

Annexure to Report No. : 000073685  
Dt : 28.02.2004

### TOXICOLOGY STUDY REPORT

PROJECT NO. : TOX / 290

SPONSOR : NATH SEEDS (NEW DELHI)  
309 - MEGHDOOT,  
94 NEHRU PLACE,  
NEW DELHI

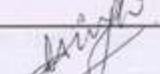
SUBJECT : ACUTE ORAL TOXICITY STUDY IN RATS

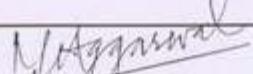
PRODUCT : Bt- COTTON SEEDS (NATH SEEDS) ALONG WITH  
NON-TRANSGENIC COTTON SEEDS

MATERIAL DESCRIPTION : BROWN COLORED COTTON SEEDS

RESULT : Under the condition of this study, the given sample of  
Bt- cotton seeds (Nath seeds) was found to be **non-toxic** to  
wistar rats, when compared to non-transgenic cotton seed  
group of wistar rats, administered orally at maximum dose  
level of 5000 mg per kg. B.wt.

Total No. of pages : 61

  
SCIENTIST  
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DY. DIRECTOR

**SHIRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH**  
(A Unit of Shriram Scientific & Industrial Research Foundation, Delhi)  
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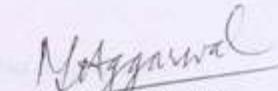
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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDY (ACUTE ORAL TOXICITY STUDY IN RAT)

### 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.

  
Asst. Director &  
Chief, Toxicology

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

Dr. Binu Bhat

Dr. Dhirendra Singh

Manoj Kumar

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDY (ACUTE ORAL TOXICITY STUDY IN RAT)

**OBJECTIVE**

- (a) To determine the acute oral toxicity to the rat of the test substance when administered 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	:	<i>Rattus Rattus albanicus</i>
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****BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDY (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  $24 \pm 2^{\circ}\text{C}$  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****Sample preparation :**

The Bt-cotton seeds (Nath seeds) as well as the Non-transgenic cotton seed samples were crushed and solutions were made in groundnut oil (vehicle) for oral administration.

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

Five 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 and third groups were administered with the non-transgenic cotton seed sample at the dose levels of 2500 and 5000 mg/kg. B.wt respectively. Similarly Bt-cotton seeds (Nath seeds) sample was provided to group fourth and fifth at the dose levels of 2500 and 5000 mg/kg. B.wt respectively.

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**BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDY (ACUTE ORAL TOXICITY STUDY IN RAT)**

**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 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 nembutal anaesthesia prior to sacrifice.

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BIOSAFETY STUDY (ACUTE ORAL TOXICITY STUDY IN RAT)

**HAEMATOLOGY :**

Following haematological estimations were performed on control and treated group of animals using Baker Haematology system 9120<sup>+</sup>.

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

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BIOSAFETY STUDY (ACUTE ORAL TOXICITY STUDY IN RAT)

**SACRIFICE AND NECROPSY**

All the experimental (test and control) 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**

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDY (ACUTE ORAL TOXICITY STUDY IN RAT)

**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**

Haematological evaluations (Tables 4.0-4.06) disclosed no significant differences in test and control groups of animals as all the parameters fall within the accepted limits of normal variations.

**Clinical biochemistry evaluations**

No significant changes were noticed among both test and control group of animals with respect to serum biochemistry evaluations (Tables 5-5.06) as all the parameters fall within the accepted limits of normal variations.

**Organ Weight**

Absolute organ weights and their ratios (Relative organ weights) with body weights are shown in tables 6-6.13. In absence of any significant change in the organ weights, these organs have failed to suggest any specific target organ to the test substance.

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### BT-COTTON SEEDS (NATH SEEDS) BIOSAFETY STUDY (ACUTE ORAL TOXICITY STUDY IN RAT)

#### GROSS PATHOLOGY

No significant gross pathological changes (tables 7.0-7.04) were noticed in the treated animals administered with Bt-cotton seeds (Nath seeds) @ 2500 mg. and 5000 mg. per kg B. wt. Postmortem examination of these groups of animals was comparable to their corresponding control group of animals.

#### HISTOPATHOLOGICAL FINDING

No remarkable microscopic changes (tables 8.0-8.04) were observed in the histological findings of any of the test animals administered with Bt-cotton seeds (Nath seeds) @ 2500 mg. and 5000 mg. per kg B. wt. The animals of these groups were comparable to corresponding control group of animals. Only few animals of control as well as test groups showed slight pulmonary congestion, focal infiltration of mononuclear cells in the lungs and slight hepatic and renal congestion.

Under the condition of this study, the given samples of 'Bt-cotton seeds (Nath seeds)' was found to be **non-toxic** to wistar rats, when compared to non-transgenic cotton seed group of wistar rats, administered orally at maximum dose level of 5000 mg per kg. B.wt.

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.

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDY (ACUTE ORAL TOXICITY STUDY IN RAT)

TABLE - I  
LD<sub>50</sub> ASSAY - MORTALITY DATA

Sex & Dosage Level	Time of Death ( Days )														Cumulative Mortality	
	1	2	3	4	5	6	7	8	9	10	11	12	13	14		
<b>MALES</b>																
CONTROL- (VEHICLE ONLY)																
0.0 mg/kg .B.wt	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	0/5	
NON-TRANSGENIC COTTON SEED SAMPLE																
5000 mg/kg .B.wt	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0/5	
BT-COTTON SEEDS (NATH SEEDS) SAMPLE																
2500 mg/kg .B.wt	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0/5	
BT-COTTON SEEDS (NATH SEEDS) SAMPLE																
5000 mg/kg .B.wt	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0/5	
<b>FEMALES</b>																
CONTROL- (VEHICLE ONLY)																
0.0 mg/kg .B.wt	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	0/5	
NON- TRANSGENIC COTTON SEED SAMPLE																
5000 mg/kg .B.wt	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0/5	
BT-COTTON SEEDS (NATH SEEDS) SAMPLE																
2500 mg/kg .B.wt	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0/5	
BT-COTTON SEEDS (NATH SEEDS) SAMPLE																
5000 mg/kg .B.wt	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0/5	

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDY (ACUTE ORAL TOXICITY STUDY IN RAT)

TABLE-2  
SUMMARY OF OBSERVATIONS  
(MALES & FEMALES)

Dosage level (gm/rat B.wt)	Clinical Observations	Necropsy Observations
Control (vehicle only) (0.00 mg/kg. B.wt.)	No toxic signs or symptoms were noticed.	No noteworthy findings
Non-transgenic cotton seed (2500 mg/kg. B.wt.)	No treatment related toxic signs or symptoms were noticed.	No noteworthy findings
Non-transgenic cotton seed (5000 mg/kg. B.wt.)	No treatment related toxic signs or symptoms were noticed.	No noteworthy findings
Bt-cotton seeds (Nath seeds) (2500 mg/kg.B.wt.)	No treatment related toxic signs or symptoms were noticed.	No noteworthy findings
Bt-cotton seeds (Nath seeds) (5000 mg/kg.B.wt.)	No treatment related toxic signs or symptoms were noticed.	No noteworthy findings

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**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	103.2	106.4	Female	100	104.4	107.6
2. Non-transgenic cotton seed (2500 mg/kg b.wt)	Male	100	102.7	105.9	Female	100	102.8	105.8
3. Non-transgenic cotton seed (5000 mg/kg b.wt)	Male	100	102.9	106.4	Female	100	102.9	106.4
4. Bi- cotton seed (Nath seeds) 2500 mg/kg b.wt	Male	100	103.1	106.6	Female	100	103.4	106.9
5. Bi- cotton seed (Nath seeds) (5000 mg/kg b.wt)	Male	100	103.2	106.4	Female	100	103.0	106.3

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E-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS

TABLE - 3.01

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

S.No.	Sex	Day 0	Day 7	Day 14	S.No.	Sex	Day 0	Day 7	Day 14
1	M	100	104.01	106.22	1	F	100	105.07	108.04
2	M	100	103.17	106.64	2	F	100	104.16	107.82
3	M	100	102.20	105.83	3	F	100	104.32	106.34
4	M	100	103.43	106.64	4	F	100	104.18	108.06
5	M	100	103.28	106.92	5	F	100	104.09	107.53
	Mean	100	103.22	106.45		Mean	100	104.36	107.56

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BT-COTTON SEEDS (SATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

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

S.No.	Sex	Day 0	Day 7	Day 14	S.No.	Sex	Day 0	Day 7	Day 14
1	M	100	102.66	104.99	1	F	100	102.95	105.80
2	M	100	103.04	106.71	2	F	100	102.42	105.57
3	M	100	102.20	105.75	3	F	100	103.30	105.86
4	M	100	103.44	106.44	4	F	100	102.61	106.59
5	M	100	102.16	105.46	5	F	100	102.84	105.32
Mean		100	102.71	105.87	Mean		100	102.82	105.83

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BT-COTTON SEEDS (INATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 3.03

WEEKLY PERCENTILE BODY WEIGHT DATA OF RATS  
 GROUP : NON TRANSGENIC COTTON SEED  
 DOSE : 5000 mg/kg b.wt.

S.No.	Sex	Day 0	Day 7	Day 14	S.No.	Sex	Day 0	Day 7	Day 14
1	M	100	103.62	107.06	1	F	100	103.61	106.88
2	M	100	102.82	106.01	2	F	100	103.76	107.29
3	M	100	102.84	105.93	3	F	100	102.32	105.76
4	M	100	102.67	106.32	4	F	100	102.50	105.97
5	M	100	102.83	106.94	5	F	100	102.58	106.15
Mean		102.95	106.45	N/mean			100	102.95	106.41

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

**TABLE - 3.04**  
**WEEKLY PERCENTILE BODY WEIGHT DATA OF RATS**  
**GROUP : Bi-COTTON SEED (NATH SEEDS)**  
**DOSE : 2500 mg/kg b.wt.**

S.No.	Sex	Day 0	Day 7	Day 14	S.No.	Sex	Day 0	Day 7	Day 14
1	M	100	102.04	105.30	1	F	100	102.79	106.36
2	M	100	103.36	106.73	2	F	100	103.49	108.11
3	M	100	102.71	106.54	3	F	100	103.90	106.38
4	M	100	103.35	107.76	4	F	100	103.44	106.94
5	M	100	103.97	106.89	5	F	100	103.12	106.92
Mean		100	103.08	106.64	Mean		100	103.35	106.93

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 3.05  
WEEKLY PERCENTILE BODY WEIGHT DATA OF RATS  
GROUP : Bi-COTTON SEED (NATH SEEDS)  
DOSE : 5000 mg/kg B.wt.

S.No.	Sex	Day 0	Day 7	Day 14	S.No.	Sex	Day 0	Day 7	Day 14
1	M	100	103.01	107.06	1	F	100	102.79	106.40
2	M	100	102.99	105.32	2	F	100	102.88	106.23
3	M	100	104.45	108.47	3	F	100	103.34	107.27
4	M	100	102.17	105.18	4	F	100	103.25	106.00
5	M	100	103.22	106.16	5	F	100	102.72	105.72
Mean		100	103.16	106.44	Mean		100	102.99	106.32

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY) STUDY IN RATS

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

Gp. No.	Sex	Day 0	Day 7	Day 14	Sex	Day 0	Day 7	Day 14
1. Control (Vehicle only)	Male	173.58 ± 4.46	179.00 ± 3.53	184.60 ± 3.83	Female	172.66 ± 4.58	180.18 ± 4.72	185.70 ± 4.98
2. Non-transgenic cotton seed 2500 mg/kg.b.wt	Male	177.40 ± 2.68	182.20 ± 3.52	187.82 ± 3.11	Female	165.40 ± 7.94	170.08 ± 8.21	175.04 ± 8.32
3. Non-transgenic cotton seed 5000 mg/kg.b.wt	Male	166.52 ± 5.65	171.44 ± 5.34	177.26 ± 5.73	Female	173.16 ± 5.32	178.26 ± 4.39	184.24 ± 4.60
4. Bi-cotton seed (Nath seeds), 2500 mg/kg.b.wt	Male	165.02 ± 8.89	170.08 ± 8.13	175.94 ± 8.17	Female	167.62 ± 8.54	173.36 ± 8.60	179.24 ± 8.60
5. Bi-cotton seed (Nath seeds) 5000 mg/kg.b.wt	Male	173.38 ± 8.99	178.84 ± 8.38	184.46 ± 7.49	Female	170.68 ± 7.25	175.80 ± 7.44	181.46 ± 7.11

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 3.07  
WEEKLY BODY WEIGHT DATA (in gms) OF RATS  
GROUP : CONTROL - Vehicle only

S.No.	Sex	Day 0	Day 7	Day 14	S.No.	Sex	Day 0	Day 7	Day 14
1	M	171.9	178.8	182.6	1	F	171.5	180.2	185.3
2	M	170.0	175.4	181.3	2	F	180.1	187.6	194.2
3	M	180.1	184.1	190.6	3	F	173.3	180.8	184.3
4	M	174.6	180.6	186.2	4	F	169.8	176.9	183.5
5	M	170.5	176.1	182.3	5	F	168.5	175.4	181.2
Mean		173.58	179.00	184.60	Mean		172.66	180.18	185.7
±		±	±	±			±	±	±
S.D.		4.46	3.53	3.83	S.D.		4.58	4.72	4.98

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BT-COTTON SEEDS (NATHE SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

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

S.No.	Sex	Day 0	Day 7	Day 14	S.No.	Sex	Day 0	Day 7	Day 14
1	M	180.1	184.9	189.1	1	F	179.2	184.5	189.6
2	M	177.2	182.6	189.1	2	F	165.1	169.1	174.3
3	M	173.9	177.8	183.9	3	F	160.4	165.7	169.8
4	M	180.0	186.2	191.6	4	F	160.7	164.9	171.3
5	M	175.8	179.6	185.4	5	F	161.6	166.2	170.2
Mean		177.40	182.2	187.82	Mean		165.40	170.08	175.04
± S.D.		± 2.68	± 3.52	± 3.11	± S.D.		± 7.94	± 8.21	± 8.32

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

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

S.No.	Sex	Day 0	Day 7	Day 14	S.No.	Sex	Day 0	Day 7	Day 14
1	M	160.0	165.8	171.3	1	F	168.6	174.7	180.2
2	M	166.2	170.9	176.2	2	F	167.3	173.6	179.5
3	M	165.1	169.8	174.9	3	F	180.3	184.5	190.7
4	M	175.6	180.3	186.7	4	F	175.8	180.2	186.3
5	M	165.7	170.4	177.2	5	F	173.8	178.3	184.5
Mean		166.52	171.44	177.26	Mean		173.16	178.26	184.24
$\pm$		$\pm$	$\pm$	$\pm$	S.D.		$\pm$	$\pm$	$\pm$
S.D.		5.65	5.34	5.73			5.32	4.39	4.60

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

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

S.No.	Sex	Day 0	Day 7	Day 14	S.No.	Sex	Day 0	Day 7	Day 14
1	M	180.9	184.6	190.5	1	F	179.2	184.9	190.6
2	M	160.4	165.8	171.2	2	F	160.2	165.8	173.2
3	M	161.9	166.3	172.5	3	F	161.3	167.6	171.6
4	M	160.9	166.3	173.4	4	F	174.2	180.2	186.3
5	M	161.0	167.4	172.1	5	F	163.2	168.3	174.5
Mean		165.02	170.08	175.94	Mean		167.62	173.36	179.24
± S.D.		8.89	8.13	8.17	± S.D.		8.54	8.60	8.60

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 3.11  
WEEKLY BODY WEIGHT DATA (in gms) OF RATS  
GROUP : Bi-COTTON SEED (NATH SEEDS) SAMPLE  
DOSE : 5000 mg/kg b.wt.

S.No.	Sex	Day 0	Day 7	Day 14	S.No.	Sex	Day 0	Day 7	Day 15
1	M	165.6	170.6	177.3	1	F	160.9	165.4	171.2
2	M	180.2	185.6	189.8	2	F	170.0	174.9	180.6
3	M	161.7	168.9	175.4	3	F	167.6	173.2	179.8
4	M	179.3	183.2	188.6	4	F	174.9	180.6	185.4
5	M	180.1	185.9	191.2	5	F	180.0	184.9	190.3
Mean		173.38	178.84	184.46	Mean		170.68	175.80	181.46
± S.D.		8.99	8.38	7.49	± S.D.		7.25	7.44	7.11

**SHRIRAM INSTITUTE**  
**BT-COTTON SEEDS (NATH SEEDS)**  
**BIO-SAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)**

TABLE : 4.0 MEAN HAEMATOLOGY DATA OF MALE RATS

Parameters	Control (Vehicle only)	Non-transgenic Cotton seed 2500 mg/kg b.wt.	Non-transgenic cotton seed 5000 mg/kg b.wt	Bt- cotton seed 2500 mg/kg b.wt	Bt- cotton seed 5000 mg/kg b.wt
WBC ( X10 <sup>3</sup> )	7.54 ± 1.06	7.40 ± 1.44	7.50 ± 0.85	7.14 ± 1.85	7.27 ± 1.57
Differential					
Lymphocytes %	82.60 ± 1.95	82.21 ± 1.92	83.00 ± 1.41	83.80 ± 1.78	83.60 ± 1.51
Neutrophils %	15.80 ± 1.48	15.60 ± 2.50	15.20 ± 1.30	14.60 ± 1.94	14.40 ± 1.51
Eosinophils %	0.60 ± 0.89	0.80 ± 1.09	0.60 ± 0.54	0.40 ± 0.54	0.40 ± 0.54
Monocytes %	1.00 ± 1.41	1.40 ± 1.94	1.20 ± 1.30	1.20 ± 1.09	1.60 ± 1.51
Basophils %	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Protime	11.80 ± 0.83	11.80 ± 0.44	12.40 ± 0.89	12.00 ± 1.00	12.20 ± 0.84
R.B.C. (x10 <sup>6</sup> ) %	7.81 ± 0.36	7.33 ± 0.66	7.82 ± 0.35	7.82 ± 0.43	7.27 ± 0.14
Hb (gm %)	12.88 ± 0.31	14.70 ± 0.43	13.30 ± 0.46	14.34 ± 0.54	13.88 ± 0.58
Hct %	35.22 ± 1.70	34.42 ± 2.32	35.70 ± 1.52	35.88 ± 1.67	35.96 ± 1.56
Platelets (x10 <sup>9</sup> )	637.20 ± 111.88	822.0 ± 149.90	763.40 ± 133.50	845.20 ± 49.19	761.6 ± 138.5

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**SHRIRAM INSTITUTE**  
**BT-COTTON SEEDS (NATH SEEDS)**  
**BIO-SAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)**

TABLE : 4.01 MEAN HAEMATOLOGY DATA OF FEMALE RATS

Parameters	Control (Vehicle only)	Non-transgenic cotton seed 2500 mg /kg b.wt.	Non-Transgenic cotton seed 5000 mg /kg b.wt	Bt- cotton seed 2500 mg /kg b.wt	Bt- cotton seed 5000 mg /kg b.wt
WBC ( X10 <sup>3</sup> )	7.64 ± 1.15	7.30 ± 1.70	7.38 ± 1.04	7.15 ± 1.82	6.76 ± 1.18
Differential					
Lymphocytes %	81.80 ± 1.64	83.80 ± 1.30	82.80 ± 1.64	83.40 ± 2.07	82.80 ± 2.38
Neutrophils %	16.60 ± 1.95	14.20 ± 1.48	15.20 ± 1.64	15.00 ± 1.22	15.60 ± 1.67
Eosinophils %	0.60 ± 0.55	0.80 ± 0.83	0.80 ± 0.83	0.60 ± 0.89	0.60 ± 0.89
Monocytes %	1.00 ± 1.00	1.20 ± 1.30	1.20 ± 1.30	1.00 ± 1.41	1.00 ± 1.41
Basophils %	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Protime	11.40 ± 0.54	11.80 ± 0.84	12.20 ± 0.84	11.60 ± 0.54	11.80 ± 0.84
R.B.C. (x10 <sup>6</sup> ) %	7.49 ± 0.40	6.96 ± 0.52	7.22 ± 0.34	7.22 ± 0.25	7.29 ± 0.30
Hb (gm %)	12.70 ± 0.50	13.86 ± 0.42	13.54 ± 0.74	13.26 ± 0.50	14.06 ± 0.52
Hct %	34.74 ± 0.54	35.36 ± 1.34	34.08 ± 0.66	35.08 ± 1.21	37.50 ± 2.89
Platelets (x10 <sup>3</sup> )	742.40 ± 118.46	843.80 ± 3917	725.60 ± 41.80	774.80 ± 108.80	835.40 ± 106.14

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## SHRIRAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)TABLE - 4.02  
HAEMATOLOGY DATA OF CONTROL GROUP-RATS TREATED WITH VEHICLE ONLY  
DIFFERENTIAL

Animal No.	Sex	WBC Count ( $\times 10^3$ )	L%	N%	E%	M%	B%	Protime	RBC Count ( $\times 10^6$ )	Hb Gm %	Hct %	Platelet Count ( $\times 10^3$ )
1	M	8.7	82	18	0	0	0	12	7.87	12.9	34.8	478.0
2	M	6.2	84	16	0	0	0	11	8.11	13.2	38.2	663.0
3	M	8.3	30	16	2	2	0	12	8.03	13.1	34.8	583.0
4	M	7.8	35	14	1	0	0	13	7.83	12.8	34.3	773.0
5	M	6.7	82	15	0	3	0	11	7.20	12.4	34.0	689.0
Mean $\pm$ S.D		7.54 $\pm$ 1.96	82.60 $\pm$ 1.95	15.80 $\pm$ 1.48	0.6 $\pm$ 0.89	1.90 $\pm$ 1.41	0.0 $\pm$ 0.9	11.80 $\pm$ 0.83	7.81 $\pm$ 0.36	12.88 $\pm$ 0.31	35.22 $\pm$ 1.70	637.20 $\pm$ 111.88
1	F	8.1	81	16	1	2	0	0	7.31	12.6	35.1	586.0
2	F	9.3	84	14	0	2	0	11	6.89	11.9	33.8	878.0
3	F	6.3	83	16	1	0	0	12	7.86	12.9	34.9	731.0
4	F	6.9	80	18	1	1	0	12	7.63	12.7	35.1	838.0
5	F	7.6	81	19	0	0	0	11	7.78	12.7	34.8	679.0
Mean $\pm$ S.D		7.64 $\pm$ 1.15	81.80 $\pm$ 1.64	16.60 $\pm$ 1.95	0.60 $\pm$ 0.55	1.90 $\pm$ 1.00	0.0 $\pm$ 0.00	11.40 $\pm$ 0.54	7.49 $\pm$ 0.40	12.70 $\pm$ 0.50	34.74 $\pm$ 0.54	742.40 $\pm$ 118.46
L = Lymphocytes			N = Neutrophils		E = Eosinophils			M = Monocytes				B = Basophils

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## SHIRAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE -4.03  
HAEMATOLOGY DATA OF NON-TRANSGENIC COTTON SEEDS GROUP RAT  
DOSE : 2500 mg /kg b.wt

DIFFERENTIAL												
Animal No.	Sex	WBC Count ( $\times 10^3$ )	L%	N%	E%	M%	B%	Protime	RBC Count ( $\times 10^9$ )	Hb gm %	Hct %	Platelet Count ( $\times 10^9$ )
1	M	7.70	80.0	16.0	0	4	0	12	7.80	14.8	35.4	966.0
2	M	6.40	83.0	15.0	2	0	0	11	6.87	14.2	32.2	599.0
3	M	6.60	85.0	12.0	0	3	0	12	8.18	15.2	37.5	910.0
4	M	6.50	82.0	16.0	2	0	0	12	7.29	15.0	35.0	894.0
5	M	9.80	81.0	19.0	0	0	0	12	6.55	14.3	32.0	741.0
Mean		7.40	82.20	15.60	0.80	1.40	0.0	11.80	7.33	14.70	34.42	822.0
S.D		1.44	1.92	2.50	1.09	0.94	0.00	0.44	0.66	0.43	2.32	149.9
1	F	7.60	85.0	14.0	1	0	0	12	7.60	14.1	33.4	909.0
2	F	9.10	84.0	14.0	0	2	0	11	6.35	14.3	33.8	905.0
3	F	6.50	85.0	12.0	2	3	0	13	6.51	14.0	37.0	792.0
4	F	4.80	82.0	16.0	1	1	0	12	7.30	13.2	35.8	790.0
5	F	8.50	85.0	15.0	0	0	0	11	7.06	13.7	34.8	823.0
Mean		7.39	83.80	14.20	0.80	1.20	0.0	11.80	6.96	13.86	35.36	843.8
S.D		1.70	1.30	1.48	0.83	1.30	0.00	0.34	0.52	0.42	1.34	59.17
L	L = Lymphocytes N = Neutrophils E = Eosinophils M = Monocytes											

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## SHRIRAM INSTITUTE

BT-COTTON SEEDS (MATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)TABLE - 4.04  
HAEMATOLOGY DATA OF NON-TRANSGENIC COTTON SEEDS GROUP RATS  
DOSE : 5000 mg /kg b.wt

Animal No.	Sex	WBC Count ( $\times 10^9$ )	DIFFERENTIAL				RBC Count ( $\times 10^9$ )	Hb gm %	Hct %	Platelet Count ( $\times 10^3$ )
			L%	M%	E%	B%				
1	M	8.4	83	16	1	0	13	7.86	13.1	35.1
2	M	6.5	85	14	0	1	11	8.10	13.8	38.2
3	M	8.3	81	15	1	3	12	8.04	13.6	35.8
4	M	7.5	83	14	1	2	13	7.85	13.4	35.3
5	M	6.8	83	17	0	0	13	7.21	12.6	34.1
Mean $\pm$ SD		7.5 $\pm$ 0.85	83.0 $\pm$ 1.41	15.20 $\pm$ 1.30	0.60 $\pm$ 0.54	1.20 $\pm$ 0.30	12.40 $\pm$ 0.00	7.82 $\pm$ 0.89	13.50 $\pm$ 0.35	35.70 $\pm$ 1.52
1	F	6.7	83	14	0	3	13	6.85	12.6	33.5
2	F	8.2	84	15	1	0	12	7.70	14.2	35.0
3	F	8.8	80	18	2	0	12	7.41	13.6	34.1
4	F	6.5	83	15	0	2	13	6.93	13.0	33.4
5	F	6.7	84	14	1	1	11	7.23	14.3	34.4
Mean $\pm$ SD		7.38 $\pm$ 1.04	83.80 $\pm$ 1.64	15.20 $\pm$ 1.64	0.80 $\pm$ 0.83	1.20 $\pm$ 1.30	12.20 $\pm$ 0.00	7.22 $\pm$ 0.84	13.54 $\pm$ 0.34	34.08 $\pm$ 0.74

L = Lymphocytes

N = Neutrophils

E = Eosinophils

M = Monocytes

B = Basophils

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## SHIRAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES(ACUTE ORAL TOXICITY STUDY IN RATS)TABLE - 4.05  
HAEMATOLOGY DATA OF Br-COTTON SEED (NATH SEEDS) GROUP RATS  
DOSE : 2500 mg /kg b.wt

DIFFERENTIAL												
Animal No.	Sex	WBC Count ( $\times 10^9$ )	L%	N%	E%	M%	B%	Protime	RBC Count ( $\times 10^6$ )	Hb gm %	Hct %	Platelet Count ( $\times 10^9$ )
1	M	7.70	82.0	16.0	1	1	0	13	7.16	13.6	33.2	914.0
2	M	5.10	85.0	12.0	0	3	0	11	7.70	14.1	35.3	855.0
3	M	8.40	84.0	14.0	1	1	0	11	8.28	14.3	36.6	813.0
4	M	5.30	82.0	17.0	0	1	0	13	7.85	14.7	37.1	785.0
5	M	9.20	86.0	14.0	0	0	0	12	8.12	15.0	37.2	859.0
Mean		7.14	83.8	14.60	0.4	1.20	0.0	12.00	7.82	14.34	35.88	845.2
S.D		1.85	1.78	1.94	0.54	1.09	0.00	±	+	+	1.67	49.19
1	F	5.47	83.0	14.0	0	3	0	12	7.54	13.3	35.2	888.0
2	F	5.40	85.0	15.0	0	0	0	11	6.98	12.6	33.4	936.0
3	F	7.70	84.0	14.0	2	0	0	12	7.03	13.3	34.8	684.0
4	F	7.40	80.0	17.0	1	2	0	12	7.46	13.1	35.2	701.0
5	F	9.80	85.0	15.0	0	0	0	11	7.11	14.0	36.8	739.0
Mean		7.15	83.40	15.0	0.60	1.00	0.0	11.60	7.22	13.26	35.08	774.80
S.D		1.82	2.07	1.22	0.89	1.41	0.00	0.54	0.25	0.50	1.21	108.80
L = Lymphocytes				E = Eosinophils				M = Monocytes				B = Basophils
N = Neutrophils				E = Eosinophils				M = Monocytes				B = Basophils

## SHIRAM INSTITUTE

BT-COTTON SEEDS(NATH SEEDS)  
BIOSAFETY STUDIES(ACUTE ORAL TOXICITY STUDY IN RATS)TABLE - 4.06  
HAEMATOLOGY DATA OF RATS OF BI-COTTON SEED (NATH SEEDS) GROUP RATS  
DOSE : 5000 mg /kg b.wt

DIFFERENTIAL												
Animal No.	Sex	WBC Count ( $\times 10^3$ )	L%	N%	E%	M%	B%	Protime	RBC Count ( $\times 10^6$ )	Hb gm %	Hct %	Platelet Count ( $\times 10^3$ )
1 M	M	9.20	84.0	16.0	0	0	0	11	7.12	13.5	34.80	578.0
2 M	M	5.40	81.0	15.0	1	3	0	12	7.48	14.1	37.10	658.0
3 M	M	5.30	84.0	14.0	0	2	0	12	7.30	14.1	37.30	905.0
4 M	M	7.90	84.0	12.0	1	3	0	13	7.17	14.6	36.80	860.0
5 M	M	7.90	85.0	15.0	0	0	0	13	7.32	13.1	33.80	807.0
Mean $\pm$ S.D.		7.27 $\pm$ 1.57	83.6 $\pm$ 1.51	14.4 $\pm$ 1.51	0.00 $\pm$ 0.00	1.60 $\pm$ 1.51	0.00 $\pm$ 0.00	12.20 $\pm$ 0.84	7.27 $\pm$ 0.14	13.88 $\pm$ 0.58	35.96 $\pm$ 1.56	761.60 $\pm$ 138.50
1 F	F	6.70	84.0	16.0	0	0	0	12	7.36	14.3	36.80	821.0
2 F	F	5.00	83.0	14.0	0	3	0	12	7.30	14.0	37.40	987.0
3 F	F	7.90	80.0	18.0	2	0	0	13	6.98	14.2	37.80	761.0
4 F	F	6.40	81.0	16.0	1	2	0	11	7.76	14.6	41.80	717.0
5 F	F	7.80	86.0	14.0	0	0	0	11	7.06	13.2	33.70	885.0
Mean $\pm$ S.D.		6.76 $\pm$ 1.18	82.80 $\pm$ 2.38	15.60 $\pm$ 1.67	0.60 $\pm$ 0.89	1.00 $\pm$ 1.41	0.00 $\pm$ 0.00	11.80 $\pm$ 0.84	7.29 $\pm$ 0.30	14.06 $\pm$ 0.52	37.50 $\pm$ 2.89	835.40 $\pm$ 106.14
L = Lymphocytes			N = Neutrophils			E = Eosinophils		M = Monocytes				B = Basophils

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## SHRI RAM INSTITUTE

BT-COTTON SEEDS (NATURAL SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 5.0 MEAN BIOCHEMISTRY DATA ON MALE RATS

Parameters	Control Group (Vehicle only)	Non-transgenic cotton seed 2500 mg/kg b.wt.			Non-transgenic cotton seed 5000 mg/kg b.wt.			Bi-cotton seed 2500 mg/kg b.wt.			Bi-cotton seed 5000 mg/kg b.wt.		
		Non-transgenic cotton seed 2500 mg/kg b.wt.	Bi-cotton seed 2500 mg/kg b.wt.	Bi-cotton seed 5000 mg/kg b.wt.	Non-transgenic cotton seed 5000 mg/kg b.wt.	Bi-cotton seed 2500 mg/kg b.wt.	Bi-cotton seed 5000 mg/kg b.wt.	Non-transgenic cotton seed 5000 mg/kg b.wt.	Bi-cotton seed 2500 mg/kg b.wt.	Bi-cotton seed 5000 mg/kg b.wt.	Non-transgenic cotton seed 5000 mg/kg b.wt.	Bi-cotton seed 2500 mg/kg b.wt.	Bi-cotton seed 5000 mg/kg b.wt.
Glucose (mg %)	88.20 ± 6.97	88.60 ± 5.02	82.00 ± 3.80	84.80 ± 6.61	84.40 ± 6.42								
BUN (mg %)	26.12 ± 2.71	26.26 ± 3.29	26.84 ± 3.24	27.40 ± 3.54	27.68 ± 2.98								
Total Protein (gm %)	7.16 ± 0.33	6.97 ± 0.18	7.14 ± 0.23	7.04 ± 0.42	7.06 ± 0.41								
S.G.P.T (I.U)	35.37 ± 3.71	34.07 ± 6.19	36.56 ± 4.87	35.38 ± 5.57	36.10 ± 4.79								
S.G.O.T (I.U)	32.96 ± 5.09	36.69 ± 4.38	37.45 ± 3.33	37.92 ± 2.06	36.55 ± 2.61								
Albumin (I.U)	4.01 ± 0.15	3.95 ± 0.17	3.91 ± 0.19	3.92 ± 0.18	3.96 ± 0.15								
SAP (U/L)	91.20 ± 9.69	96.18 ± 9.36	95.76 ± 7.69	95.64 ± 6.16	94.22 ± 10.66								

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**SHRIRAM INSTITUTE**

BIO-SAFETY STUDIES OF BT-COTTON SEEDS (NATURAL SEEDS)  
BIO-SAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

**TABLE - 5.01 MEAN BIOCHEMISTRY DATA ON FEMALE RATS**

Parameters	Control Group (Vehicle only)	Non-transgenic cotton seed 2500 mg /kg b.wt.	Non-transgenic cotton seed 5000 mg /kg b.wt.	Bi-cotton seed 2500 mg /kg b.wt.	Bi-cotton seed 5000 mg /kg b.wt.
Glucose (mg %)	83.60 ± 6.10	88.00 ± 6.20	82.00 ± 3.16	86.80 ± 6.14	83.80 ± 5.11
BUN (mg %)	25.80 ± 3.50	26.70 ± 2.54	26.40 ± 2.28	23.96 ± 3.11	28.24 ± 2.17
Total Protein (gm %)	7.16 ± 0.44	6.89 ± 0.22	7.06 ± 0.41	7.15 ± 0.41	7.24 ± 0.31
S.G.P.T (I.U)	34.35 ± 6.12	35.72 ± 4.23	33.69 ± 5.52	34.09 ± 4.09	32.25 ± 3.65
S.G.O.T(I.U)	37.17 ± 3.08	37.09 ± 3.08	32.83 ± 4.16	34.44 ± 4.28	36.95 ± 2.54
Albumin (I.U)	4.03 ± 0.19	3.88 ± 0.08	3.87 ± 0.07	3.88 ± 0.07	3.92 ± 0.12
SAP (U/L)	95.96 ± 7.00	95.02 ± 2.28	91.82 ± 9.14	92.68 ± 6.65	92.82 ± 9.91

## SHRI RAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES(ACUTE ORAL TOXICITY STUDY IN RATS)TABLE - 5.02  
BIOCHEMISTRY DATA OF CONTROL GROUP – RATS (VEHICLE-GROUND NUT OIL 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	29.3	89	6.788	36.21	28.49	3.96	89.7
2	M	28.4	78	7.322	39.47	36.10	4.22	95.2
3	M	22.7	91	7.544	29.75	29.92	4.11	78.5
4	M	25.5	97	6.829	37.41	40.40	3.92	87.8
5	M	24.7	86	7.322	34.03	29.93	3.84	104.8
Mean		26.12	88.20	7.161	35.37	32.96	4.01	91.20
±		±	±	±	±	±	±	±
S.D		2.71	6.97	0.33	3.71	5.09	0.15	9.69
1	F	20.0	86	7.466	41.32	40.33	4.18	102.8
2	F	29.3	93	7.644	40.56	36.79	3.84	84.3
3	F	25.7	78	6.548	28.28	40.36	3.92	97.3
4	F	27.4	79	7.246	32.41	34.36	4.22	96.0
5	F	26.6	82	6.899	29.38	34.03	4.21	99.4
Mean		25.8	83.6	7.160	34.35	37.17	4.03	95.96
±		±	±	±	±	±	±	±
S.D		3.50	6.10	0.44	6.12	3.08	0.187	7.00

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## SHRI RAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 5.03  
BIOCHEMISTRY DATA OF NON TRANSGENIC 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 IU	S.G.O.T IU	Albumin (gm %)	SAP U/L
1	M	21.3	89.0	6.895	32.86	38.62	4.08	87.5
2	M	24.5	81.0	7.089	28.58	35.29	3.98	101.5
3	M	27.8	92.0	6.933	39.83	38.93	3.82	85.8
4	M	28.7	94.0	6.726	41.18	40.90	3.76	98.3
5	M	29.0	87.0	7.211	27.90	29.72	4.15	107.8
Mean		26.26	88.60	6.970	34.07	36.69	3.95	96.18
± S.D.		± 3.29	± 5.02	± 0.180	± 6.19	± 4.38	± 0.166	± 9.36
1	F	29.6	83.0	6.744	40.38	38.37	3.18	94.8
2	F	23.2	96.0	6.838	36.53	40.29	4.18	92.8
3	F	26.9	92.0	7.245	29.11	36.35	3.90	97.2
4	F	28.5	81.0	6.668	37.89	32.18	3.78	92.8
5	F	25.3	88.0	6.979	34.72	38.29	4.19	97.5
Mean		26.70	88.00	6.894	35.72	37.09	3.88	95.02
± S.D.		± 2.54	± 6.20	± 0.22	± 4.23	± 3.08	± 0.08	± 2.28

## SHIRIRAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 5.04  
BIOCHEMISTRY DATA OF NON TRANSGENIC 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	28.8	81.0	7.286	40.36	36.49	4.15	108.5
2	M	31.2	86.0	6.829	34.37	39.10	4.03	93.8
3	M	22.9	78.0	7.286	36.38	41.19	3.65	91.0
4	M	25.0	86.0	6.944	42.03	38.18	3.89	96.6
5	M	26.3	79.0	7.366	29.78	32.31	3.84	88.9
Mean		26.84	82.00	7.142	36.56	37.45	3.91	95.76
±		±	±	±	±	±	±	±
S.D		3.24	3.80	0.23	4.87	3.33	0.19	7.69
1	F	23.8	78.0	7.044	27.63	29.27	3.96	94.5
2	F	29.8	84.0	6.548	38.79	36.34	3.86	86.4
3	F	26.5	80.0	7.286	32.18	30.94	3.84	98.2
4	F	24.9	82.0	6.899	29.72	38.21	3.94	78.8
5	F	27.0	86.0	6.944	40.13	29.38	3.79	101.2
Mean		26.40	82.00	7.064	33.69	32.83	3.87	91.82
±		±	±	±	±	±	±	±
S.D		2.28	3.16	0.41	5.52	4.16	0.07	9.14

## SHIRAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 5.05  
BIOCHEMISTRY DATA OF BT-COTTON SEED(NATH SEEDS) 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	28.3	90	7.643	27.63	38.39	4.17	104.8
2	M	32.0	78	6.628	38.92	40.21	4.01	98.3
3	M	22.2	84	6.722	41.21	38.92	3.67	90.5
4	M	28.0	93	7.286	31.32	34.72	3.91	94.8
5	M	26.5	79	6.944	38.83	37.39	3.82	89.8
Mean		27.4	84.8	7.044	35.38	37.92	3.92	95.64
± S.D		± 3.54	± 6.61	± 0.419	± 5.57	± 2.06	± 0.18	± 6.16
1	F	29.8	78	7.366	36.39	34.86	3.98	95.4
2	F	27.0	92	7.643	30.90	32.38	3.88	84.6
3	F	21.9	83	6.628	38.10	38.79	3.82	92.6
4	F	23.8	89	7.286	28.65	37.92	3.92	88.7
5	F	27.3	92	6.829	36.32	28.29	3.81	102.1
33.32		25.96	86.8	7.150	34.09	34.44	3.88	92.68
±		± 3.11	± 6.14	± 0.410	± 4.09	± 4.28	± 0.07	± 6.65

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## SHRI RAM INSTITUTE

BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)  
BT-COTTON SEEDS (NATH SEEDS)

TABLE - 5.06  
BIOCHEMISTRY DATA OF BT-COTTON SEED(NATH SEEDS) 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	29.0	80	7.286	29.27	33.46	3.84	104.7
2	M	23.4	88	6.899	39.82	39.36	3.96	92.9
3	M	27.8	81	6.944	36.40	34.35	4.15	90.8
4	M	31.5	79	7.643	33.82	38.78	3.78	103.9
5	M	26.7	94	6.548	41.22	26.83	4.10	78.8
Mean		27.68	83.40	7.064	36.10	36.55	3.96	94.22
±		±	±	±	±	±	±	±
S.D		2.98	6.42	0.41	4.79	2.61	0.15	10.66
1	F	28.7	91	6.944	29.36	38.92	4.09	95.0
2	F	31.8	78	7.694	30.79	37.73	3.84	84.6
3	F	27.5	84	6.932	32.98	39.23	3.99	99.3
4	F	26.3	86	7.286	38.29	33.10	3.89	79.8
5	F	26.9	80	7.366	29.83	35.81	3.78	105.4
33.32		28.24	83.80	7.244	32.15	36.95	3.92	92.82
±		±	±	±	±	±	±	±
		2.17	5.11	0.31	3.65	2.54	0.12	10.51

**SHRI RAM INSTITUTE**  
**BT-COTTON SEEDS (NATH SEEDS)**  
**BIO-SAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)**

**TABLE - 6**  
**MEAN PERCENTILE ORGAN WEIGHT DATA OF MALE RATS**

Organs	Control (Vehicle only)	DOSAGE LEVEL			Bi-cotton seed (Nath Seeds) 5000 mg/kg b.wt.	Bi-cotton seed (Nath Seeds) 5000 mg/kg b.wt.
		Non-transgenic cotton seed 2500 mg/kg b.wt.	5000 mg/kg b.wt.	25000 mg/kg b.wt.		
Lung	0.83 ± 0.075	0.82 ± 0.04	0.92 ± 0.11	0.87 ± 0.025	0.74 ± 0.27	
Liver	3.67 ± 0.30	3.43 ± 0.38	4.07 ± 0.31	3.81 ± 0.66	3.67 ± 0.23	
Kidney	1.09 ± 0.08	0.89 ± 0.10	0.99 ± 0.06	1.00 ± 0.13	0.90 ± 0.06	
Testis	1.83 ± 0.156	1.15 ± 0.365	1.20 ± 0.15	1.13 ± 0.07	1.20 ± 0.23	
Adrenal	0.03 ± 0.008	0.026 ± 0.004	0.03 ± 0.008	0.034 ± 0.01	0.06 ± 0.012	
Heart	0.44 ± 0.04	0.41 ± 0.07	0.44 ± 0.05	0.43 ± 0.04	0.47 ± 0.03	
Spleen	0.34 ± 0.08	0.30 ± 0.04	0.39 ± 0.07	0.35 ± 0.10	0.34 ± 0.06	
Brain	0.98 ± 0.085	0.97 ± 0.08	1.03 ± 0.07	1.00 ± 0.13	1.03 ± 0.04	

**SHRIRAM INSTITUTE**  
 BIOSAFETY STUDIES OF BT-COTTON SEEDS (NATH SEEDS)  
 BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

**TABLE - 6.01**  
**MEAN PERCENTILE ORGAN WEIGHT DATA OF FEMALE RATS**

Organs	DOSAGE LEVEL		
	Control (Vehicle only)	Non-transgenic cotton seed 2500 mg/kg b.wt.	Bi-cotton seed (Nath Seeds) 2500 mg/kg b.wt.
Lung	0.83 ± 0.13	0.89 ± 0.09	0.94 ± 0.09
Liver	3.50 ± 0.38	3.68 ± 0.30	3.58 ± 0.93
Kidney	0.92 ± 0.05	0.90 ± 0.028	0.92 ± 0.02
Gonads	0.05 ± 0.01	0.04 ± 0.008	0.06 ± 0.019
Adrenal	0.032 ± 0.008	0.03 ± 0.03	0.036 ± 0.008
Heart	0.42 ± 0.04	0.36 ± 0.015	0.40 ± 0.07
Uterus	0.22 ± 0.06	0.19 ± 0.02	0.20 ± 0.05
Spleen	0.34 ± 0.03	0.34 ± 0.05	0.43 ± 0.11
Brain	0.97 ± 0.06	1.14 ± 0.09	1.02 ± 0.15

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## SHRI RAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 6.02  
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)	184.60 ± 3.83	1.55 ± 0.16	6.78 ± 0.56	1.78 ± 0.11	0.06 ± 0.15	0.013 ± 0.013	0.81 ± 0.086	0.63 ± 0.16	1.80 ± 0.17
Non-transgenic Cotton seed 2500 mg/kg b.wt	187.82 ± 3.11	1.53 ± 0.098	6.44 ± 0.71	1.68 ± 0.21	2.16 ± 0.68	0.051 ± 0.009	0.78 ± 0.13	0.57 ± 0.07	1.82 ± 0.14
Non-transgenic Cotton seed 5000 mg/kg b.wt	177.26 ± 5.73	1.63 ± 0.20	7.21 ± 0.46	1.76 ± 0.09	2.12 ± 0.26	0.07 ± 0.008	0.80 ± 0.07	0.69 ± 0.12	1.82 ± 0.09
Bi-cotton seed (Nath seeds) 2500 mg/kg b.wt	172.94 ± 8.17	1.53 ± 0.097	6.75 ± 1.47	1.76 ± 0.23	1.99 ± 0.10	0.06 ± 0.019	0.77 ± 0.05	0.62 ± 0.05	1.76 ± 0.17
Bi-cotton seed (Nath seeds) 5000 mg/kg b.wt	184.46 ± 7.49	1.58 ± 0.23	6.78 ± 0.63	1.66 ± 0.15	2.23 ± 0.47	0.10 ± 0.02	0.82 ± 0.06	0.66 ± 0.11	1.91 ± 0.05

## SHRI RAM INSTITUTE

BT-COTTON SEEDS(NATH SEEDS)  
BIOSAFETY STUDIES(ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 6.03  
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)	Brain (gm)
Control (Vehicle only)	185.70 ± 4.98	1.61 ± 0.15	6.50 ± 0.81	1.70 ± 0.08	0.096 ± 0.03	0.42 ± 0.13	0.06 ± 0.16	0.78 ± 0.08	0.63 ± 0.07	1.82 ± 0.13
Non-transgenic Cotton seed 2500 mg/kg b.wt	175.04 ± 8.32	1.57 ± 0.18	6.46 ± 0.63	1.58 ± 0.11	0.08 ± 0.01	0.34 ± 0.05	0.04 ± 0.008	0.75 ± 0.12	0.60 ± 0.12	2.00 ± 0.49
Non-transgenic Cotton seed 5000 mg/kg b.wt	184.24 ± 4.60	1.63 ± 0.05	6.62 ± 1.75	1.70 ± 0.05	0.11 ± 0.03	0.37 ± 0.09	0.066 ± 0.015	0.73 ± 0.14	0.65 ± 0.16	1.88 ± 0.29
B-cotton seed (Nath seeds) 2500 mg/kg b.wt	179.24 ± 8.60	1.60 ± 0.12	6.40 ± 0.70	1.68 ± 0.12	0.12 ± 0.03	0.38 ± 0.14	0.05 ± 0.008	0.81 ± 0.09	0.62 ± 0.09	1.90 ± 0.05
B-cotton seed (Nath seeds) 5000 mg/kg b.wt	181.46 ± 7.11	1.47 ± 0.29	6.28 ± 0.64	1.68 ± 0.16	0.10 ± 0.05	0.42 ± 0.29	0.08 ± 0.053	0.71 ± 0.06	0.59 ± 0.08	1.72 ± 0.10

## SHIRIRAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

**TABLE - 6.04**  
**ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF CONTROL GROUP OF MALE RATS**  
**(VEHICLE ONLY)**

Animal No	Sex	Body Weight in gms	Lung % Wt. in Body wt	Liver % Wt. in Body gms wt	Kidney % Wt. in Body gms wt	Gonads % Wt. in Body Gms wt	Adrenal % Wt. in Body gms wt	Heart % Wt. in Body gms wt	Spleen % Wt. in Body gms wt	Brain % Wt. in Body gms wt
1	M	182.6	1.42 0.77	6.93 3.79	1.82 0.99	2.00 1.09	0.05 0.03	0.76 0.42	0.42 0.23	1.59 0.87
2	M	181.3	1.63 0.90	7.01 3.86	1.98 1.09	1.85 1.02	0.04 0.02	0.71 0.39	0.56 0.31	1.77 0.95
3	M	190.6	1.78 0.93	7.35 3.85	1.95 1.02	1.92 1.00	0.07 0.04	0.94 0.49	0.82 0.43	2.01 1.08
4	M	186.2	1.49 0.80	5.84 3.13	2.10 1.13	1.78 0.96	0.07 0.04	0.83 0.45	0.75 0.40	1.96 1.05
5	M	182.3	1.41 0.77	6.78 3.72	2.22 1.21	1.59 0.87	0.06 0.03	0.80 0.44	0.62 0.34	1.74 0.95
Mean		184.60	1.55 ±	6.78 0.83	2.01 3.04	1.83 0.99	0.06 0.03	0.81 0.44	0.63 0.34	1.80 0.98
± S.D.		3.83	± 0.16	0.075	± 0.56	± 0.30	± 0.15	± 0.08	± 0.01	± 0.08
								0.08	0.04	0.16 0.08
										0.17 0.09

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## SHIRIRAM INSTITUTE

BT-COTTON SEEDS(NATH SEEDS)  
BIOSAFETY STUDIES(ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 6.05  
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC COTTON SEED  
GROUP 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 Body wt	Wt	% in Body wt	Wt	% in Body wt	Gms	wt	Wt	% in Body wt	Gms	wt	Wt	% in Body wt	Gms	wt	Wt	% in Body wt
1	M	189.1	1.48	0.78	5.83	3.08	1.45	0.76	2.60	1.38	0.05	0.03	0.69	0.36	0.61	0.32	1.83	0.96		
2	M	189.1	1.59	0.84	7.62	4.03	1.94	1.02	3.01	1.59	0.06	0.03	0.98	0.52	0.46	0.24	1.61	0.86		
3	M	183.9	1.47	0.80	6.55	3.56	1.64	0.89	2.21	1.70	0.04	0.02	0.75	0.41	0.54	0.29	1.97	1.07		
4	M	191.6	1.68	0.87	6.13	3.19	1.86	0.74	1.58	0.82	0.06	0.03	0.82	0.42	0.65	0.34	1.94	1.01		
5	M	185.4	1.45	0.78	6.09	3.28	1.51	0.82	1.39	0.75	0.05	0.02	0.65	0.35	0.60	0.32	1.73	0.93		
Mean		187.82	1.53	0.82	6.44	3.43	1.68	0.89	2.16	1.15	0.05	0.02	0.78	0.41	0.57	0.30	1.82	0.97		
±		±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±		
S.D.		8.13	0.10	0.04	0.71	0.38	0.21	0.106	0.68	0.36	0.009	0.004	0.13	0.07	0.07	0.04	0.14	0.08		

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## SHIRAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 6.06  
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC 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	%	Wt in gms	%	Wt in gms	%	Wt in gms	%								
1	M	171.3	1.58	0.92	6.89	4.02	1.91	1.11	1.79	1.05	0.07	0.04	0.89	0.52	0.81	0.47	1.83	1.07
2	M	176.2	1.88	1.06	7.23	4.10	1.75	0.99	2.18	1.23	0.08	0.05	0.80	0.45	0.73	0.41	1.96	1.11
3	M	174.9	1.64	0.93	8.00	4.57	1.68	0.96	2.51	1.43	0.06	0.03	0.78	0.44	0.52	0.30	1.82	1.04
4	M	186.7	1.72	0.92	7.00	3.75	1.79	0.96	2.03	1.08	0.07	0.04	0.79	0.42	0.60	0.32	1.77	0.95
5	M	177.2	1.32	0.75	6.93	3.91	1.70	0.96	2.11	1.19	0.06	0.03	0.68	0.38	0.80	0.45	1.70	0.96
Mean		177.26	1.63	0.92	7.21	4.07	1.76	0.99	2.12	1.20	0.07	0.04	0.80	0.44	0.69	0.39	1.82	1.03
±			±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±
S.D.		5.73	0.20	0.11	0.17	0.31	0.09	0.06	0.26	0.15	0.008	0.008	0.07	0.05	0.12	0.07	0.09	0.07

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 6.07  
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF BT-COTTON SEED (NATH SEEDS)  
GROUP 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. gms	% in Body wt														
1	M	190.5	1.68	0.88	8.98	4.71	1.84	0.96	2.03	1.07	0.08	0.04	0.72	0.38	0.62	0.32	1.54	0.80
2	M	171.2	1.52	0.89	5.41	3.16	1.69	0.99	1.96	1.14	0.07	0.04	0.76	0.44	0.51	0.29	1.70	0.99
3	M	172.5	1.47	0.85	6.28	3.64	1.40	0.81	1.89	1.09	0.04	0.02	0.80	0.46	0.38	0.22	2.01	1.16
4	M	173.4	1.56	0.90	7.45	4.29	1.96	1.13	1.94	1.12	0.07	0.04	0.84	0.48	0.77	0.44	1.84	1.06
5	M	172.1	1.44	0.84	5.65	3.28	1.92	1.10	2.15	1.25	0.04	0.02	0.71	0.40	0.83	0.48	1.72	1.00
Mean		175.94	1.53	0.87	6.75	3.81	1.76	0.99	1.99	1.13	0.06	0.04	0.77	0.43	0.62	0.35	1.76	1.00
± S.D.		8.17	± 0.09	0.02	1.47	0.66	0.23	0.13	0.10	0.07	0.019	0.01	0.05	0.04	0.18	0.10	0.17	0.13

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 6.08  
RELATIVE ORGAN WEIGHT DATA OF BT-COTTON SEED (NATH SEEDS)  
GROUP 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	%	Wt in gms	%	Wt in gms	%	Wt in gms	%	Wt in gms
		Wt in gms	wt	Body wt	wt	Body wt	wt	Body wt	wt	Body wt
1	M	177.3	1.41	0.79	6.26	3.53	1.58	0.89	2.31	1.30
2	M	189.8	1.44	0.76	6.80	3.58	1.73	0.91	2.64	1.39
3	M	175.4	1.54	0.31	6.15	3.50	1.58	0.90	1.46	0.83
4	M	188.6	1.99	1.05	6.96	3.69	1.55	0.82	2.19	1.16
5	M	191.2	1.54	0.80	7.74	4.05	1.89	0.98	2.57	1.34
Mean		184.46	1.58	0.74	6.78	3.67	1.66	0.90	2.23	1.20
± S.D.			±	±	±	±	±	±	±	±
		7.49	0.23	0.27	0.63	0.23	0.15	0.06	0.47	0.23

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

**TABLE - 6.09**  
**ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF CONTROL GROUP OF FEMALE RATS**  
**(VEHICLE-GROUP/NDNU/T OIL ONLY)**

Animal No	Sex	Body Wt. in gms	Lung	Liver	Kidney	Gonads	Adrenal	Heart	Uterus	Spleen	Brain
		Wt. in gms	Wt. in Body Gms	Wt. in Body wt	Wt. in Body gms	Wt. in Body wt	Wt. in Body gms	Wt. in Body wt	Wt. in Body gms	Wt. in Body wt	Wt. in Body gms
1	F	185.3	1.63	0.88	7.00	3.77	1.74	0.94	0.14	0.07	0.08
2	F	194.2	1.60	0.82	7.21	3.71	1.70	0.87	0.10	0.05	0.07
3	F	184.3	1.53	0.65	6.42	3.48	1.81	0.98	0.08	0.04	0.06
4	F	183.5	1.85	1.00	6.75	3.67	1.70	0.92	0.09	0.05	0.05
5	F	181.2	1.46	0.80	5.15	2.84	1.59	0.87	0.07	0.04	0.04
Mean		185.7	1.61	0.83	6.50	3.50	1.70	0.92	0.09	0.05	0.06
±		4.98	±	0.15	0.13	0.81	0.38	0.08	0.05	0.03	0.03
S.D.											

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BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 6.10  
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC COTTON SEED  
GROUP 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 Body wt	Wt. % in Body wt	Wt. % in Body wt	Wt. % in Body wt	Wt. % in Body wt	Wt. % in Body wt	Wt. % in Body wt	Wt. % in Body wt	Wt. % in Body wt	Wt. % in Body wt
1	F	189.6	1.70	0.89	6.99	3.68	1.77	0.93	0.68	0.04	0.03
2	F	174.3	1.73	0.99	6.97	3.99	1.60	0.92	0.08	0.04	0.02
3	F	169.8	1.26	0.74	5.50	3.23	1.47	0.86	0.06	0.03	0.04
4	F	171.3	1.58	0.92	6.16	3.59	1.51	0.88	0.08	0.05	0.03
5	F	170.2	1.59	0.93	6.66	3.91	1.54	0.90	0.09	0.05	0.03
Mean $\pm$		175.04 $\pm$ 8.32	1.57 $\pm$ 0.19	0.89 $\pm$ 0.09	6.46 $\pm$ 0.63	3.68 $\pm$ 0.30	1.58 $\pm$ 0.11	0.90 $\pm$ 0.03	0.08 $\pm$ 0.01	0.04 $\pm$ 0.008	0.02 $\pm$ 0.006
S.D.											

SHBIBAM INSTITUTE

## **BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)**

TABLE - 6.11  
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC COTTON SEED  
GROUP 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 Body gms									
1	F	180.2	1.71	0.95	4.12	2.28	1.72	0.95	0.12	0.07	0.04
2	F	179.5	1.62	0.90	8.14	4.53	1.60	0.89	0.16	0.09	0.07
3	F	190.7	1.59	1.10	8.06	4.23	1.72	0.90	0.12	0.06	0.08
4	F	186.3	1.63	0.87	7.30	3.92	1.74	0.93	0.09	0.05	0.07
5	F	184.5	1.61	0.87	5.50	2.98	1.73	0.93	0.07	0.04	0.07
Mean		184.24	1.63	0.94	6.62	3.58	1.70	0.92	0.11	0.06	0.06
±			±	±	±	±	±	±	±	±	±
S.D.		4.60	0.05	0.09	1.75	0.93	0.05	0.02	0.003	0.002	0.015
									0.008	0.008	0.008
									0.14	0.07	0.07
									0.69	0.05	0.16
									0.11	0.05	0.11
									0.29	0.15	0.15

## SHRI RAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES/AUCUTE ORAL TOXICITY STUDY IN RATS

TABLE - 6.12  
**RELATIVE ORGAN WEIGHT DATA OF BT-COTTON SEED (NATH SEEDS)**  
**GROUP 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 Body gms									
1	F	190.6	1.75	0.92	7.58	3.97	1.85	0.97	0.15	0.08	0.06
2	F	173.2	1.39	0.91	6.07	3.50	1.69	0.97	0.12	0.07	0.05
3	F	171.6	1.41	0.82	6.21	3.62	1.56	0.90	0.09	0.05	0.05
4	F	186.3	1.63	0.87	6.39	3.43	1.75	0.94	0.08	0.04	0.04
5	F	174.5	1.56	0.89	5.75	3.26	1.56	0.89	0.16	0.09	0.06
Mean		179.24	1.60	0.88	6.40	3.56	1.68	0.93	0.12	0.07	0.05
± S.D.		± 8.60	± 0.12	± 0.04	± 0.70	± 0.25	± 0.12	± 0.04	± 0.03	± 0.02	± 0.008

## SHRI RAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 6.13  
 RELATIVE ORGAN WEIGHT DATA OF BT-COTTON SEED (NATH SEEDS)  
 GROUP 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 Body wt gms	%	Wt. In Body wt gms	%	Wt. In Body wt gms	%	Wt. In Body wt gms	%	Wt. In Body wt gms	%
1	F	171.2	1.48	0.86	6.72	3.92	1.65	0.96	0.16	0.09	0.13
2	F	180.6	1.37	0.76	5.61	3.10	1.53	0.85	0.09	0.05	0.02
3	F	179.8	1.34	0.74	6.04	3.36	1.84	1.02	0.08	0.05	0.03
4	F	185.4	1.20	0.65	5.88	3.17	1.84	0.99	0.05	0.03	0.05
5	F	190.3	1.97	1.03	7.17	3.76	1.53	0.80	0.15	0.08	0.14
Mean		181.46	1.47	0.80	6.28	3.50	1.68	0.92	0.10	0.06	0.08
±			±	±	±	±	±	±	±	±	±
S.D.		7.11	0.29	0.14	0.64	0.36	0.16	0.09	0.05	0.03	0.04

## SHRI RAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 7-0 INTENSITY OF GROSS PATHOLOGICAL LESIONS  
GROUP-CONTROL (VEHICLE ONLY) IN RATS

ORGAN	MALE RATS					FEMALE RATS				
	1	2	3	4	5	1	2	3	4	5
	ANIMAL NO.									
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									

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## SHRI RAM INSTITUTE

**BT-COTTON SEEDS(NATH SEEDS)**  
**BIO-SAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)**  
**GROUP-NON + TRANSGENIC COTTON SEEDS**  
**DOSE : 2500 mg/kg B.wt**

ORGAN	ANIMAL NO.	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	NAD
Liver	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Heart	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gonads	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Spleen	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Kidney	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Brain	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Adrenal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gastro- Intestinal Tracts	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

SHRI RAM INSTITUTE

## **BIOSAFETY STUDIES (ACUTE ORAL TONICITY STUDY IN RATS)**

## **BT-COTTON SEEDS (NATH SEEDS)**

TABLE - 7.02 INTENSITY OF GROSS PATHOLOGICAL LESIONS  
GROUP-NON - TRANSGENIC COTTON SEEDS  
DOSE : 5000 mg/kg. B.wt.

NAD<sup>+</sup>-No Abnormal Development

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## SHRI RAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 7.03 INTENSITY OF GROSS PATHOLOGICAL LESIONS IN RATS  
GROUP- Bi-COTTON SEEDS (NATH SEEDS)  
DOSE : 2500 mg/kg. B.WT.

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

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NAD- No Abnormal Development

## SHIRAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)

BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 7.04 INTENSITY OF GROSS PATHOLOGICAL LESIONS IN RATS

GROUP- Bi-COTTON SEEDS (NATH SEEDS)

DOSE : 5000 mg/kg. B.wt.

ORGAN	MALE RATS					FEMALE RATS					ANIMAL NO.
	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

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## SHRI RAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 8.00 INTENSITY OF HISTOPATHOLOGICAL LESIONS  
GROUP - CONTROL GROUP (VEHICLE ONLY) IN RATS

ORGAN		MALE RATS					FEMALE RATS					ANIMAL NO.
		1	2	3	4	5	1	2	3	4	5	
Lungs	NAD	NAD	Foci of M.N. cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	
Liver	NAD	NAD	NAD	Slight congestion	NAD	NAD	NAD	NAD	NAD	NAD	NAD	
Heart	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	
Gonads	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	
Spleen	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	
Kidney	Slight congestion	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	
Brain	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	
Adrenal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	
Gastro-Intestinal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	

NAD- No Abnormal Development

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## SHIRIRAM INSTITUTE

BI-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 8.01 INTENSITY OF HISTOPATHOLOGICAL LESIONS OF  
GROUP NON-TRANSGENIC COTTON SEED DOSE : 2500 mg/kg.B.wt.

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

NAD- No Abnormal Development

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## SHRI RAM INSTITUTE

BT-COTTON SEEDS (NATHE SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS  
TABLE - 8.02 INTENSITY OF HISTOPATHOLOGICAL LESIONS OF  
GROUP NON-TRANSGENIC COTTON SEED DOSE : 5000 mg/kg.B.wt.

ORGAN	MALE RATS					FEMALE RATS					
	1	2	3	4	5	1	2	3	4	5	
	Face of M.N.cell										
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	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	

NAD- No Abnormal Development

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## SHIRIRAM INSTITUTE

BT-COTTON SEEDS (NATH SEEDS)  
BIOSAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)

TABLE - 8.03 INTENSITY OF HISTOPATHOLOGICAL LESIONS  
GROUP- BI-COTTON SEEDS (NATH SEEDS)  
DOSE : 2500 mg/kg.B.wt.

ORGAN	MALE RATS					FEMALE RATS				
	1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	NAD	NAD	Foci of M.N.cell	NAD	NAD	NAD	NAD	NAD
Liver	NAD	NAD	NAD	NAD	NAD	NAD	NAD	Slight congestion	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

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**SHRI RAM INSTITUTE**

**BT-COTTON SEEDS (NATH SEEDS)**  
**BIO-SAFETY STUDIES (ACUTE ORAL TOXICITY STUDY IN RATS)**

**TABLE - 8.04 INTENSITY OF HISTOPATHOLOGICAL LESIONS**  
**GROUP- Bt-COTTON SEEDS (NATH SEEDS)**  
**DOSE : 5000 mg/kg.B.wt.**

ORGAN	ANIMAL NO.	MALE RATS					FEMALE RATS				
		1	2	3	4	5	1	2	3	4	5
Lungs	NAD	NAD	Slight congestion	NAD	NAD	Foci of M.N cell	NAD	NAD	NAD	NAD	NAD
Liver	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Heart	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gonads	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Spleen	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Kidney	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Brain	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Adrenal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
Gastro-Intestinal	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD- No Abnormal Development

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