ± 0.004	0.06 ± 0.005	0.04 ± 0.002	0.70 ± 0.07	0.40 ± 0.05	0.40 ± 0.07	0.23 ± 0.04	0.70 ± 0.08	0.39	1.62 ± 0.11	0.92 ± 0.08

TABLE - 7.13
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF TRANSGENIC CRUSHED COTTON SEED SAMPLE OF FEMALE RATS
DOSE : 5000 mg/kg b.wt.

Animal No	Sex	Body Wt. in gms	Lung		Liver		Kidney		Gonads		Adrenal		Heart		Uterus		Spleen		Brain	
			Wt. in gms	% Body wt	Wt. In Gms	% Body wt	Wt. In gms	% Body wt	Wt. In gms	% Body wt	Wt. In gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt	Wt. in gms	% Body wt
1	F	183.9	1.50	0.81	5.92	3.22	1.37	0.74	0.09	0.05	0.05	0.03	0.68	0.37	0.35	0.19	0.72	0.39	1.30	0.70
2	F	178.5	1.36	0.76	6.89	3.86	1.70	0.95	0.09	0.05	0.04	0.02	0.50	0.28	0.37	0.20	0.66	0.37	1.27	0.71
3	F	176.3	1.31	0.74	5.60	3.17	1.35	0.76	0.10	0.06	0.03	0.02	0.61	0.34	0.30	0.17	0.81	0.46	1.75	0.99
4	F	176.8	1.15	0.65	6.51	3.68	1.33	0.75	0.10	0.06	0.03	0.02	0.57	0.32	0.31	0.17	0.71	0.40	1.82	1.03
5	F	186.3	1.26	0.67	6.31	3.38	1.33	0.72	0.09	0.05	0.05	0.03	0.59	0.31	0.27	0.14	0.51	0.27	1.84	0.98
Mean ± S.D.		180.4 ± 4.48	1.32 ± 0.13	0.73 ± 0.07	6.31 ± 0.50	3.50 ± 0.30	1.42 ± 0.16	0.78 ± 0.09	0.09 ± 0.005	0.05 ± 0.003	0.04 ± 0.01	0.02 ± 0.005	0.59 ± 0.06	0.32 ± 0.03	0.32 ± 0.04	0.18 ± 0.02	0.68 ± 0.11	0.38 ± 0.07	1.60 ± 0.28	0.88 ± 0.16

TABLE - 8-0 INTENSITY OF GROSS PATHOLOGICAL LESIONS OF CONTROL GROUP (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
Gastro-Intestinal Tract	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

TABLE -8.01 INTENSITY OF GROSS PATHOLOGICAL LESIONS OF NON-TRANSGENIC CRUSHED COTTON SEED SAMPLE IN RATS

DOSE : 2500 mg/kg B.wt

	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
Gastro-Intestinal Tracts	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

TABLE -8.02 INTENSITY OF GROSS PATHOLOGICAL LESIONS OF NON - TRANSGENIC CRUSHED COTTON SEED SAMPLE IN RATS

DOSE : 5000 mg/kg. B.wt.

	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
Gastro-Intestinal Tract	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

TABLE -8.03 INTENSITY OF GROSS PATHOLOGICAL LESIONS OF TRANSGENIC CRUSHED COTTON SEED SAMPLE IN RATS

DOSE : 2500 mg/kg. B.wt.

	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
Gastro-Intestinal Tract	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

TABLE -8.04 INTENSITY OF GROSS PATHOLOGICAL LESIONS OF TRANSGENIC CRUSHED COTTON SEED SAMPLE IN RATS

DOSE : 5000 mg/kg. B.wt.

	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
Gastro-Intestinal Tract	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

TABLE -8.05 INTENSITY OF HISTOPATHOLOGICAL LESIONS OF CONTROL GROUP (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	Facid M.N.cells	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	Slight congestion	NAD
Brain	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Adrenal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gastro-Intestinal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

TABLE -8.06 INTENSITY OF HISTOPATHOLOGICAL LESIONS OF NON-TRANSGENIC CRUSHED COTTON SEED SAMPLE IN RATS

DOSE : 2500 mg/kg.B.wt.

	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	Slight congestion	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
Gastro-Intestinal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

TABLE -8.07 INTENSITY OF HISTOPATHOLOGICAL LESIONS OF NON - TRANSGENIC CRUSHED COTTON SEED SAMPLE IN RATS

DOSE : 5000 mg/kg.B.wt.

	ANIMAL NO.									
	MALE RATS					FEMALE RATS				
ORGAN	1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	Facid M.N.cell	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
Gastro-Intestinal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

TABLE -8.08 INTENSITY OF HISTOPATHOLOGICAL LESIONS OF TRANSGENIC CRUSHED COTTON SEED SAMPLE IN RATS

DOSE : 2500 mg/kg.B.wt.

	ANIMAL NO.									
	MALE RATS					FEMALE RATS				
ORGAN	1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	Facid M.N.cell	NAD	Facid M.N.cell	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
Gastro-Intestinal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

TABLE -8.09 INTENSITY OF HISTOPATHOLOGICAL LESIONS OF TRANSGENIC CRUSHED COTTON SEED SAMPLE IN RATS

DOSE : 5000 mg/kg.B.wt.

	ANIMAL NO.									
	MALE RATS					FEMALE RATS				
ORGAN	1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	Facid M.N.cell	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	Slight congestion	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
Gastro-Intestinal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development