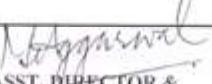


Annexure to Report No.: 000073684 Dt : 22.04.2004		
TOXICOLOGY STUDY REPORT		
PROJECT NO. : TOX-290		
SPONSOR : NATH SEEDS (NEW DELHI), 309 – MEGHDOOT, 94, NEHRU PLACE, NEW DELHI – 110 019.		
SUBJECT : SUBCHRONIC ORAL TOXICITY STUDY IN RATS (90 DAYS ORAL ADMINISTRATION)		
PRODUCT : BT- COTTON SEEDS (NATH SEEDS) ALONG WITH NON-TRANSGENIC COTTONSEEDS		
MATERIAL DESCRIPTION : BROWN COLOURED COTTON SEEDS		
RESULT : Under the conditions of this study, the 90 days repeated oral administration of Bt- cotton seeds (Nath Seeds) at the dose level of 1000 mg/kg B.wt to albino rats did not induce any observable toxic effects, when compared to the non-transgenic group of animals. Hence, No Observable Adverse Effect Level (N.O.A.E.L.) = 1000 mg/kg B.wt.		
Total No. of Pages : 122		
 SCIENTIST PATHOLOGY	 ASST. DIRECTOR & CHIEF, TOXICOLOGY	 Dy. DIRECTOR
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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

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SHRIRAM INSTITUTE**Bi-COTTON SEEDS (NATH SEEDS)
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BI-COTTON SEEDS (NATH SEEDS)
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CONFIDENTIALITY STATEMENT

This report is confidential. No part of this report or any information contained herein may be disclosed to any third party without the prior written authorisation of Nath Seeds (New Delhi).


Asstt. Director &
Chief, Toxicology

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B6-COTTON SEEDS (NATH SEEDS)
SUB CHRONIC ORAL TOXICITY STUDY IN RATS

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. 408), Department of Biotechnology, Ministry of Science and Technology, Govt. of India for non-clinical laboratory studies.

This report provides a true and accurate record of the results obtained.

**Asstt. 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) SUB CHRONIC ORAL TOXICITY STUDY IN RATS

SUMMARY

This study was designed to investigate the toxicological effects of 90 days (5 days / week) repeated oral administration of Bt-cotton seeds (Nath Seeds) and non-transgenic cotton seed to determine, whether any types of effects could be induced, and to serve as a basis for selecting appropriate range of dosage for future studies and for establishing safety criteria for human consumption.

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

Randomly five groups of 10 rats of each sex (10 males and 10 females) were made. First group was kept as control which was given only vehicle i.e. groundnut oil only. Second group was given 500 mg/kg B.wt. non-transgenic cottonseeds. Third group was fed with 1000 mg/kg B. wt. of the non-transgenic cotton seed. Similarly the Fourth group was provided with 500 mg/kg B. wt. of Bt-cotton seeds (Nath Seeds) and the fifth group was administered with 1000 mg/kg. of Bt-cotton seeds (Nath Seeds).

Under the conditions of this study, the 90 days repeated oral administration of Bt- cotton seeds (Nath Seeds) at the dose level of 1000 mg/kg B.wt to albino rats did not induce any observable toxic effects, when compared to the non-transgenic group of animals.Hence, **No Observable Adverse Effect Level (N.O.A.E.L) = 1000 mg/kg B.wt.**

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BT-COTTON SEEDS (NATH SEEDS)
SUB CHRONIC ORAL TOXICITY STUDY IN RATS

Introduction

The primary objective of the project as proposed by Nath Seeds (New Delhi), was to develop genetically modified cotton seed. This set of studies was aimed at determining sub-chronic oral toxicity in laboratory animal model.

Studies were carried out with the Bt-cotton seeds (Nath Seeds) and the non-transgenic crushed cotton seed as per the modified OECD guidelines in accordance with the regulatory guidelines for transgenic materials issued by the Department of Biotechnology, Ministry of Science and Technology, Government of India.

The approach taken to determine food and feed safety was to compare for toxicological response of test animals to the transgenic materials [(Bt-cotton seeds (Nath Seeds)] and its non-transgenic counterpart. The results of the studies were used to make a determination of substantial equivalence.

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Bt-COTTON SEEDS (NATH SEEDS) SUB CHRONIC ORAL TOXICITY STUDY IN RATS

OBJECTIVES

To assess the toxicological effects of 90 days oral administration of Bt-cotton seed (Nath Seeds) in comparison to the non-transgenic cotton seed to rats so as to provide information on the possible health hazards likely to arise from repeated exposure over a limited period of time based on OECD / DBT guidelines.

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BI-COTTON SEEDS (NATH SEEDS)
SUB CHRONIC ORAL TOXICITY STUDY IN RATS

EXPERIMENTAL DESIGN

<u>STUDY LABORATORY</u>	Dept. of Toxicology Shriram Institute for Industrial Research 19, University Road, Delhi-110007 (INDIA)
<u>STRAIN AND SPECIES</u>	Wistar (albino rats)
<u>ANIMAL SOURCE</u>	Lab animal facility, SRI, Delhi
<u>SEX</u>	Male & Female
<u>WEIGHT RANGE</u>	80-120 gms
<u>HUSBANDRY</u>	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 provided <i>ad libitum</i> .
<u>ENVIRONMENTAL CONDITIONS</u>	Room temperature : 24 ± 2°C. Relative humidity : 40 - 70 % Air exchange : 15 air changes / hour Lighting condition : 12 hours light / 24 hours
<u>AGE OF ANIMALS</u>	6-8 weeks
<u>ACCLIMATIZATION PERIOD</u>	7 days
<u>DATE OF COMMENCEMENT OF STUDY</u>	29.09.03
<u>DURATION OF STUDY</u>	90 days
<u>DATE OF TERMINATION OF STUDY</u>	27.12.03
<u>NECROPSY DATE</u>	Terminal Sacrifice : 28.12.03

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Bt-COTTON SEEDS (NATH SEEDS)
SUB CHRONIC ORAL TOXICITY STUDY IN RATS

EXPERIMENTAL PROCEDURE :**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 (vehicle) for repeated oral administration.

Fifty healthy adult male and fifty healthy adult female rats were acclimatized for 7 days and 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. The rats were randomized and assigned to 5 groups of 10 male and 10 female rats each and identified by cage tag.

Randomly five groups of 10 male and 10 female rats each were made. The first control group was kept without any cotton seed and was given only the vehicle i.e. groundnut oil. Second group was given 500 mg/kg B. wt. of the non-transgenic cotton seed. Third group was also administered with 1000 mg/kg B.wt. of the non-transgenic cotton seed. Fourth group was provided with 500 mg/kg B.wt. of Bt-cotton seeds (Nath Seeds) and the fifth group was administered with 1000 mg/kg B. wt. of the Bt-cotton seeds (Nath Seeds) respectively.

The rats were observed daily for behaviour, appearance and toxicological signs and symptoms, if any.

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BT-COTTON SEEDS (NATH SEEDS)
SUB CHRONIC ORAL TOXICITY STUDY IN RATS

ANIMAL GROUPS AND DOSAGE LEVEL :

Group	Dose mg/kg B.wt	No. of animals Male +Female
1 Control	0.0	10 +10
2 Non-transgenic	500.0	10 +10
3 Non-transgenic	1000.0	10 +10
4 Bt-cotton seeds	500.0	10 +10
5 Bt-cotton seeds	1000.0	10 +10

OBSERVATIONS :

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

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

Mortalities : If any, subjected to detailed macroscopic examination and tissue samples were preserved for histopathological examination.

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**BI-COTTON SEEDS (NATH SEEDS)
SUB CHRONIC ORAL TOXICITY STUDY IN RATS**

The following clinical laboratory determinations were made in all the animals of each group after termination of the experiment. After these studies, all animals were sacrificed. The organs were weighed and subjected to detailed macroscopic / microscopic examinations.

CLINICAL LABORATORY STUDIES

BLOOD SAMPLING

Food was withdrawn overnight prior to collection of samples. 7-8 ml of blood was withdrawn by cardiac puncture under light nembutal anaesthesia prior to sacrifice.

HAEMATOLOGY

Following haematological estimations were performed on control and treated group of animals using Baker Haematology system 9120[®].

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

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Bt-COTTON SEEDS (NATH SEEDS) SUB CHRONIC ORAL TOXICITY STUDY IN RATS

SERUM BIOCHEMISTRY

Following estimation 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)

URINALYSIS

Was performed using Boehringer Mannheim combur 10 test multistix for Specific gravity, pH, Leucocytes, Nitrite, Protein, Glucose, Ketones, Urobilinogen, Bilirubin, Blood and Sediment Microscopy.

TERMINAL STUDIES

Final Autopsy : After completion of treatment period all animals from each group were killed and subjected to detailed macroscopic examination.

The following organs were weighed :

Heart, kidneys, liver, lungs, spleen, adrenals, testis and Brain.

SHRIRAM INSTITUTE**Bi-COTTON SEEDS (NATH SEEDS)
SUB CHRONIC ORAL TOXICITY STUDY IN RATS**

Histopathology : Microscopic examination of the following tissues from all animals from each group were carried out :

Stomach	Brain
Intestine	Heart
Lungs	Kidneys (both)
Liver	Adrenals (both)
Spleen	Testis (both)

Any other macroscopically abnormal tissue.

BIOSTATISTICAL METHOD USED : Student's T-test

Pathological evaluations

The animals in all groups were given orally all the test products and control product at the same time. The gross pathological findings were observed at the end of the study period. All the animals were examined for any gross pathological changes.

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Bi-COTTON SEEDS (NATH SEEDS)
SUB CHRONIC ORAL TOXICITY STUDY IN RATS

Mortality and toxic signs

There was no mortality observed in all the test groups along with control groups of animals. No toxic signs and symptoms were noticed in all the three dose groups and control of groups of animals.

Mean body weights

No significant differences were observed in the body weight gain / loss (Appendix -1) pattern in all the test groups as compared to control group of animals.

Feed consumption

Feed consumption of all the test as well as control groups of animals was almost similar and it is presented in Appendix-2

Haematological evaluations

No significant changes were noted among all the test groups and control group of animals with respect to haematological findings (Appendix-3) as all the parameters fall within the accepted limits of normal variations for albino rats.

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Bt-COTTON SEEDS (NATH SEEDS)
SUB CHRONIC ORAL TOXICITY STUDY IN RATS

Clinical Biochemistry evaluations

Serum Biochemistry evaluations (Appendix-4) disclosed no significant differences in all the tests as well as the control groups of animals, as all the parameters fall within the accepted limits of normal variations.

Urinalysis

Urinalysis was performed with Boehringer Mannheim combur 10 strips and sediment microscopy did not reveal any difference in test and control groups of animals. The result of urine analysis for test animals were generally comparable to their control group of animals. (Appendix-5)

Organ Weight

Absolute organ weights and their ratios (relative organ weights) with their respective body weights are shown in appendix-6. Since there are no significant changes in the organ weights of the test animals, when compared with organ weights of control group animals. The compound was failing to suggest any specific target organ to the test substance (Bt-cotton seeds as well as non-transgenic) along with control group of animals (provided with vehicle i.e. groundnut oil only).

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BI-COTTON SEEDS (NATH SEEDS)
SUB CHRONIC ORAL TOXICITY STUDY IN RATS

Necropsy examinations

Necropsy examination of rats at necropsy did not reveal (Appendix-7) any significant changes in any group of animals provided with vehicle i.e. groundnut oil only, non-transgenic cotton seed (500 & 1000 mg/kg B.wt) and Bt-cotton seed (500 & 1000 mg/kg B.wt). These animals were fully comparable to control group of animals.

Histopathological examination

No significant histopathological changes (Appendix-8) were noticed in the animals of low dose group (500 mg/kg B.wt) and high dose group (1000 mg/kg B.wt) when compared to their control group of animals.

However, a few cases of focal infiltration of mononuclear cells were noticed in lungs of control as well as test group of animals. A few animals showed slight fatty changes in the liver. Kidneys appears slightly congested in test as well as control group of animals.

RESULT WITH CONCLUSION

Under the conditions of this study, the 90 days repeated oral administration of Bt. Cotton seed at the dose level of 1000 mg/kg B.wt to albino rats did not induce any observable toxic effects, when compared to non-transgenic cotton seed group of animals.

Hence, No Observable Adverse Effect Level (N.O.A.E.L.) = 1000 mg/kg.B.wt .

APPENDIX -1

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TOX-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.1
MEAN PERCENTILE WEEKLY BODY WEIGHT DATA OF
MALE RATS 90 DAYS ORAL STUDY

Week	0	1	2	3	4	5	6	7	8	9	10	11	12	13 Terminal Kill
Control (Given groundnut oil only)	110.42	121.71	143.31	158.01	167.59	177.01	185.87	196.68	206.73	216.26	224.97	233.22	240.19	
Non transgenic cotton seeds 500 mg/kg	109.58	121.40	139.49	151.40	162.95	174.66	185.41	196.68	208.84	220.59	232.23	241.54	249.62	
Non transgenic cotton seeds 1000 mg/kg	112.76	123.95	136.80	148.17	159.93	180.92	183.80	195.26	208.37	219.79	230.94	242.05	252.04	
Hi-cotton seeds (Nath seeds) 500 mg/kg	109.59	120.19	152.11	143.75	154.78	166.13	176.44	187.56	198.18	209.75	220.63	230.52	238.61	
Hi-cotton seeds (Nath seeds) 1000 mg/kg	111.24	124.58	137.89	150.28	162.81	174.83	186.99	198.63	212.04	224.10	237.00	248.99	259.73	

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TOX-290
BT-COTTON SEEDS (NATHE SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.2
MEAN PERCENTILE WEEKLY BODY WEIGHT DATA OF FEMALE RATS
90 DAYS ORAL STUDY

Week	0	1	2	3	4	5	6	7	8	9	10	11	12	13	Terminal Kill
Control (Given groundnut oil only)	100	107.59	117.55	132.10	142.54	149.11	155.50	162.38	171.36	179.07	187.16	195.84	203.84	213.05	
Non transgenic cotton seeds 500 mg/kg	100	105.70	113.91	123.66	131.58	140.36	149.60	158.48	166.47	175.26	183.05	191.14	198.45	206.22	
Non transgenic cotton seeds 1000 mg/kg	100	109.21	119.92	127.51	128.00	136.00	147.89	155.15	162.43	168.99	176.00	183.00	190.18	196.15	
Bi-cotton seeds (Nath seeds) 500 mg/kg	100	107.07	113.38	119.53	126.00	132.00	138.42	144.59	154.71	164.16	173.42	181.47	188.64	195.42	
Bi-cotton seeds (Nath seeds) 1000 mg/kg	100	107.64	117.01	124.49	132.31	140.55	148.37	156.15	163.37	172.09	181.07	189.78	196.61	200.69	

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TOX-290
HT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - I.3
AVERAGE WEEKLY BODY WEIGHT DATA (in gms) OF MALE RATS 90 DAYS STUDY

Week	0	1	2	3	4	5	6	7	8	9	10	11	12	13 Terminal Kill
Control (Given groundnut oil only)	117.46 ± 8.85	129.71 ± 12.41	142.96 ± 13.13	168.34 ± 21.24	185.60 ± 26.58	196.86 ± 25.43	207.92 ± 24.40	218.35 ± 25.08	231.02 ± 23.06	242.83 ± 25.62	254.02 ± 26.51	264.25 ± 28.65	273.94 ± 29.62	282.13 ± 30.91
Non transgenic cotton seeds 500 mg/kg	122.65 ± 6.95	134.41 ± 6.92	148.90 ± 5.61	171.09 ± 17.05	185.70 ± 16.75	199.87 ± 15.85	214.23 ± 15.58	227.41 ± 15.36	241.24 ± 15.50	256.14 ± 15.46	270.56 ± 15.04	284.83 ± 16.97	296.25 ± 17.91	306.17 ± 19.59
Non transgenic cotton seeds 1000 mg/kg	116.15 ± 6.23	130.21 ± 7.46	143.97 ± 9.07	158.90 ± 10.01	172.16 ± 10.94	185.76 ± 11.91	210.14 ± 13.71	213.49 ± 13.71	226.80 ± 13.38	242.03 ± 21.34	245.29 ± 21.37	268.24 ± 24.22	281.15 ± 24.91	292.74 ± 29.54
HT-cotton seeds (Nath seeds) 500 mg/kg	114.22 ± 4.67	125.18 ± 5.44	137.29 ± 6.45	150.90 ± 9.00	164.19 ± 11.47	176.80 ± 13.42	189.76 ± 14.91	201.53 ± 17.06	214.25 ± 20.12	226.36 ± 22.96	239.58 ± 24.39	252.01 ± 24.22	263.30 ± 24.91	272.54 ± 29.54
HT-cotton seeds (Nath seeds) 1000 mg/kg	113.54 ± 9.24	126.30 ± 10.31	141.45 ± 10.84	156.57 ± 11.32	170.63 ± 10.86	184.86 ± 12.24	198.50 ± 14.04	212.31 ± 15.75	225.76 ± 15.76	240.76 ± 17.33	254.45 ± 17.89	269.10 ± 19.29	282.71 ± 21.86	294.90 ± 23.66

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TOX-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.4
AVERAGE WEEKLY BODY WEIGHT DATA (in gms) OF FEMALE RATS 90 DAYS STUDY

Week	0	1	2	3	4	5	6	7	8	9	10	11	12	13 Terminal Kill
Control (Coconut groundnut oil only)	115.51 \pm 8.06	124.28 \pm 8.11	135.78 \pm 9.08	152.60 \pm 12.29	164.64 \pm 11.19	172.22 \pm 10.02	179.62 \pm 9.97	187.57 \pm 8.66	197.94 \pm 8.57	206.85 \pm 10.95	216.19 \pm 11.64	226.22 \pm 11.64	235.46 \pm 13.85	246.10 \pm 16.42
Non transgenic cotton seeds 500 mg/kg	110.83 \pm 4.03	117.15 \pm 4.78	126.25 \pm 4.72	137.06 \pm 5.32	145.83 \pm 5.04	155.56 \pm 6.04	165.81 \pm 7.06	175.63 \pm 7.67	184.50 \pm 7.30	194.25 \pm 7.96	202.85 \pm 10.67	211.95 \pm 11.44	219.95 \pm 13.47	228.56 \pm 15.85
Non transgenic cotton seeds 1000 mg/kg	121.98 \pm 6.77	123.22 \pm 6.12	146.28 \pm 6.61	155.54 \pm 7.13	165.44 \pm 7.80	172.69 \pm 8.67	180.29 \pm 8.53	189.26 \pm 12.97	198.14 \pm 13.45	206.14 \pm 14.80	214.48 \pm 17.34	222.95 \pm 18.92	231.98 \pm 19.92	239.26 \pm 20.72
Bt-cotton seeds (Bt- seeds) 500 mg/kg	117.67 \pm 4.64	125.99 \pm 4.55	133.30 \pm 3.96	140.66 \pm 4.21	148.27 \pm 4.60	155.35 \pm 4.59	162.88 \pm 3.84	170.14 \pm 4.96	182.05 \pm 6.19	193.17 \pm 6.90	204.07 \pm 8.70	213.54 \pm 11.07	221.98 \pm 11.97	230.00 \pm 14.26
Bt-cotton seeds (Nath seeds) 1000 mg/kg	109.77 \pm 5.31	118.16 \pm 4.57	128.45 \pm 4.12	136.66 \pm 4.62	145.24 \pm 5.30	154.28 \pm 4.97	162.87 \pm 5.20	171.41 \pm 5.83	179.34 \pm 5.59	188.91 \pm 7.24	198.76 \pm 8.59	209.43 \pm 11.70	215.82 \pm 13.43	220.30 \pm 13.45

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TOX-290
BT- COTTON SEEDS (NATIVE SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.5
WEEKLY BODY WEIGHT DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : CONTROL (Vehicle-Groundnut oil only)

Anim- al No.	Sex	Body Weights on												
		0 Week	1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	12 th Week Terminal kill
1	M	120.3	138.5	143.1	160.0	170.2	181.7	190.8	196.3	203.2	212.3	224.4	232.5	243.9
2	M	111.2	120.7	134.3	150.2	167.1	179.8	196.2	212.8	231.6	247.8	260.3	273.7	285.6
3	M	128.7	140.6	158.9	211.0	232.7	239.6	246.7	253.9	260.2	267.4	273.5	278.3	280.5
4	M	115.7	132.7	150.2	167.3	180.3	200.6	214.9	230.9	245.8	260.2	275.9	289.5	283.6
5	M	128.7	141.2	158.0	169.6	180.3	188.4	195.6	201.3	213.8	220.4	225.9	231.5	300.2
6	M	124.5	138.5	153.1	197.8	228.1	240.2	252.3	266.1	280.3	292.8	304.2	317.8	247.6
7	M	112.2	122.4	131.6	150.6	169.2	180.3	196.4	210.5	226.7	241.3	255.2	267.3	299.1
8	M	109.5	115.6	123.9	173.4	200.1	208.1	215.6	221.4	232.6	245.9	260.6	273.8	286.8
9	M	124.9	138.2	150.6	167.8	175.9	183.6	190.1	198.3	209.1	219.6	225.1	230.5	302.1
10	M	105.9	112.7	125.8	145.7	152.0	166.3	180.6	192.1	206.9	220.6	235.4	247.6	241.6
Mean		117.46	129.71	142.96	168.34	185.60	196.86	207.92	218.53	231.02	242.83	254.02	264.25	282.13
S.D		8.85	12.41	13.13	21.24	26.58	25.43	24.40	25.08	25.06	25.62	26.51	28.65	30.91

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.6
WEEKLY BODY WEIGHT DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : CONTROL (Vehicle-Groundnut oil only)

Animal No.	Sex	Body Weights on										13 th Week Terminal kill			
		0 Week	1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	12 th Week	13 th Week Terminal kill
1	F	1008	108.7	119.9	130.6	145.8	158.7	163.8	175.2	190.7	200.4	215.7	233.6	242.7	254.0
2	F	111.6	122.1	134.3	157.8	172.9	182.6	190.2	198.3	205.8	212.6	219.2	229.1	233.6	242.0
3	F	113.2	122.6	135.9	150.4	161.7	171.9	178.6	185.3	192.8	202.9	210.7	218.7	22.5	226.0
4	F	118.2	125.8	138.8	157.7	167.6	173.1	177.3	183.6	190.5	195.8	201.5	209.4	218.6	225.0
5	F	121.8	128.7	132.7	145.1	158.7	164.9	175.3	182.2	195.8	206.7	217.6	230.5	245.7	256.0
6	F	103.5	113.7	122.8	136.1	148.3	155.3	154.7	176.7	190.6	198.6	210.7	227.3	245.9	264.0
7	F	120.9	129.1	139.4	167.3	176.9	181.5	185.7	191.3	197.6	204.5	210.3	216.7	223.2	249.0
8	F	118.9	124.7	140.2	153.2	165.9	174.9	186.7	195.8	215.1	228.7	242.1	250.6	262.3	271.0
9	F	123.8	165.6	150.2	167.3	179.5	185.5	193.7	200.1	207.4	215.7	223.6	230.1	236.2	249.0
10	F	122.4	131.8	143.6	160.2	169.5	173.8	180.3	187.2	193.1	202.6	210.5	216.2	223.9	225.0
Mean		115.51	124.28	135.78	152.6	164.64	172.22	179.62	187.57	197.94	206.85	216.19	226.22	235.46	246.1
S.D		8.06	8.11	9.08	12.29	11.19	10.02	9.97	8.66	8.57	9.77	10.95	11.64	13.85	16.42

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TOX-290
BT-COTTON SEEDS (NAT SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.7
WEEKLY BODY WEIGHT DATA (in gms) OF MALE RATS
DURATION : 90 DAYS
GROUP : NON TRANSGENIC COTTON SEEDS (500 mg/ kg.b.wt)

Anim- al No.	Sex	Body Weights on										13 th Week Terminal kill			
		0 Week	1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	12 th Week	13 th Week Terminal kill
1	M	121.8	135.2	151.3	168.7	180.3	200.6	223.1	239.6	254.2	270.5	286.3	300.2	312.6	323.0
2	M	116.9	128.7	145.9	162.3	180.5	200.3	215.6	231.5	250.6	269.8	285.4	304.2	320.6	332.3
3	M	122.8	131.7	146.2	160.3	171.5	183.2	193.6	210.7	221.8	236.2	250.8	261.5	270.3	278.6
4	M	125.8	140.6	154.7	208.7	219.9	226.7	233.7	240.7	247.1	255.6	265.3	272.1	280.8	286.1
5	M	122.9	140.7	153.8	184.8	200.7	214.6	230.3	247.1	262.3	279.1	292.2	307.1	315.0	328.3
6	M	105.8	118.1	135.4	150.3	164.9	180.1	195.3	204.4	220.1	235.8	251.2	265.4	280.7	292.1
7	M	129.8	136.7	148.8	162.3	175.8	186.7	200.7	214.1	230.2	243.8	260.7	271.4	290.7	301.6
8	M	127.6	140.3	151.3	185.4	202.6	219.8	234.6	245.1	258.9	270.2	282.9	301.7	315.2	326.7
9	M	127.6	136.8	148.7	162.8	180.3	193.6	207.1	220.3	234.1	250.2	265.3	280.1	286.3	294.3
10	M	125.5	135.2	152.9	165.3	180.4	193.1	208.3	220.6	233.1	250.2	265.1	278.6	290.3	298.7
Mean		122.65	134.41	148.90	171.09	185.70	199.87	214.23	227.41	241.24	256.14	270.52	284.83	296.25	306.17
S.D		6.95	6.92	5.61	17.05	16.75	15.85	15.58	15.36	15.30	15.46	15.04	16.97	17.91	19.59

n = n.s. ->

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TOX-290
BT-COTTON SEEDS (NATHE SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.8
WEEKLY BODY WEIGHT DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : NON TRANSGENIC COTTON SEEDS (500 mg/kg.b.wt.)

Anim- al No.	Sex	Body Weights on											13 th Week Terminal kill		
		0 Week	1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	12 th Week	13 th Week Terminal kill
1	F	108.2	115.2	123.9	135.9	143.6	156.7	166.8	175.7	183.3	195.6	203.7	215.6	222.8	230.3
2	F	118.2	126.1	135.2	148.3	157.8	169.8	178.2	189.1	197.3	205.8	212.7	220.5	227.6	231.3
3	F	114.7	121.9	130.8	140.1	149.6	155.4	171.3	182.3	189.1	197.3	205.1	213.2	220.8	239.3
4	F	108.2	114.1	122.9	135.1	143.9	153.6	170.9	181.9	190.2	201.4	210.4	218.3	232.7	244.4
5	F	110.9	115.3	128.2	137.6	145.7	153.9	165.3	170.2	175.9	180.6	184.3	190.6	195.2	198.8
6	F	106.9	113.1	122.8	138.9	145.1	152.3	160.2	170.4	179.6	188.6	195.6	208.7	217.4	227.9
7	F	109.3	115.6	124.7	132.7	140.8	148.9	152.7	163.2	174.6	190.7	202.8	214.3	225.1	234.5
8	F	107.3	114.2	123.2	134.1	145.7	157.8	168.1	180.2	191.4	202.1	220.7	230.1	240.4	250.6
9	F	116.2	123.4	130.6	139.6	146.3	158.6	163.8	171.5	180.5	185.2	190.6	196.2	202.1	208.4
10	F	108.4	112.6	120.2	128.3	139.8	148.6	160.8	171.8	183.1	195.2	202.6	210.9	215.4	220.1
Mean		110.83	117.15	126.25	137.06	145.83	155.56	165.81	175.60	184.50	194.25	202.85	211.84	219.95	228.56
S.D		± 4.05	± 4.78	± 4.72	± 5.32	± 5.04	± 6.04	± 7.06	± 7.67	± 7.30	± 7.96	± 10.67	± 11.44	± 13.47	± 15.85

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TOX-290
 BT- COTTON SEEDS (NATH SEEDS)
 SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -1.9
WEEKLY BODY WEIGHT DATA (in gms) OF MALE RATS
DURATION : 90 DAYS
GROUP : NON TRANSGENIC COTTON SEEDS (1000 mg/ kg.b.wt.)

Anim- al No.	Sex	0 Week	Body Weights on										13 th Week Terminal kill		
			1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	12 th Week	
1	M	113.4	130.6	145.6	161.3	173.1	185.2	198.1	210.2	225.4	241.6	257.3	272.3	285.1	292.7
2	M	122.4	140.1	158.2	173.1	187.3	204.1	225.7	248.6	262.4	280.5	293.6	310.1	325.7	352.9
3	M	110.2	126.1	141.3	158.4	173.2	190.4	209.2	223.1	240.3	260.1	273.2	288.7	302.1	318.9
4	M	109.8	120.6	132.7	145.6	156.3	170.2	181.5	195.4	208.6	218.7	230.6	242.3	256.7	267.1
5	M	120.4	131.9	142.7	154.8	172.5	187.6	200.3	212.6	225.9	240.1	257.8	270.5	286.3	298.3
6	M	105.8	117.8	128.3	139.6	150.4	161.7	173.8	185.4	197.2	210.6	222.4	235.6	248.3	259.6
7	M	124.4	140.2	153.6	165.8	173.7	185.4	196.8	207.3	216.2	230.1	243.6	251.9	262.7	269.3
8	M	115.1	127.3	140.2	166.3	180.4	193.6	210.8	222.4	238.3	250.9	262.3	275.4	287.6	295.4
9	M	121.4	136.7	150.2	163.9	175.8	188.6	206.3	209.4	218.6	227.6	238.3	245.1	255.6	262.7
10	M	118.6	130.8	146.9	160.2	178.3	190.8	208.9	220.5	235.1	260.1	279.8	290.5	301.4	310.3
	Mean	109.51	116.51	130.21	143.97	158.90	172.16	185.76	210.14	213.49	226.80	242.03	255.29	268.24	281.15

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TOX-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.10
WEEKLY BODY WEIGHT DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : NON TRANSGENIC COTTON SEEDS (1000 mg/ kg.b.wt.)

Anim- al No.	Sex	0 Week	Body Weights on										13 th Week Terminal kill		
			1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	12 th Week	
1	F	110.3	122.4	137.1	145.9	155.2	160.1	163.9	175.8	180.6	184.9	190.2	196.7	203.6	209.6
2	F	120.4	133.6	147.2	153.7	163.7	169.2	177.6	186.2	195.6	203.7	212.4	220.4	231.6	244.8
3	F	125.7	136.1	150.7	158.3	165.2	175.8	186.7	200.7	210.2	222.3	235.1	250.7	263.8	274.6
4	F	115.1	126.7	139.6	150.1	162.2	168.3	177.1	185.2	192.3	201.6	210.6	218.3	227.3	229.1
5	F	125.2	135.6	147.2	155.9	167.3	176.1	182.6	190.6	198.1	208.6	217.3	225.8	231.6	235.0
6	F	120.3	130.0	144.1	153.6	163.2	168.2	177.3	185.9	194.5	200.5	209.9	218.7	227.3	237.0
7	F	125.8	138.6	149.6	160.2	170.3	178.2	186.1	193.7	199.9	205.9	210.7	215.37	220.3	224.8
8	F	119.3	130.1	140.7	149.3	157.2	165.7	172.8	180.4	186.3	192.4	200.5	205.6	213.7	218.3
9	F	135.3	143.7	160.3	170.6	180.3	187.5	195.6	203.6	223.8	231.6	240.8	251.6	260.8	266.6
10	F	122.4	135.4	146.3	157.8	169.8	176.9	183.7	190.5	200.1	209.9	217.3	226.4	239.8	252.8
Mean		121.98	133.22	146.28	155.54	165.44	172.60	180.29	189.26	198.14	206.14	214.48	222.95	231.98	239.26
S.D		6.77	6.12	6.61	6.91	7.13	7.80	8.67	8.53	12.07	13.45	14.80	17.34	18.92	20.72

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TOX-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.11
WEEKLY BODY WEIGHT DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : Bi-COTTON SEEDS (NATH SEEDS) (500 mg/kg.b.wt.)

Anim- al No.	Sex	Body Weights on												13 th Week Terminal kill
		0 Week	1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	
1	M	109.2	115.4	122.8	130.7	138.7	147.6	159.6	167.8	175.4	182.1	189.8	196.4	208.7
2	M	111.3	123.6	140.2	152.6	164.2	176.7	190.4	203.7	220.4	233.6	247.1	260.6	270.2
3	M	108.2	120.3	133.7	145.9	162.8	180.8	200.3	215.6	230.9	248.7	261.3	276.7	290.8
4	M	108.5	118.9	130.6	144.2	160.7	171.2	180.3	189.8	198.6	207.8	229.6	240.8	248.6
5	M	120.4	130.6	140.9	162.3	185.4	200.3	215.6	230.6	248.7	261.2	278.6	290.5	303.6
6	M	115.4	126.8	140.1	153.7	165.8	177.2	190.3	201.5	216.1	230.8	243.7	255.1	269.3
7	M	120.2	130.8	143.6	155.7	163.8	170.7	179.6	187.4	196.7	203.6	215.9	229.7	240.4
8	M	114.5	126.7	138.2	150.3	161.6	177.3	190.7	204.7	218.6	230.8	243.6	258.9	270.7
9	M	116.9	127.8	140.2	159.8	171.2	188.1	200.7	210.6	221.8	237.2	250.4	267.8	280.6
10	M	117.6	130.9	142.6	153.8	167.7	178.3	190.1	203.6	215.1	227.8	235.8	243.6	258.7
Mean		114.22	125.18	137.29	150.90	164.19	176.80	189.76	201.53	214.23	226.36	239.58	252.01	263.30
S.D		± 4.67	± 5.44	± 6.45	± 9.00	± 11.47	± 13.42	± 14.91	± 17.06	± 20.12	± 22.96	± 24.39	± 26.37	± 27.31

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TOX-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.12
WEEKLY BODY WEIGHT DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : Bt-COTTON SEEDS (NATH SEEDS) (500 mg/ kg.b.wt.)

Anim- al No.	Sex	0 Week	Body Weights on										Terminal kill	
			1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week		
1	F	121.4	130.2	138.3	145.6	153.2	160.1	166.7	173.2	189.7	203.6	218.7	233.2	242.3
2	F	115.6	126.7	132.6	140.2	148.7	155.3	163.1	171.5	185.9	198.3	210.6	224.9	237.6
3	F	113.0	120.7	127.9	135.1	142.2	150.1	157.9	165.3	178.8	192.3	209.4	217.6	226.3
4	F	115.9	125.7	131.5	140.4	150.6	156.2	163.1	170.2	180.4	190.3	198.7	205.6	217.9
5	F	126.0	133.7	139.8	146.7	152.7	160.3	165.0	178.8	190.5	203.7	215.6	225.9	232.8
6	F	117.3	125.6	132.8	140.3	149.3	156.9	163.7	169.8	177.8	188.6	199.7	208.3	240.7
7	F	113.0	120.8	129.6	136.8	142.8	150.3	159.6	168.1	180.1	188.6	195.4	200.7	214.7
8	F	123.2	130.6	137.2	145.4	153.1	160.8	169.3	174.6	186.9	194.8	200.4	208.9	219.8
9	F	112.4	120.3	129.8	135.9	141.2	148.1	156.9	160.8	170.3	182.6	195.8	204.5	212.4
10	F	118.9	125.6	133.5	140.2	148.9	155.2	163.4	169.1	180.1	188.9	196.4	205.8	217.6
Mean		117.67	124.99	133.30	140.66	148.27	155.53	162.88	170.14	182.05	193.17	204.07	213.54	221.98
S.D		4.64	4.55	3.96	4.11	4.60	4.54	3.84	4.96	6.19	6.90	8.70	11.07	11.97
		[±]	[±]	[±]	[±]	[±]	[±]	[±]	[±]	[±]	[±]	[±]	[±]	[±]

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.13
WEEKLY BODY WEIGHT DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : BI-COTTON SEEDS (NATH SEEDS) (1000 mg/kg.b.wt.)

Animal No.	Sex	Body Weights on												Terminal kill	
		0 Week	1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	12 th Week	
1	M	106.7	117.8	130.2	142.6	156.7	170.1	180.2	190.3	204.8	217.6	231.5	246.8	260.7	272.0
2	M	109.7	115.7	130.7	146.2	160.7	176.3	191.5	207.8	220.1	238.6	253.8	270.5	288.6	308.0
3	M	105.0	120.7	138.6	152.5	167.3	178.2	192.1	205.6	220.4	238.7	250.1	266.3	285.4	305.0
4	M	106.8	120.9	138.1	155.6	170.2	182.6	198.6	210.8	223.8	240.1	254.3	266.8	276.8	285.0
5	M	116.2	131.2	145.6	160.7	173.2	182.7	190.3	202.8	215.9	226.1	237.9	250.4	260.3	273.0
6	M	118.3	132.7	150.1	168.4	180.2	196.3	211.5	225.1	240.6	256.3	270.4	288.6	300.9	315.0
7	M	109.3	121.9	135.7	150.2	166.8	182.4	196.8	210.6	221.7	235.6	248.7	255.2	262.6	270.0
8	M	118.0	131.2	145.9	160.3	178.6	190.6	202.8	218.6	230.1	243.7	260.1	276.8	290.6	303.0
9	M	136.0	150.2	165.8	180.3	192.4	212.6	230.6	248.3	262.1	280.6	294.6	310.9	330.6	342.0
10	M	109.4	120.2	133.8	148.9	160.2	176.8	190.6	203.2	218.1	230.6	243.1	258.7	270.6	276.0
Mean	\pm	113.54	126.3	141.45	156.57	170.63	184.86	198.50	212.31	225.76	240.76	254.45	269.10	282.71	294.90
S.D		9.24	10.31	10.84	11.32	10.86	12.24	14.04	15.73	15.76	13.33	13.89	19.29	21.86	23.66

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.14
WEEKLY BODY WEIGHT DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : BT-COTTON SEEDS (NATH SEEDS) (1000 mg/kg.b.wt.)

Anim -al No.	Sex	0 Week	1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	12 th Week	13 th Week	Terminal kill
1	F	105.9	112.7	130.2	140.2	147.6	155.7	164.3	175.9	183.6	195.6	213.8	230.7	234.6	238.3	
2	F	107.2	118.6	127.6	138.3	146.1	157.2	166.2	174.5	182.9	190.8	201.7	220.1	225.7	231.5	
3	F	105.4	114.1	128.3	136.1	143.2	151.4	160.1	170.2	179.8	189.6	200.3	214.6	230.6	234.0	
4	F	106.8	115.7	126.2	134.8	144.2	153.2	160.7	168.9	176.2	185.4	187.3	190.3	193.1	197.7	
5	F	105.4	114.3	124.9	131.5	140.3	149.6	157.2	165.1	173.4	178.6	190.2	201.4	207.6	210.3	
6	F	107.1	116.7	125.6	132.6	140.1	148.2	156.7	163.4	171.5	180.3	191.4	200.8	205.7	210.8	
7	F	120.2	125.8	131.2	140.3	149.8	157.3	166.1	175.3	182.6	190.5	200.8	212.6	225.7	229.9	
8	F	110.2	117.8	125.7	132.1	140.3	150.7	159.8	168.1	176.8	189.3	198.6	207.6	207.6	211.3	
9	F	111.6	120.3	126.2	134.5	143.6	154.2	163.4	169.9	176.4	185.4	193.2	200.4	206.9	211.8	
10	F	117.9	125.6	138.6	146.2	157.2	165.3	174.2	183.1	190.2	203.6	210.3	215.8	220.7	227.1	
Mean		109.77	118.16	128.45	136.66	145.24	154.28	162.87	171.41	179.34	188.91	198.76	209.43	215.82	220.30	
S.D		5.31	4.57	4.12	4.62	5.30	4.97	5.20	5.83	5.59	7.24	8.59	11.70	13.43	13.45	

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -1.19
MEAN BODY WEIGHT DATA GAIN DATA OF MALE RATS 90 DAYS ORAL STUDY

Week	1	2	3	4	5	6	7	8	9	10	11	12	13	Terminal Kill
Control (given GROUNDNUT oil only)	12.53 ± 3.74	24.79 ± 6.02	51.18 ± 16.21	67.43 ± 22.88	73.06 ± 22.71	89.76 ± 22.05	94.92 ± 22.77	100.90 ± 24.41	124.67 ± 25.70	135.86 ± 27.67	146.09 ± 30.50	150.94 ± 30.85	155.28 ± 31.80	
Non transgenic cotton seeds 500 mg/kg	11.75 ± 3.20	26.84 ± 4.09	37.93 ± 15.59	46.50 ± 19.40	54.32 ± 22.67	67.00 ± 26.70	72.32 ± 28.51	78.38 ± 31.58	84.73 ± 35.16	90.98 ± 38.64	97.39 ± 42.64	103.74 ± 46.25	110.57 ± 50.03	
Non transgenic cotton seeds 1000 mg/kg	14.06 ± 2.56	28.58 ± 4.77	42.75 ± 6.60	55.96 ± 7.62	62.78 ± 10.66	73.18 ± 12.30	79.22 ± 24.49	85.51 ± 26.34	92.23 ± 29.43	98.94 ± 32.67	105.58 ± 36.13	112.18 ± 39.60	118.62 ± 43.13	
Bt-cotton seeds (Nath seeds) 500 mg/kg	10.96 ± 1.94	17.01 ± 6.92	23.57 ± 11.46	49.97 ± 9.11	56.28 ± 12.05	62.30 ± 15.32	68.15 ± 18.57	73.23 ± 23.46	79.40 ± 27.15	85.70 ± 30.94	91.97 ± 34.68	101.24 ± 38.87	106.47 ± 41.41	
Bt-cotton seeds (Nath seeds)	12.75 ± 1.2	26.91 ± 4.2	42.03 ± 5.6	56.09 ± 7.0	70.32 ± 8.1	83.96 ± 9.7	97.77 ± 11.2	112.22 ± 12.7	127.22 ± 13.9	139.91 ± 15.5	169.17 ± 18.0	180.36 ± 19.2		

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TOX-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.20
MEAN WEEKLY BODY WEIGHT GAIN DATA OF FEMALE RATS 90 DAYS ORAL STUDY

Week	1	2	3	4	5	6	7	8	9	10	11	12	13 Terminal Kill
Control (given GROUNDNUT oil only)	8.70 \pm 1.97	20.16 \pm 3.82	36.93 \pm 7.81	49.13 \pm 6.89	57.01 \pm 7.36	64.20 \pm 7.02	69.70 \pm 7.95	82.43 \pm 9.18	86.88 \pm 10.48	92.82 \pm 14.77	101.25 \pm 19.04	104.68 \pm 20.52	108.95 \pm 23.80
Non transgenic cotton seeds 500 mg/kg	6.32 \pm 1.21	10.87 \pm 4.86	26.23 \pm 3.46	35.00 \pm 3.04	44.73 \pm 4.30	49.85 \pm 7.34	54.82 \pm 10.09	59.53 \pm 12.46	64.31 \pm 15.18	92.02 \pm 11.80	96.51 \pm 12.93	100.70 \pm 14.70	104.96 \pm 16.93
Non transgenic cotton seeds 1000 mg/kg	11.24 \pm 1.57	17.29 \pm 6.73	22.90 \pm 9.60	28.17 \pm 12.36	32.75 \pm 14.34	37.17 \pm 16.39	43.35 \pm 19.19	46.93 \pm 21.13	50.84 \pm 23.17	54.18 \pm 25.38	58.82 \pm 27.75	62.92 \pm 30.29	66.94 \pm 32.74
Bt-cotton seeds (Nath seeds) 500 mg/kg	8.32 \pm 1.28	15.63 \pm 1.29	22.99 \pm 1.36	30.60 \pm 2.31	37.66 \pm 2.04	45.20 \pm 2.42	52.47 \pm 3.24	64.38 \pm 3.76	75.50 \pm 4.81	86.40 \pm 7.60	95.87 \pm 9.73	104.28 \pm 11.00	112.28 \pm 13.81
Bt-cotton seeds (Nath seeds) 1000 mg/kg	8.39 \pm 1.58	18.68 \pm 3.99	26.89 \pm 4.47	35.47 \pm 4.16	44.51 \pm 4.19	53.10 \pm 4.16	61.63 \pm 4.95	69.57 \pm 5.23	79.42 \pm 6.49	88.99 \pm 8.63	99.66 \pm 12.41	106.05 \pm 13.72	110.50 \pm 13.56

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - I.21
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : CONTROL (VEHICLE-GROUNDNUT OIL ONLY)

Anim No.	Sex	Body Weights on												13 th Week Terminal kill
		1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	12 th Week	
1	M	18.3	22.8	39.7	49.9	61.4	70.5	76.0	82.9	92.0	104.1	111.2	123.6	130.9
2	M	9.5	23.1	39.0	55.9	68.6	85.0	101.6	120.4	136.6	149.1	162.5	174.4	187.9
3	M	11.9	30.2	82.3	104.0	110.9	118.0	125.2	131.5	138.7	144.8	149.6	151.8	154.9
4	M	17.0	34.5	51.6	64.6	84.9	99.2	114.9	130.1	144.5	160.2	173.8	184.5	192.1
5	M	12.5	29.3	40.9	51.6	89.7	66.9	72.6	85.1	91.7	96.9	102.8	111.4	118.9
6	M	14.0	28.6	73.3	101.6	115.7	123.8	141.6	155.8	168.3	179.7	193.3	203.4	213.3
7	M	10.2	19.4	38.4	57.0	68.1	84.2	98.3	114.5	129.1	143.0	155.1	167.2	174.6
8	M	6.1	14.4	63.9	90.6	98.6	106.1	111.1	123.1	136.4	151.1	164.3	180.9	192.6
9	M	13.3	25.7	42.9	51.0	58.7	65.2	73.4	84.2	94.7	100.2	105.6	111.3	116.7
10	M	6.8	19.9	39.8	46.1	60.4	74.7	86.2	101.0	114.7	129.5	141.7	149.4	157.8
Mean		12.53	24.79	51.18	67.43	73.06	89.76	94.92	100.90	124.67	135.86	146.09	150.94	155.28
±		±	±	±	±	±	±	±	±	±	±	±	±	±
S.D.		3.74	6.02	16.21	22.88	22.71	22.05	82.77	24.41	25.70	27.67	30.50	30.85	31.8

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TOX-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.22
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : CONTROL (VEHICLE- GROUNDNUT OIL ONLY)

Anim al No.	Sex	Body Weights on										13 th Week Terminal kill		
		1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week			
1	F	7.9	19.1	29.8	45.0	57.9	63.8	74.4	89.9	99.6	120.7	132.8	141.9	153.2
2	F	10.5	22.7	46.2	61.3	71.0	78.6	86.7	94.2	101.0	109.7	117.5	122.0	130.4
3	F	9.4	22.7	37.2	48.5	58.7	65.4	72.1	79.6	89.7	99.5	105.5	109.3	112.8
4	F	7.6	20.6	39.5	49.4	54.9	59.1	65.4	72.3	77.6	83.3	91.2	100.4	106.8
5	F	6.9	10.9	23.3	36.9	43.1	53.5	60.4	74.0	84.9	106.7	117.3	128.9	134.2
6	F	10.2	19.3	32.6	44.8	51.8	61.2	73.2	87.1	95.1	126.6	142.3	154.2	160.5
7	F	8.2	18.5	46.4	56.0	60.6	64.8	70.44	76.7	83.6	89.4	95.8	102.3	128.1
8	F	5.8	21.1	34.3	47.0	56.0	67.8	76.9	96.2	109.8	123.2	136.3	145.4	192.1
9	F	11.8	26.4	43.55	55.3	61.7	69.9	76.9	83.6	91.9	99.8	106.3	112.4	125.2
10	F	9.4	21.2	37.8	47.1	51.4	57.9	64.8	70.7	80.7	88.1	93.9	101.5	102.6
Mean		8.70	26.16	36.98	49.13	57.01	64.2	69.70	82.43	86.88	92.82	101.25	104.68	108.95
S.D.		± 1.97	± 3.82	± 7.86	± 6.89	± 7.36	± 7.02	± 7.95	± 9.18	± 10.48	± 14.77	± 19.04	± 20.52	± 23.68

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TOX-290
BT-COTTON SEEDS (NATURAL SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.23
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : NON TRANSGENIC COTTON SEEDS (500 mg/kg,B.wt)

Anim -al No.	Sex	Body Weights on										13 ^a Week Terminal kill
		1 ^a Week	2 ^a Week	3 ^a Week	4 ^a Week	5 ^a Week	6 ^a Week	7 ^a Week	8 ^a Week	9 ^a Week	10 ^a Week	
1	M	12.4	29.5	46.9	58.5	78.8	111.3	117.8	132.4	148.7	164.5	178.4
2	M	11.8	29.0	45.4	63.6	83.4	98.7	114.6	133.7	152.9	168.5	187.3
3	M	8.9	29.3	43.4	54.6	66.3	70.8	87.9	99.0	113.4	128.0	138.7
4	M	14.8	28.9	82.9	94.1	100.9	107.8	114.9	121.3	129.8	139.5	146.3
5	M	17.8	30.9	61.9	77.8	91.7	107.4	124.2	139.4	156.2	169.3	184.2
6	M	12.3	29.6	44.5	59.1	74.3	89.5	98.6	114.3	130.0	145.4	159.6
7	M	6.9	19.0	32.5	46.0	56.9	70.9	84.3	129.1	140.4	130.9	147.6
8	M	12.7	23.7	57.8	75.0	92.2	107.0	117.5	131.3	142.6	155.3	174.1
9	M	9.2	21.1	35.2	52.7	66.0	79.5	92.7	106.5	122.6	137.7	152.5
10	M	9.7	27.4	39.8	54.9	67.6	82.8	95.1	107.6	124.7	139.6	153.1
Mean		11.75	26.84	37.93	46.5	54.32	67.00	72.32	78.38	84.73	90.98	97.39
S.D.		3.20	4.09	15.59	19.40	22.67	26.67	28.51	31.58	35.16	38.64	42.64

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BT-COTTON SEEDS(NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.24
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : NON TRANSGENIC COTTON SEEDS (500 mg/kg.B.wt)

Animal No.	Sex	Body Weights on										13 th Week Terminal kill	
		1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	
1	F	7.00	15.7	27.7	35.4	48.5	58.6	67.5	75.1	87.4	95.5	107.4	114.6
2	F	7.9	17.0	30.1	39.6	51.6	60.0	70.9	79.1	87.6	94.5	102.3	109.4
3	F	7.2	16.1	25.4	34.9	40.7	56.6	67.6	70.4	82.6	90.4	98.5	106.1
4	F	5.9	14.7	26.9	35.7	45.4	62.7	71.7	82.0	93.2	102.2	110.1	124.5
5	F	4.4	17.3	26.7	34.8	43.0	54.0	59.3	65.0	69.7	73.4	79.7	84.3
6	F	6.2	15.9	32.0	38.2	145.4	33.3	63.5	72.7	81.7	88.7	101.8	110.5
7	F	6.3	15.4	23.4	31.5	639.6	47.4	53.6	65.3	81.4	93.5	105.0	115.5
8	F	6.9	15.9	26.8	38.4	50.5	60.8	72.9	84.1	94.8	113.4	122.8	133.1
9	F	7.2	14.4	23.4	30.1	42.4	47.6	55.3	64.3	69.0	74.4	80.0	85.9
10	F	4.2	11.8	19.9	31.4	40.2	52.4	65.4	74.7	86.8	94.2	102.4	107.0
Mean		6.32	10.87	26.23	35.00	44.73	49.83	54.82	59.53	64.31	92.02	96.51	100.70
S.D.		± 1.21	± 4.86	± 3.46	± 3.04	± 4.70	± 7.34	± 10.09	± 12.46	± 13.18	± 11.81	± 12.93	± 14.70

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)

SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.25
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : NON TRANSGENIC COTTON SEEDS (1000 mg/kg,B.wt)

Anim -al No.	Sex	Body Weights on												13 th Week Terminal kill
		1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week	11 th Week	12 th Week	
1	M	17.2	32.2	47.9	59.7	71.8	84.7	96.8	112.0	128.2	143.9	158.9	171.7	179.3
2	M	17.7	35.8	50.7	64.9	81.7	101.3	126.2	140.0	158.1	171.2	187.7	203.3	230.5
3	M	15.9	31.1	48.2	63.0	80.2	99.0	112.9	130.1	149.9	163.0	178.3	191.9	208.7
4	M	10.8	22.9	35.8	46.5	60.4	71.7	85.6	98.8	108.9	120.8	132.5	146.5	157.3
5	M	11.5	22.3	34.4	52.1	67.2	79.9	92.2	105.5	119.7	137.4	150.1	165.9	177.9
6	M	12.0	22.5	33.8	44.6	55.9	68.0	79.6	91.4	104.8	116.8	129.8	142.5	153.8
7	M	15.8	29.2	41.4	49.4	61.0	72.4	82.9	91.8	105.7	119.2	127.5	138.3	144.9
8	M	12.2	23.1	31.2	45.3	78.5	95.7	107.3	123.2	135.8	147.2	160.3	172.7	180.3
9	M	15.3	28.8	42.5	54.4	67.2	174.9	88.0	97.2	106.2	116.9	123.7	134.2	141.3
10	M	12.2	28.3	41.6	59.7	72.2	90.3	101.9	116.2	145.5	155.2	171.9	182.8	191.7
Mean		14.06	28.38	42.75	55.96	62.78	73.18	79.22	85.51	92.23	98.94	103.38	112.18	118.62
S.D.		2.56	4.77	6.60	7.62	10.66	24.39	24.59	26.34	29.45	32.67	36.13	39.60	43.13

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TOX-290
BT-COTTON SEEDS(NATI SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.26
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : NON TRANSGENIC COTTON SEEDS (1000 mg/kg.B.wt)

Anim -al No.	Sex	Body Weights on										13 th Week Terminal kill	
		1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week		
1	F	12.1	26.8	35.6	44.9	49.8	58.6	63.5	70.3	74.6	79.9	86.4	93.3
2	F	13.2	26.8	33.3	43.3	48.8	57.2	65.8	75.2	83.3	92.0	100.0	111.2
3	F	10.4	25.0	32.6	49.5	50.1	61.0	75.0	84.5	96.6	109.4	125.0	138.1
4	F	11.6	24.5	35.0	47.1	53.2	62.0	70.1	77.2	86.5	93.5	103.2	112.2
5	F	10.4	22.0	30.7	42.1	50.9	57.4	65.4	72.9	83.4	92.1	100.6	106.4
6	F	9.7	23.8	33.3	42.9	47.9	57.0	65.6	74.2	80.2	89.6	98.4	107.0
7	F	12.8	23.8	34.4	44.5	52.4	60.3	67.9	74.1	80.1	84.9	89.5	94.5
8	F	10.8	21.4	30.0	37.9	46.4	53.5	61.1	67.0	73.1	81.2	86.3	94.4
9	F	8.4	23.0	35.3	45.0	52.2	60.3	68.3	88.5	96.3	103.5	116.3	125.5
10	F	13.0	23.9	35.4	47.4	54.5	61.3	68.1	77.7	87.5	94.9	104.0	117.4
Mean		11.24	22.90	28.17	32.75	37.17	41.35	46.93	50.84	54.81	58.82	62.92	66.94
S.D.		± 1.37	6.73	0.60	12.36	14.34	16.39	19.19	21.17	23.17	25.38	30.29	32.72

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - I.27
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : Bi-COTTON SEEDS (NATH SEEDS) (500 mg/kg,B.wt)

Anim -al No.	Sex	Body Weights on										13 th Week Terminal kill	
		1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week		
1	M	6.20	13.6	21.5	29.5	38.4	50.4	58.6	66.2	72.9	80.6	87.2	99.5
2	M	12.3	28.9	41.3	52.9	65.4	79.1	92.4	109.1	122.3	135.8	149.8	158.9
3	M	12.1	25.5	37.7	54.6	72.6	92.1	107.4	122.7	140.5	153.1	168.5	180.6
4	M	10.4	22.1	35.7	52.2	62.7	71.8	81.3	90.1	99.3	121.1	132.3	140.1
5	M	10.2	20.5	41.9	65.0	79.9	95.2	110.2	128.3	140.8	158.2	170.1	183.2
6	M	11.4	24.7	38.3	50.4	61.8	74.9	86.1	100.7	115.4	128.3	139.7	153.9
7	M	10.6	23.4	33.5	43.6	50.5	59.4	67.2	76.5	83.4	95.7	109.5	120.2
8	M	12.2	23.7	35.8	47.1	62.8	76.2	90.2	104.1	116.3	129.1	144.4	156.2
9	M	10.9	23.3	42.9	54.3	71.2	83.9	93.7	104.9	120.3	133.5	150.9	163.7
10	M	13.3	25.0	36.2	50.1	60.7	72.5	86.0	97.5	110.2	118.2	126.0	132.5
Mean ± S.D.		10.96 ± 1.94	23.57 ± 6.92	49.97 ± 11.46	62.30 ± 12.05	68.15 ± 15.32	73.23 ± 18.57	79.40 ± 23.46	85.70 ± 27.15	91.97 ± 30.94	101.24 ± 34.68	106.47 ± 38.87	108.4 ± 41.41

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.28
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : Bt-COTTON SEEDS (NATH SEEDS) (500 mg/kg,B.wt)

Anim -al No.	Sex	Body Weights on										13% Week Terminal kill		
		1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week			
1	F	8.8	16.9	24.2	31.8	38.7	45.3	51.8	68.3	82.2	98.3	111.8	120.9	128.2
2	F	11.1	17.0	24.6	33.1	39.7	47.5	55.9	70.3	82.7	95.0	109.3	122.0	136.7
3	F	7.7	14.9	22.1	29.2	37.1	44.9	52.3	65.8	79.3	96.4	104.6	113.0	124.8
4	F	9.8	15.6	24.5	34.7	40.3	47.2	54.3	64.5	74.4	82.8	89.7	102.0	115.9
5	F	7.7	13.8	20.7	26.7	34.3	39.0	52.8	64.5	77.7	89.6	99.9	106.8	114.7
6	F	8.3	15.5	23.0	32.0	39.6	46.4	52.8	60.5	71.3	82.4	91.0	97.4	102.5
7	F	7.8	16.6	23.8	29.8	37.3	46.6	55.1	67.1	75.6	82.4	87.7	94.6	99.7
8	F	7.4	14.0	22.2	29.9	37.6	46.1	51.4	63.7	71.6	77.2	85.7	92.4	97.1
9	F	77.9	17.4	23.5	28.8	35.7	44.5	48.4	57.9	70.2	83.4	92.1	100.0	106.5
10	F	6.7	14.6	21.3	30.0	36.3	44.5	50.2	61.2	70.0	77.5	86.9	93.7	98.7
Mean														
\pm														
S.D.		8.32	15.63	22.99	30.60	37.60	45.20	52.47	64.38	75.5	86.40	95.87	104.28	112.28
		\pm	\pm	\pm	\pm									
		1.28	1.29	1.36	2.31	2.04	2.42	2.24	3.76	4.81	7.60	9.73	11.00	13.81

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TOX-290
BT-COTTON SEEDS(NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -1.29
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : Bi-COTTON SEEDS(NATH SEEDS) (1000 mg/kg,B.wt)

Anim -al No.	Sex	Body Weights on										13 ^a Week Terminal kill	
		1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week		
1	M	111.1	23.5	35.9	50.0	63.4	73.5	83.6	98.1	110.9	124.8	140.1	154.0
2	M	6.0	21.0	36.5	51.0	66.6	81.8	98.1	110.4	128.9	144.1	160.8	178.9
3	M	15.7	23.6	37.5	52.3	63.2	77.1	90.6	115.4	133.7	135.1	161.3	180.4
4	M	14.1	31.3	48.8	63.4	75.8	91.8	104.0	117.0	133.3	147.5	160.0	170.0
5	M	15.0	29.4	44.5	57.00	66.5	74.1	86.6	99.7	109.9	121.7	134.2	144.1
6	M	14.4	31.8	50.1	61.9	78.00	93.2	106.8	122.3	138.00	152.1	170.3	182.6
7	M	12.6	26.4	40.0	57.5	73.1	87.5	101.3	112.4	126.3	139.4	145.9	153.3
8	M	13.2	27.9	42.3	60.6	72.6	84.8	100.6	112.1	125.7	142.1	158.8	172.6
9	M	14.2	29.8	44.3	56.4	76.6	94.6	112.3	126.1	144.3	158.6	174.9	194.6
10	M	11.2	24.4	39.5	50.8	67.4	81.2	93.8	108.7	121.2	133.7	149.3	161.2
Mean		12.75	26.91	42.03	56.09	70.32	81.96	97.77	112.22	125.22	140.75	152.21	160.99
S.D.		2.81	3.69	4.92	4.89	5.54	7.74	9.09	8.81	11.03	13.41	12.70	10.00

SHIRAM INSTITUTE

TON-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -1.30

WEEKLY BODY WEIGHT GAIN DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : BT-COTTON SEEDS (NATH SEEDS) (1000 mg/kg.B.wt)

Anim al No.	Sex	Body Weights on										13 th Week Terminal kill	
		1 st Week	2 nd Week	3 rd Week	4 th Week	5 th Week	6 th Week	7 th Week	8 th Week	9 th Week	10 th Week		
1	F	6.8	24.3	34.3	41.7	49.8	58.4	70.0	77.7	89.7	107.9	124.8	128.7
2	F	11.4	20.4	31.1	38.9	50.0	39.0	66.9	75.7	83.6	94.5	112.9	118.5
3	F	8.7	22.9	30.7	37.8	46.0	54.7	64.8	74.4	84.2	94.9	109.2	125.2
4	F	8.9	19.4	28.0	37.4	46.4	52.9	62.1	69.4	78.6	80.5	83.5	90.3
5	F	8.9	19.5	26.1	34.9	44.2	51.8	59.7	68.0	73.2	84.8	96.0	102.2
6	F	9.6	18.5	25.5	33.0	41.1	49.6	56.3	64.4	73.2	84.3	93.7	98.6
7	F	5.6	11.0	20.1	29.6	37.1	45.9	55.1	62.4	70.3	80.6	92.4	105.5
8	F	7.6	15.5	21.9	30.1	40.5	49.6	57.9	66.6	79.1	88.4	97.4	101.1
9	F	8.7	14.6	22.9	32.0	42.6	54.8	58.3	64.8	73.6	81.6	88.8	95.3
10	F	7.7	20.7	28.3	39.3	47.4	56.3	65.2	72.3	85.7	92.4	97.9	102.8
Mean		8.39	18.68	26.89	35.47	44.51	53.1	61.63	69.57	79.12	88.99	99.66	106.05
S.D.		1.58	3.99	4.47	4.16	4.19	4.16	4.95	5.23	6.49	8.63	12.41	13.72
													13.56

APPENDIX -2

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -2.0
MEAN FEED CONSUMPTION DATA OF MALE AND FEMALE RATS
(90 DAYS REPEATED ORAL TOXICITY STUDY)

Dose Levels	Average feed consumption in gm)	Average feed consumption in gm)
Control (Fed on pellets only)	134.50 ± 13.76	130.36 ± 13.79
Non-transgenic cotton seeds 500 mg/kg	132.19 ± 12.65	129.72 ± 14.02
Non-transgenic cotton seeds 1600 mg/kg	132.12 ± 12.34	170.46 ± 17.50
Bi-Cotton seeds (Nath seeds) 500 mg/kg	130.02 ± 11.64	131.00 ± 12.90
Bi-Cotton seeds (Nath seeds) 1000 mg/kg	129.68 ± 11.49	132.90 ± 15.59

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TOX-290
BT-COTTON SEEDS (NATI SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 2.1
FEED CONSUMPTION DATA OF MALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (in gms.)	CONTROL (given GROUNDSEED oil only)	NON TRANSGENIC COTTON SEEDS		BT-COTTON SEEDS (NATI SEEDS)	
			500 mg./kg. B.wt	1600 mg./kg. B.wt	500 mg./kg. B.wt	1600 mg./kg. B.wt
0	175	158.4	134.6	121.5	130.6	128.7
1	175	153.3	136.4	140.7	137.3	132.4
2	175	154.1	142.1	151.8	140.7	109.3
3	175	142.7	133.1	150.1	109.6	125.7
4	175	150.3	120.2	127.3	126.7	123.6
5	175	154.2	126.5	140.4	118.8	112.9
6	175	142.0	128.9	126.2	137.9	139.0
7	175	162.3	116.7	135.1	126.1	132.6
8	175	149.6	138.3	130.8	129.6	150.9
9	175	142.6	170.1	140.3	139.2	136.3
10	175	150.3	111.8	118.0	112.0	130.4
11	175	168.2	115.1	140.1	104.5	142.1
12	175	119.4	129.6	128.6	127.4	139.6
13	175	151.6	138.6	135.4	135.2	117.0
14	175	124.6	147.0	136.2	130.1	100.0
15	175	134.3	136.9	126.7	110.9	129.8
16	175	124.8	142.9	136.0	141.4	132.6
17	175	146.1	138.0	140.3	139.0	138.2
18	175	165.4	126.5	132.0	125.6	140.9
19	175	132.9	137.6	145.6	125.0	120.4
20	175	145.1	158.1	129.8	109.5	142.2

Contd.

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TOX-290
BIT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -2.1 (Contd.)
FEED CONSUMPTION DATA OF MALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (in grams)	CONTROL (given GERMINDUST oil only)	NON TRANSGENIC COTTON SEEDS		Bt-COTTON SEEDS (NATH SEEDS)	
			500 mg./kg. B.wt	1000 mg./kg. B.wt	500 mg./kg. B.wt	1000 mg./kg. B.wt
21	17.5	142.3	113.9	143.2	129.0	130.4
22	17.5	106.3	107.9	125.6	123.6	124.7
23	17.5	129.0	127.8	142.0	138.0	135.7
24	17.5	132.8	133.7	130.6	142.6	126.8
25	17.5	128.0	139.4	150.4	131.5	143.0
26	17.5	118.3	132.1	136.1	130.4	125.2
27	17.5	121.0	132.4	120.3	145.2	138.6
28	17.5	121.4	130.7	125.0	130.2	126.4
29	17.5	126.7	129.8	132.4	138.6	137.8
30	17.5	129.8	137.2	116.2	119.3	126.3
31	17.5	105.8	127.2	104.5	121.0	117.6
32	17.5	135.0	121.6	119.2	126.0	110.3
33	17.5	117.0	125.2	112.0	129.0	156.5
34	17.5	124.8	135.0	121.5	126.1	107.8
35	17.5	144.9	146.7	124.6	129.8	113.2
36	17.5	143.6	129.8	129.0	116.9	125.6
37	17.5	110.2	126.3	124.0	116.5	109.0
38	17.5	141.0	140.5	128.0	130.6	134.6
39	17.5	124.9	132.7	127.1	126.0	123.6
40	17.5	135.0	122.6	118.0	123.0	133.0
41	17.5	143.0	130.7	119.4	116.0	135.3

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TOX-299
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 2.1 (Contd.)
FEED CONSUMPTION DATA OF MALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (in gms.)	CONTROL (given GROUNDNUT oil only)	NON TRANSGENIC COTTON SEEDS			BT-COTTON SEEDS (NATH SEEDS)	
			300 mg./kg. B.wt	1000 mg./kg. B.wt	500 mg./kg. B.wt	1000 mg./kg. B.wt	
42	175	146.5	118.0	130.0	129.7	122.0	
43	175	131.0	119.7	128.5	134.0	130.3	
44	175	132.5	149.6	121.6	139.5	148.4	
45	175	140.9	140.5	108.8	138.0	139.0	
46	175	115.2	150.7	154.0	151.4	155.0	
47	175	128.9	118.7	140.6	123.4	123.0	
48	175	126.9	154.8	150.0	158.9	139.0	
49	175	109.5	140.6	131.5	152.2	133.6	
50	175	128.6	138.0	121.3	133.8	149.0	
51	175	116.6	125.6	123.0	118.0	128.6	
52	175	137.0	132.0	129.0	142.9	133.8	
53	175	109.8	117.4	143.2	118.2	129.2	
54	175	123.5	129.0	142.8	124.3	136.0	
55	175	121.8	138.0	114.3	130.9	149.0	
56	175	142.2	104.2	121.3	125.4	123.0	
57	175	138.3	132.0	128.0	165.0	117.4	
58	175	112.8	126.0	129.4	114.2	118.5	
59	175	120.7	119.1	144.0	118.1	140.0	
60	175	158.6	117.9	138.3	146.4	134.0	
61	175	126.8	118.2	144.7	142.7	126.9	
62	175	153.2	134.0	132.9	129.8	125.8	

Contd...



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TOX-29
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS
TABLE - 2.1 (Contd.)
FEED CONSUMPTION DATA OF MALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Green GROUNDNUT oil seed)	NON TRANSGENIC COTTON SEEDS		BT-COTTON SEEDS (NATH SEEDS)	
			500 mg./kg. B.wt	1000 mg./kg. B.wt	500 mg./kg. B.wt	1000 mg./kg. B.wt
63	175	118.2	143.0	105.3	149.2	148.2
64	175	136.4	142.1	129.8	105.2	114.4
65	175	122.0	130.8	145.2	123.4	130.0
66	175	133.5	125.0	131.1	124.6	120.4
67	175	143.0	133.0	126.9	148.3	131.0
68	175	142.3	129.4	135.8	115.4	110.5
69	175	129.0	139.8	135.0	125.0	126.6
70	175	143.0	128.6	154.2	127.9	140.8
71	175	143.9	149.1	159.8	131.7	123.3
72	175	125.8	133.2	125.0	132.6	150.7
73	175	136.0	135.7	136.1	105.0	142.3
74	175	130.6	145.2	149.0	126.2	139.1
75	175	129.6	151.0	113.0	118.4	138.6
76	175	132.3	107.2	129.0	128.1	128.9
77	175	115.0	113.3	858.0	149.8	140.3
78	175	116.2	113.4	115.6	120.3	148.3
79	175	127.9	129.8	109.1	120.2	146.8
80	175	138.0	138.0	116.7	133.6	126.2
81	175	125.9	144.0	123.0	135.2	123.3
82	175	121.2	165.0	158.0	126.4	124.1
83	175	148.3	140.6	131.0	122.9	127.8

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BT-COTTON SEEDS(NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 21 (Contd.)
FEED CONSUMPTION DATA OF MALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Given GROUNDNUT oil only)	NON TRANSGENIC COTTON SEEDS		BT-COTTON SEEDS (NATH SEEDS) 500 mg./kg. B.wt	500 mg./kg. B.wt	1000 mg./kg. B.wt	1000 mg./kg. B.wt
			500 mg./kg. B.wt	1000 mg./kg. B.wt				
34	175	149.1	129.3	135.9	124.6	145.5		
45	175	160.2	149.3	143.2	126.0	139.8		
60	175	146.1	128.9	129.0	133.2	143.3		
87	175	122.2	136.6	145.0	137.0	129.0		
13	175	138.0	125.9	135.6	125.0	108.8		
19	175	139.0	133.2	139.0	118.0	129.6		
90	175	136.4	109.9	138.0	134.4	138.0		

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TOX-290
BT-COTTON SEEDS (NATU SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 2.2
FEED CONSUMPTION DATA OF FEMALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (in gms.)	CONTROL (given GROUNDNUT oil only)	NON TRANSGENIC COTTON SEEDS			BT-COTTON SEEDS (NATU SEEDS)		
			500 mg./kg. B.wt	1000 mg./kg. B.wt	500 mg./kg. B.wt	1000 mg./kg. B.wt	1500 mg./kg. B.wt	
0	175	147.6	138.2	131.2	141.7	139.1		
1	175	157.0	151.4	150.4	154.2	143.0		
2	175	121.3	124.0	131.8	145.0	157.2		
3	175	158.5	167.6	127.0	197.3	128.4		
4	175	148.8	163.5	136.2	121.0	144.4		
5	175	162.8	169.8	134.7	129.8	125.7		
6	175	125.6	172.3	102.5	142.7	122.1		
7	175	126.0	159.6	148.5	134.9	139.4		
8	175	133.4	147.7	126.8	130.3	146.2		
9	175	109.6	139.6	147.0	150.2	137.3		
10	175	135.9	125.5	118.1	119.3	163.1		
11	175	129.8	128.5	129.1	111.3	102.0		
12	175	166.6	122.0	154.0	131.8	100.0		
13	175	125.2	127.3	130.4	135.8	108.6		
14	175	129.6	126.0	139.0	142.6	150.1		
15	175	140.3	135.0	132.8	149.0	142.4		
16	175	106.5	118.4	129.7	130.4	140.5		
17	175	127.3	125.7	150.1	141.0	156.0		
18	175	170.2	129.6	156.7	134.0	129.8		
19	175	113.6	119.4	108.9	148.4	126.1		
20	175	123.7	122.0	117.6	121.6	138.6		

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -2.2 (Contd.)
FEED CONSUMPTION DATA OF FEMALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (in gms.)	CONTROL (@oven GROUNDNU-T oil only)	NON TRANSGENIC COTTON SEEDS		BT-COTTON SEEDS (NATH SEEDS)	
			500 mg./kg. B.wt	1000 mg./kg. B.wt	500 mg./kg. B.wt	1000 mg./kg. B.wt
21	175	140.0	120.9	136.2	160.7	123.4
22	175	159.0	119.5	140.5	123.7	144.2
23	175	153.2	112.8	107.8	108.5	123.7
24	175	122.7	126.7	135.4	119.2	105.6
25	175	137.8	140.0	126.2	130.5	116.0
26	175	109.0	132.3	127.2	140.2	129.4
27	175	120.5	103.9	135.2	137.8	138.8
28	175	126.4	116.3	142.0	119.2	142.2
29	175	108.7	140.0	128.4	110.2	138.4
30	175	112.7	138.2	122.7	122.4	131.8
31	175	105.0	114.0	119.0	105.8	109.6
32	175	121.7	135.6	125.8	114.0	108.0
33	175	150.2	116.0	119.2	104.9	113.0
34	175	139.0	135.0	132.4	130.0	141.0
35	175	103.2	116.7	118.5	125.2	144.1
36	175	125.0	119.0	133.2	114.0	123.8
37	175	132.1	141.3	117.5	113.8	111.9
38	175	130.0	118.4	155.0	123.0	145.7
39	175	138.0	132.0	136.0	150.3	123.1
40	175	135.5	142.1	122.8	135.9	137.2
41	175	133.0	109.3	124.0	141.0	115.0

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 2.2 (Contd.)
FEED CONSUMPTION DATA OF FEMALE RATS 90 DAYS ORAL STUDY

DAY'S	FEED WT. (In gms)	CONTROL GROUNDNUT oil only)	NON TRANSGENIC COTTON SEEDS		BT-COTTON SEEDS (NATH SEEDS)	
			500 mg./kg. B.wt	1000 mg./kg. B.wt	500 mg./kg. B.wt	1000 mg./kg. B.wt
42	175	145.0	125.7	140.8	132.3	139.0
43	175	124.7	131.6	131.0	124.0	124.2
44	175	119.4	132.0	123.1	126.2	139.0
45	175	126.0	129.4	129.1	127.6	110.4
46	175	140.3	120.0	140.0	148.3	135.0
47	175	138.3	121.3	122.6	134.3	130.2
48	175	151.1	133.6	130.4	121.8	136.2
49	175	126.0	133.3	123.8	109.3	124.4
50	175	130.2	142.4	122.2	115.7	130.6
51	175	100.9	130.1	131.9	135.0	134.7
52	175	120.4	115.7	123.0	138.6	129.8
53	175	140.8	118.2	117.6	133.7	131.3
54	175	152.8	118.3	130.0	146.4	162.0
55	175	140.7	141.3	142.9	126.8	107.3
56	175	132.0	116.3	133.8	135.5	118.2
57	175	127.8	140.5	130.0	135.8	109.8
58	175	142.9	137.8	140.0	120.4	122.4
59	175	123.2	136.0	132.8	117.2	162.9
60	175	113.0	147.2	131.8	148.0	128.6
61	175	139.8	125.4	139.9	121.4	162.9
62	175	124.3	140.6	140.5	125.0	157.1

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 BT-COTTON SEEDS (NATII SEEDS)
 SUBCHRONIC ORAL TOXICITY STUDY IN RATS
 TABLE - 2.2 (Contd.)
 FEED CONSUMPTION DATA OF FEMALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (in grams)	CONTROL (given INDNUIT oil only)	NON TRANSGENIC COTTON SEEDS		BT-COTTON SEEDS (NATII SEEDS)	
			500 mg./kg. B.wt	[500 mg./kg. B.wt]	500 mg./kg. B.wt	[500 mg./kg. B.wt]
63	175	138.8	115.6	116.3	109.8	144.0
64	175	142.0	117.6	129.8	126.0	139.0
65	175	129.6	141.2	113.6	122.4	129.0
66	175	132.4	137.1	126.8	159.8	122.0
67	175	142.1	129.3	130.9	136.3	110.3
68	175	118.0	129.8	140.0	139.0	126.6
69	175	125.8	132.6	120.6	162.3	114.2
70	175	166.2	159.2	127.7	131.4	129.6
71	175	130.2	129.3	139.8	139.2	128.7
72	175	104.3	128.6	115.6	108.6	114.9
73	175	115.6	144.2	120.5	122.8	135.6
74	175	109.2	140.2	116.9	115.6	109.2
75	175	131.3	154.3	144.2	140.6	134.8
76	175	125.8	108.7	112.3	104.8	170.3
77	175	144.0	115.8	130.1	122.4	148.3
78	175	159.8	124.9	108.9	115.2	141.3
79	175	139.8	109.1	124.2	142.6	110.6
80	175	142.3	145.1	140.7	128.0	104.9
81	175	115.7	149.8	133.8	123.9	123.0
82	175	168.9	136.2	104.9	144.3	141.1
83	175	166.7	137.2	114.5	140.2	124.2

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BT-COTTON SEEDS (NATURAL SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 22 (Contd.)
FEED CONSUMPTION DATA OF FEMALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In grams)	CONTROL (given GROUNDNUT oil only)	NON TRANSGENIC COTTON SEEDS		BT-COTTON SEEDS (NATURAL SEEDS)	
			500 mg./kg. B.wt	1000 mg./kg. B.wt	500 mg./kg. B.wt	1000 mg./kg. B.wt
84	175	129.8	114.9	150.6	150.3	136.0
85	175	130.6	115.0	170.3	125.0	128.2
86	175	134.0	117.2	121.5	152.6	125.9
87	175	130.5	129.8	112.3	142.6	133.8
88	175	135.8	116.3	109.8	136.5	119.8
89	175	130.2	140.2	124.8	138.9	125.6
90	175	123.7	136.6	171.6	129.0	160.0

APPENDIX - 3

[REDACTED]

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)

SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -3.1
MEAN HAEMATOLOGY DATA OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Parameters	Control (Groundnut oil only)	NON-TRANSGENIC COTTON SEEDS	Bi-COTTON SEEDS (NATH SEEDS)
	500 mg/kg. B.wt.	1000 mg/kg. B.wt.	500 mg/kg. B.wt.
WBC (X10 ³)	8.21 ± 2.08	7.48 ± 1.15	7.44 ± 1.77
Differential			7.38 ± 0.94
Lymphocytes %	83.00 ± 2.54	82.30 ± 2.31	81.60 ± 1.77
Neutrophils %	15.20 ± 1.31	16.30 ± 2.62	16.90 ± 1.91
Eosinophils %	0.80 ± 0.78	0.40 ± 0.52	0.40 ± 0.51
Monocytes %	1.00 ± 1.41	1.00 ± 1.63	1.10 ± 1.59
Basophils %	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Protime	11.90 ± 0.73	11.80 ± 0.78	12.10 ± 0.75
R.B.C. (x10 ⁶) %	7.22 ± 0.30	7.32 ± 0.30	7.30 ± 0.31
Hb (gm %)	13.38 ± 0.42	13.22 ± 0.69	13.20 ± 0.42
Hct %	34.80 ± 2.2	36.12 ± 1.42	37.23 ± 1.03
Platelets (x10 ³)	829.7 ± 97.8	829.9 ± 101.06	781.60 ± 67.20
			868.80 ± 162.4
			818.70 ± 88.77
			1000 mg/kg. B.wt.
			7.34 ± 1.43

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TOX-290

BT-COTTON SEEDS (NATH SEEDS)

SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 3.2
MEAN HAEMATOLOGY DATA OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Parameters	Control (Groundnut oil only)	NON-TRANSGENIC COTTON SEEDS	Bi-COTTON SEEDS (NATH SEEDS)
WBC ($\times 10^3$)	7.94 ± 1.69	500 mg/kg. B.wt. 7.63 ± 1.67	1000 mg/kg. B.wt. 6.86 ± 1.29
Differential			
Lymphocytes %	81.90 ± 2.47	83.40 ± 2.63	82.80 ± 1.03
Neutrophils %	16.20 ± 1.98	15.50 ± 2.59	15.40 ± 1.95
Eosinophils %	0.40 ± 0.51	0.50 ± 0.70	0.70 ± 0.69
Monocytes %	1.00 ± 1.63	0.69 ± 1.07	1.10 ± 1.29
Basophils %	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Protime	12.00 ± 0.81	12.10 ± 0.73	11.80 ± 0.78
R.B.C. ($\times 10^6$) %	7.10 ± 0.12	7.11 ± 0.23	7.21 ± 1.99
Hb (gm %)	12.75 ± 0.50	12.58 ± 0.65	12.70 ± 0.49
Hct %	34.82 ± 1.44	35.87 ± 2.10	36.71 ± 1.78
Platelets ($\times 10^7$)	711.80 ± 73.35	797.80 ± 122.70	772.10 ± 77.88
			843.00 ± 83.12
			796.10 ± 61.40
			6.90 ± 1.12

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS
TABLE -3.3
HAEMATOLOGY DATA OF MALE RATS (GROUNDNUT OIL ONLY) AT TERMINAL SACRIFICE

Animal No.	SEX	WBC Count	DIFFERENTIAL			Protime	RBC count ($\times 10^6$)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%					
1	M	6.2	82	14	1	3	0	13	7.82	14.3
2	M	8.40	81	16	2	1	0	12	7.62	13.1
3	M	9.70	85	15	0	0	0	12	7.44	13.3
4	M	5.90	86	14	0	0	0	11	7.13	13.5
5	M	11.90	79	16	1	4	0	12	6.94	12.4
6	M	7.30	80	18	1	1	0	13	7.09	13.7
7	M	9.50	84	14	2	0	0	12	7.04	13.5
8	M	10.50	85	15	0	0	0	12	7.20	13.2
9	M	5.90	86	14	0	0	0	11	6.92	12.9
10	M	7.00	82	16	1	1	0	11	7.02	13.0
Mean		8.21	85.00	15.20	0.89	1.00	0.0	111.9	7.22	13.38
S.D		± 2.08	2.54	± 1.31	± 0.78	± 1.41	± 0.60	0.73	± 0.39	± 0.42

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TOX-290

BT- COTTON SEEDS (NATHI SEEDS)

SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -3.4
HAEMATOLOGY DATA OF FEMALE RATS (GROUNDNUT OIL ONLY)
AT TERMINAL SACRIFICE

Animal No.	SEX	WBC Count	DIFFERENTIAL				Protime	RBC count ($\times 10^7$)	Hb gm %	HCT %	Platelets- Count
			L%	N%	E%	M%					
1	F	7.5	81	15	1	2	0	11	7.12	13.5	34.5
2	F	8.3	78	17	1	4	0	11	7.10	12.9	33.4
3	F	9.9	79	20	1	0	0	12	7.12	13.1	36.8
4	F	6.3	82	18	0	0	0	13	7.03	12.6	33.2
5	F	7.2	83	14	0	3	0	13	6.89	11.9	32.8
6	F	11.2	80	18	2	0	0	12	7.08	12.5	35.1
7	F	7.2	82	15	1	2	0	12	6.98	12.1	34.2
8	F	6.7	86	14	0	0	0	11	7.13	12.6	35.6
9	F	9.2	82	16	1	1	0	12	7.36	13.2	35.8
10	F	5.9	83	15	0	0	0	13	7.19	13.1	36.8
Mean		7.94	81.90	16.20	0.70	1.20	0.0	12.00	7.10	12.75	34.82
S.D		± 1.69	± 2.47	± 1.98	± 0.67	± 1.47	± 0.00	± 0.81	± 0.12	± 0.50	± 1.44

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TOX-290
BT-COTTON SEEDS (NATHE SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -35
HAEMATOLOGY DATA OF MALE RATS
GROUP: NON-TRANSGENIC COTTON SEEDS AT TERMINAL SACRIFICE
DOSE : 500 mg/kg.B.wt.

Animal No.	Sex	WBC Count	DIFFERENTIAL				Pretime	RBC count ($\times 10^6$)	Hb gm %	HCT %	Platelet Count	
			L%	N%	E%	M%						
1	M	6.4	85	15	0	0	13	7.45	13.8	37.2	864	
2	M	6.2	81	16	1	2	12	7.87	14.2	38.9	991	
3	M	7.8	80	20	0	0	11	7.02	12.0	35.2	708	
4	M	7.3	80	20	0	0	11	7.80	12.7	35.8	831	
5	M	6.4	82	12	1	3	12	7.10	13.0	35.4	893	
6	M	8.7	79	18	1	2	0	13	7.47	13.9	37.4	648
7	M	6.7	84	14	1	1	9	12	7.07	12.8	35.4	914
8	M	9.8	85	15	0	0	12	7.21	13.4	36.8	768	
9	M	8.1	85	15	0	0	11	7.07	12.6	34.2	879	
10	M	7.4	82	18	0	0	11	7.19	12.8	34.9	786	
Mean		7.48	82.30	16.30	0.40	1.00	0.00	11.80	7.325	13.22	36.12	829.9
S.D		1.15	2.31	2.62	0.51	1.63	0.90	0.78	0.30	0.69	1.42	101.06

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TOX-290
BT-COTTON SEEDS (BATH SEEDS)

TABLE - 3.6
HAEMATOLOGY DATA OF FEMALE RATS
GROUP- NON-TRANSGENIC COTTON SEEDS AT TERMINAL SACRIFICE

Animal No.	SEX	WBC Count	DIFFERENTIAL			Proline	RBC count (x10 ⁶)	Hb gm %	HCT %	Platelet Count
			L%	N%	E%					
1	F	10.7	86	14	0	0	12	7.65	13.9	40.3
2	F	5.5	83	14	0	5	9	12	7.36	13.4
3	F	6.0	86	11	1	2	9	13	7.97	12.8
4	F	9.0	82	16	2	0	0	13	6.99	12.2
5	F	6.0	84	16	0	0	12	6.87	11.9	34.3
6	F	6.9	86	14	0	0	0	11	6.96	12.0
7	F	7.2	80	19	1	0	0	12	7.11	12.7
8	F	7.3	86	14	0	0	12	7.07	12.5	35.3
9	F	8.4	79	19	1	1	0	11	6.94	11.9
10	F	9.3	82	18	0	0	0	13	7.09	12.5
Mean		7.63	83.4	15.50	0.50	0.60	0.60	12.1	7.11	12.58
S.D		1.67	2.63	2.59	0.70	1.07	0.00	±	±	±
							0.75	0.23	0.65	2.10
										122.7

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TOX-290
BT-COTTON SEEDS(NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -3.7
HAEMATOLOGY DATA OF MALE RATS
GROUP : NON-TRANSGENIC COTTON SEEDS AT TERMINAL SACRIFICE DOSE : 1000 mg/kg.B.wt.

Animal No.	SEX	WBC Count	DIFFERENTIAL				Protime	RBC count (10^6)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%	M%					
1	M	7.6	84	14	0	2	0	13	7.97	13.6	37.5
2	M	7.4	79	15	1	5	0	12	7.58	13.1	36.3
3	M	6.9	83	17	0	0	0	12	7.69	13.2	36.5
4	M	5.9	81	18	1	0	0	11	7.62	12.6	36.2
5	M	6.6	82	15	1	2	0	12	7.64	13.3	37.0
6	M	6.9	82	18	0	0	0	13	7.67	12.8	36.4
7	M	6.1	81	17	1	1	0	13	7.20	13.2	38.4
8	M	9.8	79	20	0	1	0	12	7.18	13.2	37.9
9	M	5.9	84	16	0	0	0	12	7.25	14.1	39.3
10	M	11.3	81	19	0	0	0	11	7.66	12.9	36.8
Mean		7.44	81.00	16.90	0.40	1.10	0.0	12.1	7.30	13.20	37.23
S.D		± 1.77	± 1.77	± 1.91	± 0.52	± 1.59	± 0.00	± 0.73	± 0.31	± 0.42	± 1.03

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TOX-290

BT-COTTON SEEDS(NATH SEEDS)

SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -3.8
HAEMATOLOGY DATA OF FEMALE RATS
GROUP : NON-TRANSGENIC COTTON SEEDS AT TERMINAL SACRIFICE
DOSE : 1000 mg/kg.B.WT.

Animal No.	SEX	WBC Count	DIFFERENTIAL				Protime	RBC count ($\times 10^6$)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%	M%					
1	F	5.8	82	18	0	0	12	7.85	13.2	38.4	638
2	F	7.2	84	15	1	2	0	11	7.11	12.6	36.3
3	F	6.0	82	17	1	0	0	13	7.06	13.4	40.6
4	F	6.4	83	13	1	3	0	12	7.28	13.0	38.0
5	F	5.9	84	16	0	0	0	11	6.91	11.9	34.8
6	F	9.9	84	16	0	0	0	12	7.01	12.3	35.4
7	F	7.7	83	17	0	0	0	13	7.13	12.8	36.2
8	F	7.6	82	13	2	3	0	11	7.45	12.8	36.1
9	F	6.3	81	17	1	1	0	11	7.01	12.0	35.1
10	F	5.8	83	14	1	2	0	12	7.10	13.0	36.2
Mean \pm S.D		6.86 \pm 1.29	82.8 \pm 1.03	15.40 \pm 1.95	0.70 \pm 0.69	1.10 \pm 1.29	0.00 \pm 0.00	7.21 \pm 0.78	11.8 \pm 1.99	36.71 \pm 0.49	772.1 \pm 77.88

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BT-COTTON SEEDS(NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -3.9
HAEMATOLOGY DATA OF MALE RATS
GROUP : BT-COTTON SEEDS(NATH SEEDS) AT TERMINAL SACRIFICE

Animal No.	SEX	WBC Count	DIFFERENTIAL			Protime	RBC count ($\times 10^6$)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%					
1	M	7.1	85	32	1	2	0	12	7.62	14.8
2	M	7.4	84	15	0	1	0	11	7.22	14.7
3	M	8.0	82	17	0	1	0	13	8.24	14.1
4	M	6.8	80	18	2	0	0	13	7.70	14.4
5	M	9.7	81	15	2	2	0	12	7.44	15.1
6	M	6.4	81	19	0	0	0	11	8.12	15.3
7	M	7.1	84	16	0	0	0	13	7.88	14.1
8	M	6.6	82	18	0	0	0	12	7.94	15.2
9	M	7.7	86	12	1	1	0	11	8.01	14.8
10	M	7.0	83	17	0	0	0	11	14.3	40.9
Mean		7.38	82.80	15.9	0.60	0.70	0.0	12.09	7.79	14.68
S.D.		± 0.94	± 1.93	± 2.42	± 0.84	± 0.82	± 0.00	± 0.89	± 0.33	± 0.41

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TOX-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -3.10
HAEMATOLOGY DATA OF FEMALE RATS
GROUP : BT-COTTON SEEDS (NATH SEEDS) AT TERMINAL SACRIFICE
DOSE : 500 mg/kg B.wt.

Animal No.	SEX	WBC Count	DIFFERENTIAL			Pretime RBC count ($\times 10^6$)	Hb gm %	HCT %	Platelets- Count
			L%	N%	E%				
1	F	6.3	84	14	1	0	12	7.18	41.2
2	F	7.3	84	16	0	0	11	7.22	43.6
3	F	6.8	80	19	0	1	13	7.11	43.3
4	F	5.8	82	18	0	0	12	7.20	44.1
5	F	9.2	81	14	2	3	0	11	7.08
6	F	7.0	86	14	0	0	12	6.99	42.0
7	F	6.3	81	19	0	0	12	7.20	43.5
8	F	8.1	80	15	2	3	0	11	7.14
9	F	6.3	83	16	0	1	0	13	7.10
10	F	7.2	80	19	1	0	12	7.06	42.3
Mean		7.63	82.1	16.4	0.60	0.90	12.00	7.14	43.20
\pm		\pm	\pm	\pm	\pm	\pm	\pm	\pm	\pm
S.D		1.60	2.07	2.17	0.84	1.19	0.9	0.82	0.07

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -3.11

HAEMATOLOGY DATA OF MALE RATS

GROUP : BT-COTTON SEEDS (NATH SEEDS) AT TERMINAL SACRIFICE

DOSE : 1000 mg/kg.B.wt.

Animal No.	SEX	WBC Count	DIFFERENTIAL				Proline	RBC count (10^6)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%	M%					
1	M	8.3	79	14	3	4	0	12	7.38	13.6	38.1
2	M	7.1	87	13	0	0	0	11	7.22	13.8	38.2
3	M	7.6	81	14	2	3	0	13	7.16	13.5	37.4
4	M	9.8	93	15	1	1	0	11	7.21	13.8	38.0
5	M	6.5	86	14	0	0	0	11	7.89	13.3	39.8
6	M	9.5	84	16	0	0	0	12	7.99	14.5	40.5
7	M	5.7	83	16	1	0	0	12	7.18	13.6	37.6
8	M	6.2	83	17	0	0	0	11	7.94	14.1	39.7
9	M	6.3	82	17	0	1	0	13	7.94	14.0	39.5
10	M	6.4	80	20	0	0	0	13	8.10	14.6	40.9
Mean		7.34	82.8	15.60	0.70	0.90	0.00	12.00	7.60	13.98	38.97
\pm		± 1.43	± 2.48	± 2.06	± 1.00	± 1.44	0.00	± 0.31	± 0.39	± 0.36	± 1.25
S.D											88.77

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)

SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

Animal No.	SEX	WBC Count	DIFFERENTIAL			Prutime	RBC count ($\times 10^6$)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%					
1	F	6.4	83	14	2	1	0	12	7.21	12.6
2	F	5.8	84	14	0	2	0	11	7.24	12.9
3	F	7.4	80	16	1	3	0	11	7.46	13.3
4	F	7.1	81	15	2	2	0	13	7.42	13.3
5	F	9.7	82	16	1	1	0	11	7.46	13.4
6	F	5.9	82	18	0	0	0	12	7.52	14.3
7	F	6.4	79	19	1	3	0	13	7.22	13.1
8	F	7.2	85	15	0	0	0	13	7.19	14.3
9	F	6.2	82	16	2	0	0	12	7.26	13.5
10	F	6.9	82	17	0	1	0	11	7.12	13.4
Mean		6.9	82.0	16.0	0.90	1.1	0.0	11.9	7.31	13.40
S.D.		± 1.12	1.76	1.63	0.87	0.99	0.00	0.87	0.14	0.57

DOSE : 1000 mg/kg.B.wt.

APPENDIX - 4

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TOX-299
BT-COTTON SEEDS (NATU SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 4.1
MEAN BIOCHEMISTRY DATA ON MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Parameters	Control (Given groundnut oil only)	Non-Transgenic cotton seeds	Bt-cotton seeds (Nath seeds)
B. SUGAR (mg %)	84.6 ± 5.19	500 mg/kg B.wt.	1000 mg/kg B.wt.
BUN (mg %)	27.25 ± 2.76	83.60 ± 5.10	85.40 ± 6.18
Total Protein (gm %)	7.06 ± 0.30	26.50 ± 4.50	27.69 ± 3.99
S.G.O.T (U/L)	37.12 ± 4.13	7.08 ± 0.21	6.94 ± 6.18
S.G.P.T (U/L)	35.06 ± 4.46	37.66 ± 2.61	36.07 ± 4.68
Albumin (gm %)	3.96 ± 0.19	36.71 ± 2.46	34.40 ± 4.83
SAP (U/L)	94.84 ± 10.36	3.93 ± 0.15	3.95 ± 0.14
		95.95 ± 7.84	4.07 ± 0.32
		95.96 ± 5.75	3.96 ± 0.16
		93.27 ± 9.27	93.74 ± 10.36

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TOX-296
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 4.2
MEAN BIOCHEMISTRY DATA ON FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Parameters	Control (Given groundnut oil only)	Non-Transgenic cotton seeds		Bt-cotton seeds (Nath seeds)	
		500 mg/kg B.wt.	1000 mg/kg B.wt.	500 mg/kg B.wt.	1000 mg/kg B.wt.
B. SUGAR (mg %)	85.80 ± 5.84	83.20 ± 4.10	84.90 ± 4.28	84.90 ± 3.54	85.20 ± 4.07
BUN (mg %)	27.61 ± 4.30	25.86 ± 3.68	27.96 ± 1.84	26.21 ± 3.21	27.46 ± 3.13
Total Protein (gm %)	7.23 ± 0.27	7.03 ± 0.37	6.99 ± 0.18	7.04 ± 0.29	7.12 ± 0.25
S.G.O.T (L.U)	37.69 ± 2.78	36.80 ± 2.89	36.26 ± 2.74	36.75 ± 4.57	36.82 ± 2.98
S.G.P.T (L.U)	35.70 ± 2.78	34.18 ± 4.23	34.57 ± 2.74	33.68 ± 4.17	33.55 ± 3.71
Albumin (gm %)	3.97 ± 0.16	3.89 ± 0.12	4.01 ± 0.31	3.93 ± 0.15	3.92 ± 0.16
SAP (U/L)	96.24 ± 10.14	94.25 ± 8.62	93.98 ± 7.43	95.08 ± 7.43	96.36 ± 5.72

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TOX-290
RF-COTTON SEEDS (NATHI SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -4.3

BIOCHEMISTRY DATA OF CONTROL (GROUNDNUT OIL ONLY) GROUP OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

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	28.5	95	6.798	37.72	29.39	3.69	97.8
2	M	21.8	81	7.246	40.32	41.33	4.02	103.5
3	M	31.3	85	7.644	28.38	36.58	4.21	98.3
4	M	27.5	82	6.834	36.15	43.12	3.90	87.2
5	M	29.2	79	6.939	40.58	33.89	3.68	89.7
6	M	27.9	86	7.286	29.31	39.83	3.76	79.8
7	M	24.8	78	6.665	36.36	37.92	4.17	104.3
8	M	29.3	90	6.944	34.19	38.72	3.92	100.3
9	M	27.5	87	7.206	37.84	32.83	4.08	108.4
10	M	24.7	83	6.894	29.84	37.79	3.98	78.9
Mean		27.25	84.6	7.077	35.06	37.12	3.96	94.84
± S.D		^a 2.76	^a 5.67	^a 0.30	^a 4.46	^a 4.13	^a 0.191	^a 10.36

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TOX-290
HT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -4.4
BIOCHEMISTRY DATA OF CONTROL (GROUND NUT OIL ONLY) GROUP OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

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	F	25.1	88	6.878	35.37	37.43	4.17	73.80
2	F	29.8	76	7.246	32.96	39.36	3.92	99.40
3	F	27.2	63	7.322	37.17	31.77	4.09	101.80
4	F	23.1	79	7.089	29.82	31.94	4.11	88.70
5	F	31.9	91	7.286	36.69	38.79	3.68	94.70
6	F	32.4	84	6.894	34.35	40.56	3.79	96.30
7	F	29.0	96	7.644	37.17	38.89	4.05	99.20
8	F	24.5	90	7.322	38.70	39.84	3.84	89.50
9	F	33.0	86	7.644	39.07	38.84	3.86	105.60
10	F	20.9	85	6.979	35.72	37.72	3.89	112.10
Mean		27.61	85.80	7.21	35.70	37.69	3.969	96.24
± S.D.		4.30	± 5.84	± 0.27	± 2.78	± 2.73	± 0.16	± 10.14

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BT-COTTON SEEDS (NATH SEEDS)

SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -4.5
BIOCHEMISTRY DATA OF NON-TRANSGENIC COTTON SEEDS
 (500 mg/kg B.wt) GROUP OF MALE RATS
DURATION : 90 DAYS **TIME : TERMINAL SACRIFICE**

Animal No.	Sex	BUN (mg %)	Glucose (mg %)	Total Protein (gm%)	S.G.P.T LU	S.G.O.T LU	Albulin (gm%)	SAP U/L
1	M	24.8	96	6.944	36.72	35.95	3.67	95.7
2	M	32.2	91	7.023	39.47	33.72	3.95	99.4
3	M	31.0	86	6.979	32.36	36.40	3.86	96.4
4	M	22.8	84	6.970	34.40	34.35	4.07	109.3
5	M	29.3	78	6.979	39.06	39.57	3.79	93.2
6	M	31.4	81	6.834	36.49	39.38	4.11	98.5
7	M	20.0	87	7.389	37.22	38.75	3.99	79.0
8	M	21.9	76	7.211	35.96	38.35	4.03	89.7
9	M	22.3	78	7.621	34.27	40.55	4.13	93.9
10	M	29.3	89	7.089	40.69	41.56	3.74	95.5
Mean		26.5	83.60	7.08 \pm 0.21	36.71 \pm 2.46	37.66 \pm 2.61	3.93 \pm 0.15	95.95 \pm 7.84
\pm S.D		\pm 4.50	\pm 5.10					

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TOX-290
BT-COTTON SEEDS (NATI SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 4.6
BIOCHEMISTRY DATA OF NON-TRANSGENIC COTTON SEEDS
(500 mg/kg B.wt.) GROUP OF FEMALE RATS

Animal No.	Sex	BUN (mg %)	Glucose (mg %)	Total Protein (g/m%	S.G.P.T		S.G.O.T	Albumin (gm%)	SAP U/L
					TIME : 90 DAYS	TIME : TERMINAL SACRIFICE			
1	F	25.2	85	7.089	35.00	35.33	3.37	103.6	
2	F	32.0	90	6.345	37.29	33.70	4.11	91.2	
3	F	30.1	85	6.879	32.70	40.47	3.94	95.5	
4	F	28.0	85	7.289	36.30	41.38	3.70	102.5	
5	F	24.2	80	7.211	37.44	35.88	3.87	87.5	
6	F	24.3	86	7.623	34.36	32.26	3.80	101.3	
7	F	21.2	77	6.668	29.93	38.56	3.99	99.3	
8	F	29.1	80	6.744	35.29	33.74	3.78	87.3	
9	F	25.2	87	7.209	38.22	36.06	3.39	83.9	
10	F	23.5	79	7.211	35.26	38.22	4.02	102.4	
Mean \pm S.D		25.86 \pm 3.68	83.2 \pm 4.10	7.09 \pm 0.37	34.18 \pm 4.23	36.80 \pm 2.89	3.89 \pm 0.12	94.23 \pm 8.62	

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -4.7
BIOCHEMISTRY DATA OF NON-TRANSGENIC COTTON SEEDS
(1000 mg/kg B.wt.) GROUP OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

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	21.3	69	6.479	38.28	34.89	3.99	99.8
2	M	26.2	81	6.744	39.06	41.07	4.02	95.2
3	M	30.9	76	6.668	31.43	41.43	3.68	86.2
4	M	31.6	82	7.289	37.51	35.38	4.70	96.2
5	M	29.3	84	7.623	28.22	29.36	3.94	105.4
6	M	31.3	80	7.021	32.82	38.22	3.84	94.8
7	M	28.4	89	6.979	23.77	29.58	4.10	97.1
8	M	28.7	63	6.993	37.19	37.71	3.82	98.2
9	M	21.2	92	6.722	35.82	38.32	3.89	85.8
10	M	21.0	76	6.944	40.11	34.82	4.62	100.9
Mean ± S.D		27.69 2.99	65.40 6.18	6.94 0.32	34.40 4.83	36.07 4.68	3.95 0.14	95.99 5.75

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BT-COTTON SEEDS (NATL SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 4.8
BIOCHEMISTRY DATA OF NON-TRANSGENIC COTTON SEEDS
(1000 mg/kg B.wt.) GROUP OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

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	F	29.6	93	7.023	36.24	37.30	3.94	98.2
2	F	28.4	86	6.798	39.59	32.82	4.07	91.6
3	F	28.2	82	6.947	32.49	40.11	3.79	97.6
4	F	29.5	92	7.089	29.24	39.66	4.11	99.0
5	F	35.9	93	7.256	38.83	36.22	3.84	101.4
6	F	27.8	87	6.947	37.93	35.71	4.09	97.2
7	F	26.1	91	3.749	28.75	31.35	4.83	93.5
8	F	30.5	85	6.394	39.71	37.43	3.69	79.0
9	F	29.8	78	7.023	32.61	35.88	3.84	84.8
10	F	35.8	82	6.668	30.35	34.72	4.15	102.5
Mean		27.96	84.90	6.99	34.57	36.26	4.01	93.98
± S.D.		5	4.28	0.18	5	5	0.21	7.43

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TOX-29
BET-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -4.9
BIOCHEMISTRY DATA OF BI-COTTON SEEDS (NATH SEEDS)
(500 mg/kg B.wt) GROUP OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

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	26.9	44	6.668	36.38	37.93	3.98	78.9
2	M	24.8	79	6.798	29.39	34.19	4.11	98.2
3	M	22.6	90	7.923	31.72	38.72	3.63	108.4
4	M	23.9	93	6.878	40.52	37.84	4.14	92.6
5	M	31.4	84	6.944	28.38	32.81	3.87	109.5
6	M	30.5	86	7.089	36.35	28.84	4.12	97.2
7	M	29.6	93	7.246	33.89	37.79	4.37	79.8
8	M	30.1	78	7.246	29.31	43.12	3.72	91.6
9	M	21.4	80	6.788	39.83	41.33	3.88	98.3
10	M	29.8	86	7.614	36.56	40.38	4.19	87.2
Mean		27.3	84.8	7.0	34.79	37.59	4.07	93.27
\pm		\pm	\pm	\pm	\pm	\pm	\pm	\pm
S.D		3.52	4.94	0.29	4.38	3.84	0.32	9.27

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -4.10
BIOCHEMISTRY DATA OF OF BT-COTTON SEEDS (NATH SEEDS)
(500 mg/kg B.wt) GROUP OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

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	F	26.2	88	6.944	33.60	35.26	3.97	99.3
2	F	21.3	81	6.668	35.70	38.56	4.00	92.7
3	F	29.3	84	6.894	37.29	35.29	3.66	93.7
4	F	23.8	90	6.979	32.70	38.22	4.18	100.1
5	F	36.9	86	7.013	35.84	38.56	3.92	102.5
6	F	21.6	79	7.266	32.16	40.47	3.82	98.3
7	F	28.4	81	7.013	24.36	41.38	4.00	94.6
8	F	29.0	83	6.722	29.39	29.86	3.80	80.1
9	F	24.8	86	7.266	35.39	41.33	3.87	83.9
10	F	25.0	89	7.649	38.22	28.58	4.01	105.0
Mean \pm S.D		26.23 \pm 3.21	84.90 \pm 3.54	7.04 \pm 0.29	35.68 \pm 4.17	36.75 \pm 4.57	3.91 \pm 0.15	95.08 \pm 7.43

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Bt-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 4.11
BIOCHEMISTRY DATA OF OF Bt-COTTON SEEDS (NATH SEEDS)
(1000 mg/kg B.wt.) GROUP OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal No.	Sex	BUN (mg %)	Glucose (mg %)	Total Protein (gm%)	S.G.P.T 1.U	S.G.O.T 1.U	Albumin (gm%)	SAP U/L
1	M	29.3	78	6.944	36.36	37.92	3.74	96.7
2	M	27.8	85	6.668	34.91	32.92	4.07	102.4
3	M	31.6	83	7.286	38.74	37.80	4.16	97.2
4	M	26.2	86	6.979	28.94	38.33	3.95	86.1
5	M	28.7	78	6.834	39.77	39.97	3.73	88.6
6	M	29.5	85	7.644	38.33	39.63	3.81	78.7
7	M	27.3	88	7.322	37.32	41.13	4.12	105.2
8	M	22.8	93	7.089	32.87	40.12	3.97	99.4
9	M	28.3	82	7.286	39.94	42.19	4.13	107.3
10	M	25.0	90	6.894	33.66	34.20	4.01	77.8
Mean		26.77	84.8	7.09	35.83	38.50	3.96	93.74
± S.D.		^a 5.27	^b 4.32	^c 0.28	^d 3.49	^e 2.92	^f 0.16	^g 10.36

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TONICITY STUDY IN RATS

TABLE - 4.12
BIOCHEMISTRY DATA OF OF Bi-COTTON SEEDS (NATH SEEDS)
(1000 mg/kg B.wt.) GROUP OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal No.	Sex	B.I.N (mg %)	Glucose (mg %)	Total Protein (gm %)	S.G.P.T IU	S.G.O.T IU	Albumin (gm %)	S.A.P IU/L
1	F	30.8	80	6.976	29.93	29.23	4.14	100.2
2	F	36.2	92	6.975	32.10	40.14	3.88	95.6
3	F	28.0	82	6.834	33.41	34.96	4.05	86.7
4	F	30.2	85	7.389	38.28	38.82	4.14	99.5
5	F	25.6	91	7.211	33.63	36.37	3.64	102.8
6	F	21.6	84	7.623	29.31	31.92	3.75	95.2
7	F	30.1	83	6.744	38.09	38.63	4.01	97.5
8	F	28.4	89	7.211	38.74	37.84	3.80	98.6
9	F	29.8	82	7.259	28.94	31.89	3.97	86.2
10	F	23.4	94	7.689	32.83	38.25	3.94	101.3
Mean		27.46	85.2	7.12	33.45	36.82	3.92	96.36
± S.D		± 3.13	± 4.07	± 0.25	± 0.6	± 2.71	± 0.16	± 5.72

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE -4.12
BIOCHEMISTRY DATA OF BT-COTTON SEEDS (NATH SEEDS)
(1000 mg/kg B.wt.) GROUP OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal No.	Sex	BUN (mg %)	Glycose (mg %)	Total Protein (gm%)	S.G.P.T L.U.	S.G.O.T L.U.	Albumin (gm%)	SAP U/L
1	F	30.8	80	6.976	28.93	39.23	4.14	100.2
2	F	26.2	92	6.979	32.40	46.14	3.58	95.6
3	F	28.0	82	6.834	33.41	34.96	4.05	86.7
4	F	30.2	85	7.269	38.28	38.81	4.14	99.5
5	F	23.0	91	7.211	33.63	36.37	3.64	102.8
6	F	21.6	84	7.635	29.31	31.92	3.75	98.2
7	F	20.1	83	6.744	33.09	28.83	4.01	97.5
8	F	28.9	89	7.211	38.74	37.84	3.46	94.6
9	F	29.8	82	7.269	28.94	31.89	3.92	86.2
10	F	25.4	84	7.089	32.83	38.25	3.95	101.3
Mean		27.46	85.2	7.12	33.55	36.82	3.92	96.36
± S.D.		3.13	± 4.07	± 0.25	± 3.21	± 2.98	± 0.16	± 5.72

APPENDIX - 5

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE- 5.1
URINE ANALYSIS DATA OF CONTROL DOSE (GROUNDNUT OIL ONLY) GROUP OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

S.No.	Colour of Appearance	Sp. Gravity	NO ₂	pH	Protein	Glucose	Ketones	Urobil	Biliru	WBC	RBC	Epithelial cell	Cast	Bacteria	Crystals
1.	TP	1.020	--	8	+	++	--	--	--	++	++	+	+	+	+
2.	TPV	1.025	--	8	-	++	--	--	--	--	--	+	+	+	+
3.	TP	1.030	--	7	-	--	--	--	--	--	--	+	-	-	-
4.	TV	1.025	--	9	+	--	--	--	--	--	--	+	+	+	+
5.	TPV	1.020	--	7	+	--	--	--	--	--	--	+	-	-	-
6.	TP	1.030	--	8	+	--	--	--	--	--	--	+	+	+	+
7.	TPV	1.020	--	7	-	--	--	--	--	--	--	+	-	-	-
8.	TP	1.050	--	9	+	--	--	--	--	--	--	+	+	+	+
9.	TV	1.015	--	7	-	--	--	--	--	--	--	+	-	-	-
10.	TP	1.020	--	7	+	--	--	--	--	--	--	+	-	-	-

TV : TURID YELLOW TPV : TURID PALE YELLOW TP : TURID PALE + : Slight
++ : Moderate ± : Traces

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE-5.2
URINE ANALYSIS DATA OF CONTROL DOSE (GROUNDNUT OIL ONLY) GROUP OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

S.No.	Colour of Appearance	Sp. Gravity	NO ₁	pH	Protein	Glucose	Ketones	Urobil.	Biliru.	WBC	RBC	Epithelial cell	Cast	Bacteria	Crystals
1.	TPY	1.015	++	9	-	+++	---	---	---	+++	+++	+	+	+	+
2.	TY	1.050	++	9	+	---	---	---	---	---	---	+	+	+	+
3.	TP	1.010	++	8	-	---	---	---	---	---	---	+	+	+	+
4.	TPY	1.050	++	7	-	---	---	---	---	---	---	+	+	+	+
5.	TY	1.020	++	7	+	---	---	---	---	---	---	+	+	+	+
6.	TPY	1.030	++	8	-	---	---	---	---	---	---	+	+	+	+
7.	TY	1.025	++	8	+	---	---	---	---	---	---	+	+	+	+
8.	TP	1.015	++	7	-	+++	---	---	---	---	---	+	+	+	+
9.	TY	1.030	++	8	+	---	---	---	---	---	---	+	+	+	+
10.	TPY	1.025	++	7	-	---	---	---	---	---	---	+	+	+	+

TY : TURRID YELLOW TPY : TURRID PALE YELLOW TP : TURRID PALE +: Slight ++: Moderate ± : Traces

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE-5.3
URINE ANALYSIS DATA OF NON TRANSGENIC GROUP OF MALE RATS
DOSE : 500 mg/kg B.wt DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

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BT-COTTON SEEDS (NATI SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS
TABLE-5.4
URINE ANALYSIS DATA OF NON TRANSGENIC GROUP OF FEMALE RATS
DOSE : 500 mg/kg,B.wt DURATION : 90 DAYS **TIME : TERMINAL SACRIFICE**

S.No.	Colour of Appearance	Sp. Gravity	NO ₂	pH	Protein	Glucose	Ketones	Urobil	Biliru	WBC	RBC	Epithelial cell	Cast	Bacteria	Crystals
1.	TP	1.035	--	9	+	--	--	--	--	--	--	+	+	-	*
2.	TV	1.010	--	8	+	--	--	--	--	--	--	+	-	-	-
3.	TPY	1.030	--	8	+	--	--	--	--	--	--	+	-	+	+
4.	TV	1.020	--	7	+	--	--	--	--	--	--	+	-	-	-
5.	TV	1.050	--	8	+	--	--	--	--	--	--	+	-	-	-
6.	TP	1.015	--	8	+	--	--	--	--	--	--	+	-	-	+
7.	TV	1.020	--	7	+	--	--	--	--	--	--	+	-	-	-
8.	TPY	1.035	--	9	+	--	--	--	--	--	--	+	+	-	-
9.	TP	1.025	--	7	+	--	--	--	--	--	--	+	+	-	-
10.	TPY	1.070	--	8	+	--	--	--	--	--	--	+	-	+	+

TY: TURID YELLOW TPY : TURID PALE YELLOW TP : TURID PALE

++: Slight ++: Moderate +: Moderate

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BT-COTTON SEEDS (NATHE SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE-5-5
URINE ANALYSIS DATA OF NON TRANSGENIC GROUP OF MALE RATS
DOSE : 1600 mg/kg.B.wt DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

S.No.	Appearance	Colour of Sp. Gravity	NO _x	pH	Protein	Glucone	Ketones	Urobil	Biliru	WBC	RBC	Epithelial cell	Cast	Bacteria	Crystals
1.	TP	1.050	—	7	+	—	—	—	—	—	—	—	—	+	+
2.	TPY	1.030	—	9	±	++	++	—	—	—	—	—	+	+	+
3.	TPY	1.025	—	8	±	++	++	—	—	—	—	—	+	+	+
4.	TY	1.015	—	7	—	—	—	—	—	—	—	—	—	—	—
5.	TP	1.010	—	8	—	—	—	—	—	—	—	—	—	—	—
6.	TPY	1.020	—	7	±	++	++	—	—	—	—	—	+	+	+
7.	TPY	1.020	—	9	±	++	++	—	—	—	—	—	+	+	+
8.	TP	1.015	—	7	+	—	—	—	—	—	—	—	—	+	—
9.	TY	1.030	—	7	±	—	—	—	—	—	—	—	—	—	—
10.	TP	1.010	—	8	—	—	—	—	—	—	—	—	—	+	+
TY : TURBID YELLOW TPY : TURBID PALE YELLOW												TP : TURBID PALE	+ ; Slight	+++ Moderate	++ : +

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SHRI RAM INSTITUTE

TOX-259
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE-5.6
URINE ANALYSIS DATA OF NON TRANSGENIC GROUP OF FEMALE RATS
DOSE : 1000 mg/kg,B.wt DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

S.No.	Colour of Appearance	Sp Gravity	NO ₂	pH	Protein	Glucose	Ketones	Urobilin	Biliru	WBC	RBC	Epithelial cell	Cast	Bacteria	Crystals
1.	TP	1.030	++	8	+	+++	+++	+++	+++	+++	+++	+++	+	+	+
2.	TP	1.015	++	7	-	+++	+++	+++	+++	+++	+++	+++	-	-	-
3.	TP	1.015	++	7	+	+++	+++	+++	+++	+++	+++	+++	-	-	-
4.	TY	1.025	++	7	-	+++	+++	+++	+++	+++	+++	+++	-	-	-
5.	TPY	1.050	++	9	+	+++	+++	+++	+++	+++	+++	+++	+	+	+
6.	TPY	1.020	++	9	-	+++	+++	+++	+++	+++	+++	+++	+	+	+
7.	TY	1.015	++	7	-	+++	+++	+++	+++	+++	+++	+++	+	+	+
8.	TPY	1.030	++	9	+	+++	+++	+++	+++	+++	+++	+++	-	-	-
9.	TP	1.010	++	7	-	+++	+++	+++	+++	+++	+++	+++	-	-	-
10.	TY	1.020	++	8	-	+++	+++	+++	+++	+++	+++	+++	+	+	+

TY : TURBID YELLOW TPY : TURRID PALE YELLOW TP : TURRID PALE + : Slight ++ : Moderate = : Traces

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SHRI RAM INSTITUTE

TOX-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE-5.7
URINE ANALYSIS DATA OF TRANSGENIC GROUP OF MALE RATS
DOSE : 500 mg/kg.B.wt DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

S.No.	Colour of Sp. Appearance	Sp. Gravity	NO ₂	pH	Protein	Glucose	Ketones	Urobil.	Biliru.	WBC	RBC	Epithelial cell	Cast	Bacteria	Crystals
1.	TY	1.010	—	7	+	—	—	—	—	—	—	—	—	+	—
2.	TY	1.030	—	8	—	++	—	—	—	—	—	—	—	—	—
3.	TP	1.040	—	9	—	++	—	—	—	—	—	—	—	—	—
4.	TP	1.020	—	8	+	—	—	—	—	—	—	—	—	+	+
5.	TPY	1.030	—	9	+	—	—	—	—	—	—	—	—	+	+
6.	TPY	1.015	—	9	+	—	—	—	—	—	—	—	—	+	+
7.	TY	1.010	—	7	—	—	—	—	—	—	—	—	—	+	—
8.	TP	1.025	—	7	+	—	—	—	—	—	—	—	—	+	+
9.	TP	1.015	—	8	+	—	—	—	—	—	—	—	—	—	—
10.	TPY	1.020	—	9	+	—	—	—	—	—	—	—	—	+	—

TY : TURBID YELLOW TPY : TURBID PALE YELLOW TP : TURBID PALE + : Slight ++ : Moderate ± : Traces

SHRI RAM INSTITUTE

TOX-290
BE-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE-5.8
URINE ANALYSIS DATA OF BE-COTTON SEEDS (NATH SEEDS) GROUP OF FEMALE RATS
DOSE : 500 mg/kg.B.wt DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

S.No.	Color of Appearance	Sp. Gravity	Nit.	pH	Protein	Glucose	Ketones	Urobil.	Hb/Hct	WBC	RBC	Epithelial cell	Cast	Bacteria	Crystals
1.	TPY	1.010	++	7	-	--	--	--	--	++	+	-	-	-	-
2.	TP	1.025	++	7	-	--	--	--	--	-	-	-	-	-	-
3.	TV	1.050	++	8	-	--	--	--	--	-	-	-	-	-	-
4.	TPY	1.050	++	9	-	--	--	--	--	-	-	-	-	-	-
5.	TV	1.050	++	8	-	--	--	--	--	-	-	-	-	-	-
6.	TV	1.020	++	7	-	--	--	--	--	-	-	-	-	-	-
7.	TP	1.025	++	8	-	--	--	--	--	-	-	-	-	-	-
8.	TP	1.015	++	7	-	--	--	--	--	-	-	-	-	-	-
9.	TPY	1.050	++	8	-	--	--	--	--	-	-	-	-	-	-
10.	TPY	1.050	++	9	-	--	--	--	--	-	-	-	-	-	-

TY : TURBID YELLOW TPY : TURBID PALE YELLOW TP : TURBID PALE

* : Slight ** : Moderate *** : Traces

SHRI RAM INSTITUTE

TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE-5.9

URINE ANALYSIS DATA OF BT-COTTON SEEDS (NATH SEEDS) GROUP OF MALE RATS
DOSE : 1000 mg/kg,B.wt DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

S.No.	Colour of Appearance	Sp. Gravity	NO ₂	pH	Protein	Glucose	Ketones	Urobil.	Biliru.	WBC	RBC	Epithelial cell	Cat.	Bacteria	Crystals
1.	TPY	1.030	—	9	+	—	—	—	—	+++	+++	—	+	+	+
2.	TPY	1.020	—	7	+	—	—	—	—	+++	+++	—	—	—	+
3.	TPY	1.010	—	7	+	—	—	—	—	+++	+++	—	—	—	—
4.	TY	1.030	—	7	+	—	—	—	—	+++	+++	—	—	—	—
5.	TY	1.020	—	8	+	—	—	—	—	++	++	—	—	—	—
6.	TP	1.015	—	7	+	—	—	—	—	++	++	—	—	—	—
7.	TP	1.025	—	8	+	—	—	—	—	++	++	—	—	—	—
8.	TY	1.015	—	7	+	—	—	—	—	++	++	—	—	—	—
9.	TP	1.020	—	7	+	—	—	—	—	++	++	—	—	—	—
10.	TPY	1.030	—	8	+	—	—	—	—	++	++	—	—	—	—

TY : TURRID YELLOW TPY : TURRID PALE YELLOW TP : TURRID PALE + : Slight ++ : Moderate * : Traces

SHIRIRAM INSTITUTE

TOX-299
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE-5.10
URINE ANALYSIS DATA OF BT-COTTON SEEDS (NATH SEEDS) GROUP OF FEMALE RATS
DOSE : 1000 mg/kg.B.wt DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

S.No.	Color of Appearance	Sp. Gravity	NO ₂	pH	Protein	Glucose	Ketones	Urobil	Bilir	WBC	RBC	Epithelial cell	Cast	Bacterin	Crystals
1.	TP	1.030	---	8	±	—	—	—	—	—	—	—	+	+	+
2.	TY	1.020	---	7	+	++	++	++	++	—	—	—	+	+	—
3.	TY	1.015	---	8	—	—	—	—	—	—	—	—	+	+	—
4.	TPY	1.030	---	9	±	++	++	++	++	—	—	—	+	—	—
5.	TPY	1.015	---	9	+	++	++	++	++	—	—	—	+	+	+
6.	TPY	1.025	---	8	+	++	++	++	++	—	—	—	+	+	—
7.	TP	1.015	—	7	—	—	—	—	—	—	—	—	—	—	—
8.	TP	1.020	---	7	—	—	—	—	—	—	—	—	—	—	—
9.	TY	1.020	—	8	—	++	++	++	++	—	—	—	+	—	—
10.	TY	1.010	—	7	—	—	—	—	—	—	—	—	—	+	+

TY : TURBID YELLOW TPY : TURBID PALE YELLOW TP : TURBID PALE + : Slight ++ : Moderate ± : Traces

APPENDIX - 6

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.1
MEAN PERCENTILE ORGAN WEIGHT DATA OF MALE RATS AT TERMINAL SACRIFICE

Organs	POSAGE GROUP			
	Control (Given GROUT/SDUT oil only)	No-Transgenic cotton seeds 500 mg/kg.B.wt.	1000 mg/kg.B.wt.	Bi-cotton seeds (Nath seeds) 500 mg/kg.B.wt
Lung	0.72 ± 0.05	0.65 ± 0.07	0.69 ± 0.09	0.69 ± 0.04
Liver	3.13 ± 0.40	3.08 ± 0.60	2.99 ± 0.21	3.01 ± 0.50
Kidney	0.30 ± 0.13	0.70 ± 0.15	0.74 ± 0.09	0.69 ± 0.05
Testis	0.98 ± 0.21	0.89 ± 0.05	1.00 ± 0.18	0.97 ± 0.10
Adrenal	0.02 ± 0.004	0.016 ± 0.003	0.016 ± 0.004	0.02 ± 0.003
Heart	0.17 ± 0.08	0.33 ± 0.06	0.34 ± 0.04	0.33 ± 0.03
Spleen	0.26 ± 0.03	0.20 ± 0.03	0.21 ± 0.04	0.22 ± 0.03
Brain	0.70 ± 0.13	0.66 ± 0.05	0.69 ± 0.71	0.69 ± 0.07

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BT-COTTON SEEDS (MATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS
TABLE - 6.2
MEAN PERCENTILE ORGAN WEIGHT DATA OF FEMALE RATS AT TERMINAL SACRIFICE

Organ	Control (Given GROUNDNUT oil only)	DOSAGE GROUP		
		Non - Transgenic cotton seeds 500 mg/kg.B.wt.	1000 mg/kg.B.wt	Bi-cotton seeds (Non seeds) 1000 mg/kg.B.wt
Lung	0.74 ± 0.09	0.78 ± 0.08	0.82 ± 0.15	0.84 ± 0.13
Liver	1.18 ± 0.30	3.50 ± 0.34	3.42 ± 0.68	3.35 ± 0.29
Kidney	0.69 ± 0.06	0.70 ± 0.04	0.68 ± 0.12	0.68 ± 0.08
Ovaries	0.03 ± 0.003	0.03 ± 0.008	0.034 ± 0.009	0.04 ± 0.012
Uterus	0.24 ± 0.07	0.20 ± 0.03	0.21 ± 0.09	0.26 ± 0.13
Adrenal	0.02 ± 0.003	0.02 ± 0.003	0.016 ± 0.003	0.023 ± 0.004
Heart	0.33 ± 0.08	0.34 ± 0.03	0.33 ± 0.06	0.31 ± 0.03
Spleen	0.25 ± 0.06	0.24 ± 0.04	0.27 ± 0.10	0.23 ± 0.045
Brain	0.81 ± 0.07	0.80 ± 0.06	0.77 ± 0.09	0.78 ± 0.04

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.3
AVERAGE ORGAN WEIGHT DATA OF MALE RATS AT TERMINAL SACRIFICE

Organ	Control (Given GRC/SDNU/T oil only)	Dosage Group		
		Non-Transgenic cotton seeds 500 mg/kg.B.wt.	1000 mg/kg.B.wt.	Bi-cotton seed (Nath seeds) 500 mg/kg.B.wt.
Lung	2.02 ± 0.19	1.97 ± 0.18	2.01 ± 0.29	1.90 ± 0.14
Liver	8.81 ± 0.79	8.95 ± 1.15	8.73 ± 0.77	8.38 ± 1.43
Kidney	2.25 ± 0.28	2.10 ± 0.19	2.14 ± 0.24	1.90 ± 0.13
Testis	2.74 ± 0.30	2.73 ± 0.12	2.89 ± 0.35	2.66 ± 0.22
Adrenal	0.06 ± 0.01	0.05 ± 0.009	0.03 ± 0.012	0.055 ± 0.013
Heart	1.05 ± 0.16	0.95 ± 0.09	1.00 ± 0.01	0.90 ± 0.07
Spleen	0.63 ± 0.08	0.59 ± 0.12	0.61 ± 0.10	0.62 ± 0.09
Brain	1.95 ± 0.19	2.02 ± 0.15	2.00 ± 0.07	1.87 ± 0.13

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BT, COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.4
AVERAGE ORGAN WEIGHT DATA OF FEMALE RATS AT TERMINAL SACRIFICE

Organs	Control (Given GROUNDSEED oil only)	DOSAGE GROUP		
		500 mg/kg B.wt.	1000 mg/kg B.wt	1000 mg/kg B.wt
Lung	1.83 ± 0.23	1.80 ± 0.17	1.94 ± 0.26	1.93 ± 0.31
Liver	8.34 ± 0.96	7.84 ± 0.98	8.01 ± 1.05	7.69 ± 0.73
Kidney	1.64 ± 0.18	1.60 ± 0.16	1.62 ± 0.19	1.58 ± 0.14
Ovaries	0.076 ± 0.004	0.074 ± 0.012	0.08 ± 0.02	0.085 ± 0.02
Uterus	0.61 ± 0.21	0.47 ± 0.09	0.50 ± 0.17	0.60 ± 0.28
Adrenal	0.05 ± 0.008	0.05 ± 0.05	0.045 ± 0.009	0.033 ± 0.009
Heart	0.83 ± 0.12	0.77 ± 0.11	0.78 ± 0.09	0.73 ± 0.07
Spleen	0.62 ± 0.14	0.57 ± 0.12	0.59 ± 0.08	0.54 ± 0.09
Brain	1.96 ± 0.12	1.83 ± 0.07	1.83 ± 0.08	1.81 ± 0.11

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TOX-290
BT-COTTON SEEDS (MATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.5
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF CONTROL (GROUNDNUT OIL ONLY) GROUP OF
MALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Testis		Adrenal		Heart		Spleen		Brain	
			Wt. in gms	% Body wt														
1	M	251.2	1.93	0.77	8.25	3.28	2.44	0.97	3.00	1.19	0.06	0.02	1.14	0.45	0.70	0.28	2.40	0.95
2	M	259.1	1.91	0.64	9.77	3.26	2.17	0.72	2.18	0.96	0.07	0.02	1.15	0.38	0.72	0.24	1.84	0.63
3	M	281.6	2.00	0.70	9.53	3.36	1.92	0.67	2.97	1.04	0.06	0.02	0.83	0.29	0.63	0.22	2.02	0.71
4	M	307.8	1.97	0.64	9.47	3.07	1.84	0.59	2.61	0.93	0.05	0.04	0.96	0.31	0.49	0.16	1.85	0.60
5	M	247.6	1.87	0.75	7.67	3.17	2.21	0.89	2.03	1.14	0.04	0.06	1.00	0.40	0.60	0.34	2.01	0.62
6	M	337.8	2.47	0.71	8.39	2.48	2.40	0.71	1.63	0.48	0.07	0.02	0.86	0.25	0.75	0.22	1.79	0.53
7	M	286.8	2.01	0.70	8.42	2.95	1.64	0.92	3.36	1.17	0.06	0.02	1.13	0.39	0.63	0.22	1.86	0.65
8	M	302.1	2.23	0.74	9.00	2.97	2.37	0.78	2.33	0.74	0.07	0.02	1.08	0.36	0.66	0.22	1.93	0.64
9	M	241.6	1.87	0.77	9.61	4.06	1.94	0.80	2.63	1.08	0.08	0.05	0.94	0.39	0.63	0.26	2.01	0.64
10	M	265.7	1.94	0.73	7.68	2.91	2.34	0.96	3.20	1.21	0.06	0.02	1.37	0.32	0.51	0.19	1.75	0.66
Mean		282.11	2.02	0.72	8.31	3.15	2.25	0.80	2.74	0.98	0.06	0.02	1.03	0.37	0.63	0.26	1.95	0.70
S.D.		30.91	0.19	0.05	0.79	0.40	0.24	0.13	0.49	0.23	0.01	0.04	0.16	0.08	0.08	0.03	0.19	0.13

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TOX-299
WT- COTTON SEEDS (NATH SEEDS)
WT-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.6
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF CONTROL (GROUNDNUT OIL ONLY) GROUP OF
FEMALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Ovaries		Uterus		Adrenai		Heart		Spleen		Brain		
			Wt. gms	% wt.	Wt. in gms	% wt.															
1	F	254.0	1.85	0.73	9.02	3.55	1.88	0.74	0.08	0.03	0.97	0.58	0.05	0.02	0.86	0.38	0.30	0.20	1.96	0.77	
2	F	247.0	1.77	0.71	7.70	3.16	1.84	0.76	0.07	0.02	0.96	0.56	0.15	0.04	0.016	0.38	0.36	0.74	0.30	1.31	0.73
3	F	226.0	1.35	0.59	7.35	3.46	1.52	0.67	0.08	0.03	0.37	0.23	0.06	0.026	0.96	0.40	0.71	0.31	2.05	0.90	
4	F	223.0	2.08	0.92	7.70	3.42	1.49	0.66	0.06	0.03	0.40	0.17	0.04	0.017	0.99	0.44	0.34	0.24	1.87	0.83	
5	F	256.0	1.70	0.70	10.20	3.98	1.83	0.77	0.08	0.03	0.42	0.16	0.05	0.019	0.94	0.37	0.66	0.26	1.96	0.76	
6	F	264.0	1.98	0.75	9.18	3.47	1.70	0.64	0.07	0.03	0.80	0.30	0.05	0.019	0.96	0.32	0.76	0.29	2.08	0.78	
7	F	249.0	2.07	0.83	8.36	3.55	1.65	0.66	0.08	0.03	0.55	0.21	0.04	0.016	0.74	0.16	0.46	0.18	2.00	0.80	
8	F	271.0	1.82	0.67	7.98	3.93	1.79	0.63	0.09	0.03	0.45	0.20	0.06	0.022	0.71	0.36	0.55	0.19	2.01	0.74	
9	F	249.0	2.03	0.81	8.62	3.46	1.41	0.56	0.07	0.03	0.78	0.31	0.05	0.02	0.93	0.37	0.35	0.14	2.17	0.97	
10	F	225.0	1.65	0.73	6.79	3.01	1.39	0.62	0.08	0.03	0.48	0.21	0.06	0.026	0.61	0.27	0.46	0.20	1.76	0.78	
Mean			246.10	1.81	0.74	8.34	3.58	1.64	0.66	0.08	0.03	0.61	0.24	0.05	0.022	0.85	0.23	0.56	0.81		
± S.D.			16.42	0.23	0.69	0.96	0.29	0.18	0.06	0.00	0.00	0.21	0.07	0.008	0.003	0.12	0.08	0.14	0.06	0.12	

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.7
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC COTTON SEEDS
(500 mg/kg.B.wt) GROUP OF MALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung			Liver			Kidney			Adrenal			Heart			Spleen		
			Wt. in gms	% Wt. in Body wt	Wt. in Body wt gms	Wt. in Body wt gms	% Wt. in Body wt													
1	M	323.04	2.08	0.64	8.69	2.69	2.14	0.66	2.96	0.91	0.04	0.01	1.02	0.32	0.75	0.25	1.97	0.60		
2	M	322.30	1.74	0.54	9.47	2.83	3.09	0.63	2.80	0.84	0.06	0.02	1.05	0.31	0.60	0.18	1.94	0.58		
3	M	298.62	2.15	0.71	7.38	4.41	1.98	1.10	2.73	0.98	0.04	0.02	0.87	0.48	0.41	0.23	2.02	0.72		
4	M	286.09	1.92	0.67	8.38	2.93	1.91	0.66	2.53	0.88	0.03	0.017	0.96	0.33	0.54	0.18	1.94	0.68		
5	M	326.30	2.34	0.71	9.98	3.04	2.41	0.73	2.77	0.84	0.05	0.015	0.95	0.29	0.52	0.16	1.92	0.59		
6	M	292.94	1.89	0.65	10.78	3.60	2.14	0.73	2.65	0.90	0.04	0.014	0.91	0.31	0.72	0.25	1.96	0.67		
7	M	301.62	2.05	0.68	10.39	3.44	2.46	0.66	2.61	0.86	0.03	0.016	0.86	0.32	0.80	0.26	1.96	0.68		
8	M	326.68	1.83	0.56	8.29	2.51	2.00	0.61	2.65	0.81	0.06	0.018	0.90	0.27	0.54	0.16	1.43	0.74		
9	M	294.32	1.78	0.60	7.75	2.46	1.92	0.59	2.79	0.94	0.04	0.014	0.82	0.28	0.49	0.17	1.92	0.65		
10	M	298.73	1.63	0.61	8.48	2.83	1.95	0.65	2.81	0.94	0.038	0.016	1.12	0.37	0.57	0.19	2.07	0.69		
Mean		306.17	1.97	0.65	8.95	3.08	2.10	0.70	2.73	0.89	0.046	0.016	0.91	0.33	0.59	0.20	1.92	0.66		
S.E.		0.07	1.15	0.60	0.20	0.15	0.12	—	—	—	—	—	0.09	0.005	0.12	0.05	—	—		
S.D.		19.59	0.19	0.07	—	—	—	—	—	—	—	—	—	—	—	—	—	—		

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TOX-290
BT-COTTON SEEDS (NATU SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.8
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC COTTON SEEDS (500 mg/kg.B.wt.) GROUP OF
FEMALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in grams	Lung	Liver	Kidney	Ovaries	Uterus	Adrenal	Heart	Spleen	Brain	
		Wt. in Body wt.	%	Wt. in Body wt.	%	Wt. in Body wt.	%	Wt. in Body wt.	%	Wt. in Body wt.	%	
		grms	wt.	grms	wt.	grms	wt.	grms	wt.	grms	wt.	
1	F	210.3	1.83	0.79	7.67	3.53	1.68	0.75	0.08	0.03	0.61	0.26
2	F	231.3	1.99	0.85	6.71	2.90	1.53	0.66	0.06	0.02	0.53	0.23
3	F	259.3	1.82	0.76	7.29	3.04	1.60	0.67	0.06	0.02	0.52	0.22
4	F	244.4	1.78	0.73	8.58	3.51	1.64	0.69	0.08	0.03	0.42	0.17
5	F	198.8	1.99	0.95	7.72	3.80	1.45	0.73	0.08	0.04	0.59	0.19
6	F	227.9	1.68	0.74	8.21	3.60	1.46	0.64	0.08	0.03	0.55	0.24
7	F	234.5	1.66	0.76	7.90	3.37	1.67	0.71	0.05	0.02	0.44	0.19
8	F	250.6	2.13	0.85	10.11	4.04	1.96	0.78	0.09	0.03	0.60	0.25
9	F	208.4	1.59	0.76	6.91	3.11	1.40	0.67	0.08	0.04	0.38	0.18
10	F	229.1	1.62	0.73	7.28	3.30	1.59	0.72	0.08	0.04	0.42	0.19
Mean		228.56	1.89	0.78	7.84	3.50	1.60	0.70	0.074	0.03	0.47	0.20
S.D.		15.85	0.17	0.08	0.98	0.34	0.16	0.04	0.01	0.008	0.09	0.03

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TOX-290
BT. COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.9
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC COTTON SEEDS
(1000 mg/kg-B.wt) GROUP OF MALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung			Liver			Kidney			Testis			Adrenal			Heart			Spleen			Brain		
			Wt in gms	%	Wt in Body wt	Wt in gms	%	Wt in Body wt	Wt in gms	%	Wt in Body wt	Wt in gms	%	Wt in Body wt	Wt in gms	%	Wt in Body wt	Wt in gms	%	Wt in Body wt	Wt in gms	%	Wt in Body wt	Wt in gms	%	
1	M	292.7	1.90	0.65	1.92	3.05	1.90	0.65	2.80	0.95	0.03	0.010	0.96	0.33	0.55	0.19	2.12	0.72	—	—	—	—	—	—		
2	M	332.9	2.27	0.69	9.83	2.78	2.43	0.69	2.95	0.84	0.03	0.008	0.98	0.27	0.68	0.19	1.99	0.56	—	—	—	—	—	—		
3	M	318.9	2.31	0.72	9.40	3.07	2.02	0.63	2.82	0.88	0.06	0.018	1.15	0.36	0.61	0.19	2.00	0.63	—	—	—	—	—	—		
4	M	367.1	1.68	0.63	7.72	2.89	1.87	0.70	2.96	1.10	0.04	0.015	0.81	0.30	0.49	0.18	2.94	0.76	—	—	—	—	—	—		
5	M	298.3	1.61	0.54	8.93	2.99	2.06	0.69	2.21	0.75	0.06	0.02	1.01	0.34	0.36	0.18	2.02	0.67	—	—	—	—	—	—		
6	M	359.6	1.62	0.62	7.79	3.00	1.92	0.75	2.90	1.12	0.04	0.015	0.92	0.35	0.44	0.17	2.94	0.78	—	—	—	—	—	—		
7	M	366.3	2.15	0.60	8.39	3.11	2.31	0.86	3.29	1.22	0.05	0.018	1.06	0.39	0.70	0.25	1.87	0.69	—	—	—	—	—	—		
8	M	295.4	2.17	0.80	9.23	3.12	2.37	0.87	3.16	1.07	0.06	0.02	1.01	0.35	0.64	0.22	2.06	0.69	—	—	—	—	—	—		
9	M	362.7	2.14	0.81	8.56	3.33	2.26	0.86	3.38	1.28	0.05	0.019	1.11	0.42	0.79	0.30	2.01	0.76	—	—	—	—	—	—		
10	M	310.1	2.07	0.67	7.92	2.55	2.07	0.67	2.51	0.90	0.06	0.019	1.02	0.33	0.67	0.21	1.90	0.61	—	—	—	—	—	—		
Mean		282.74	2.01	0.69	8.73	2.99	2.14	0.74	2.99	1.00	0.05	0.016	1.00	0.34	0.61	0.21	2.00	0.69	—	—	—	—	—	—		
S.D.		29.54	0.29	0.01	0.77	0.21	0.24	0.09	0.35	0.18	0.05	0.004	0.096	0.04	0.10	0.04	0.07	0.71	—	—	—	—	—	—		

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TOX-299
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.10
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF NON-TRANSGENIC COTTON SEEDS
(1000 mg/kg Body) GROUP OF FEMALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Ovaria		Uterus		Adrenal		Heart		Spleen		Brain	
			WL in gms	%	WL in gms	%	WL in gms	%	WL in gms	%	WL in gms	%	WL in gms	%						
1	F	269.6	2.00	0.95	9.69	4.62	1.86	0.88	0.07	0.03	0.51	0.24	0.04	0.019	0.94	0.45	0.57	0.27	1.92	0.92
2	F	244.8	1.41	0.57	6.31	2.58	1.35	0.53	0.07	0.03	0.46	0.19	0.03	0.012	0.67	0.27	0.72	0.29	1.90	0.78
3	F	274.0	1.86	0.67	7.80	2.84	1.51	0.55	0.07	0.03	0.34	0.17	0.06	0.012	0.79	0.28	0.71	0.26	1.80	0.65
4	F	229.1	1.02	0.54	8.12	3.54	1.68	0.75	0.06	0.026	0.52	0.22	0.05	0.02	0.77	0.34	0.47	0.20	1.96	0.85
5	F	235.0	1.76	0.75	7.64	3.25	1.49	0.63	0.06	0.03	0.39	0.16	0.04	0.017	0.75	0.32	0.58	0.23	1.86	0.79
6	F	237.0	2.44	1.03	9.52	4.01	1.96	0.82	0.08	0.03	0.60	0.25	0.04	0.017	0.93	0.39	0.62	0.26	1.86	0.78
7	F	224.8	2.08	0.92	8.48	3.77	1.56	0.69	0.09	0.04	0.71	0.32	0.05	0.022	0.67	0.30	0.64	0.28	1.75	0.76
8	F	218.3	2.14	0.98	8.71	3.98	1.78	0.81	0.10	0.05	0.84	0.38	0.04	0.018	0.84	0.38	0.58	0.26	1.83	0.84
9	F	266.6	1.87	0.70	7.27	2.75	1.33	0.57	0.08	0.03	0.30	0.11	0.04	0.015	0.77	0.26	0.53	0.19	1.73	0.65
10	F	252.8	1.95	0.77	7.23	2.86	1.52	0.60	0.14	0.05	0.37	0.15	0.06	0.023	0.69	0.27	0.52	0.20	1.72	0.64
Mean [±] S.D.		239.26	1.94	0.82	8.01	3.42	1.92	0.88	0.08	0.04	0.50	0.21	0.05	0.018	0.78	0.33	0.59	0.27	1.83	0.77
		20.72	0.26	0.15	1.05	0.68	0.19	0.12	0.02	0.009	0.17	0.09	0.009	0.003	0.09	0.06	0.08	0.11	0.08	0.09

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.11
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF BT-COTTON SEEDS (NATH SEEDS)
(500 mg/kg,B.wt) GROUP OF MALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung			Liver			Kidney			Testis			Adrenal			Heart			Spleen			Brain		
			Wt. in gms	% Body wt	Wt. in gms	Wt. in gms	% Body wt																			
1	M	217.6	1.63	0.73	5.89	2.61	1.54	0.70	2.26	1.03	0.04	0.018	0.46	0.39	0.59	0.23	1.77	0.81								
2	M	277.4	1.86	0.67	7.10	2.56	1.72	0.62	2.49	0.89	0.06	0.03	0.83	0.30	0.71	0.25	1.79	0.61								
3	M	301.7	1.88	0.62	8.85	2.93	1.01	0.59	2.56	0.85	0.05	0.016	0.98	0.33	0.76	0.25	2.07	0.69								
4	M	255.3	1.76	0.69	7.65	2.99	1.15	0.68	2.64	1.03	0.05	0.019	0.79	0.31	0.49	0.19	1.97	0.77								
5	M	318.5	2.15	0.67	10.84	3.40	2.17	0.74	2.90	0.91	0.04	0.012	0.99	0.31	0.55	0.17	1.92	0.60								
6	M	260.8	1.95	0.69	8.88	3.16	1.92	0.68	2.96	1.05	0.04	0.014	0.95	0.34	0.62	0.22	1.85	0.69								
7	M	252.0	1.90	0.75	7.80	3.09	1.03	0.73	2.90	1.15	0.07	0.027	0.88	0.35	0.59	0.25	1.69	0.67								
8	M	281.0	1.93	0.69	8.20	2.95	1.98	0.70	2.99	1.06	0.07	0.025	0.81	0.29	0.70	0.25	1.98	0.70								
9	M	292.4	2.00	0.68	9.77	3.34	2.07	0.76	2.89	0.98	0.07	0.024	0.91	0.31	0.62	0.21	1.76	0.62								
10	M	258.7	1.93	0.73	8.91	3.44	2.04	0.78	2.12	0.82	0.06	0.023	0.98	0.38	0.64	0.25	1.93	0.74								
Mean		273.60	1.90	0.69	8.38	3.05	1.90	0.69	2.66	0.97	0.055	0.02	0.90	0.33	0.62	0.22	1.87	0.69								
S.D.		28.75	0.14	0.04	1.43	0.30	0.23	0.08	0.32	0.10	0.013	0.005	0.07	0.024	0.09	0.05	0.13	0.07								

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TOX-290
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.12
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF BT-COTTON SEEDS (NATH SEEDS)

Animal No	Sex	Body Weight in gms	500 mg/kg B.wt.) GROUP OF FEMALE RATS AT TERMINAL SACRIFICE			500 mg/kg B.wt.) GROUP OF FEMALE RATS AT TERMINAL SACRIFICE			500 mg/kg B.wt.) GROUP OF FEMALE RATS AT TERMINAL SACRIFICE		
			Lung	Liver	Kidney	Ovaries	Uterus	Adrenal	Heart	Spleen	Brain
1	F	249.6	1.92	6.77	7.89	3.16	1.39	0.53	0.08	0.15	0.37
2	F	252.3	1.28	0.90	3.79	3.48	1.75	0.69	0.08	0.13	0.31
3	F	237.8	1.55	0.65	7.92	3.33	1.79	0.58	0.08	0.10	0.60
4	F	229.8	1.65	0.71	8.86	2.98	1.46	0.65	0.08	0.14	0.55
5	F	240.7	2.46	1.02	7.63	3.17	1.69	0.70	0.12	0.15	0.66
6	F	219.8	2.16	0.98	7.83	3.56	1.71	0.78	0.10	0.14	0.74
7	F	212.7	1.71	0.80	6.67	3.17	1.56	0.77	0.12	0.16	0.71
8	F	220.3	2.21	1.00	8.82	4.00	1.72	0.78	0.08	0.13	0.40
9	F	218.9	1.89	0.86	6.95	3.17	1.53	0.72	0.13	0.06	0.39
10	F	217.6	1.67	0.76	7.58	3.48	1.54	0.70	0.08	0.14	0.41
Mean		229.65	1.95	0.84	7.69	3.35	1.57	0.68	0.09	0.14	0.60
S.D.		± 14.26	± 0.21	± 0.13	0.73	0.29	0.14	0.07	± 0.012	± 0.015	0.04

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.13
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF BT-COTTON SEEDS (NATH SEEDS)
(1000 mg/kg.B.wt.) GROUP OF MALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Testis		Adrenal		Heart		Spleen		Brain	
			Wt. in gms	%	Wt. in gms	%	Wt. in gms	%	Wt. in gms	%								
1 M	M	272.0	1.55	0.57	6.43	3.34	1.00	0.37	2.37	0.95	0.06	0.022	0.81	0.79	0.49	0.13	1.54	0.56
2 M	M	308.0	2.14	0.69	9.92	3.23	2.14	0.66	3.07	0.94	0.07	0.022	0.97	0.31	0.69	0.22	1.92	0.62
3 M	M	303.0	1.71	0.56	9.41	3.23	2.11	0.69	2.77	0.91	0.06	0.019	0.97	0.32	0.62	0.20	1.93	0.64
4 M	M	285.0	1.97	0.69	8.37	3.11	1.93	0.68	2.62	0.92	0.04	0.014	0.92	0.22	0.55	0.19	1.89	0.66
5 M	M	275.0	2.47	0.90	7.89	2.89	1.90	0.69	2.75	1.00	0.06	0.022	0.88	0.32	0.49	0.18	1.81	0.66
6 M	M	315.0	2.03	0.64	9.08	3.18	2.05	0.65	2.70	0.96	0.05	0.016	0.97	0.31	0.48	0.15	2.11	0.63
7 M	M	270.0	1.71	0.63	7.19	2.56	1.71	0.63	3.08	1.14	0.04	0.015	0.93	0.34	0.59	0.22	1.53	0.56
8 M	M	303.0	1.95	0.64	7.33	2.47	1.95	0.64	2.96	0.97	0.04	0.013	1.01	0.33	0.60	0.20	2.09	0.69
9 M	M	342.0	2.05	0.61	9.87	2.88	2.09	0.61	3.01	1.01	0.06	0.017	1.18	0.34	0.56	0.17	1.81	0.56
10 M	M	376	1.49	0.58	8.02	4.55	1.39	0.68	2.87	1.06	0.04	0.023	0.91	0.35	0.55	0.20	1.91	0.69
Mean		264.90	1.95	0.66	8.58	3.10	1.86	0.63	2.84	0.97	0.05	0.018	0.96	0.32	0.56	0.19	1.87	0.63
S.D.		23.66	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 6.14
ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF BT-COTTON SEEDS (NATH SEEDS)
(1000 mg/Kg,B.wt.) GROUP OF FEMALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in grams	Lung		Liver		Kidney		Ovaries		Uterus		Adrenal		Heart		Spleen		Brain	
			Wt. in gms	%	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	230.3	1.69	0.71	10.49	4.36	1.71	0.72	0.07	0.03	0.49	0.20	0.08	0.033	0.94	0.40	0.06	0.19	1.82	0.76
2	F	231.3	1.84	0.79	8.76	3.78	1.75	0.70	0.05	0.02	0.55	0.24	0.03	0.011	0.76	0.30	0.05	0.18	1.90	0.87
3	F	234.0	1.83	0.78	6.94	2.96	1.34	0.74	0.07	0.03	0.42	0.18	0.05	0.011	0.92	0.39	0.02	0.20	1.94	0.85
4	F	197.7	1.73	0.87	6.39	3.23	1.43	0.72	0.08	0.04	0.54	0.27	0.06	0.020	0.67	0.24	0.09	0.25	1.78	0.90
5	F	210.7	1.48	0.70	7.11	3.20	1.49	0.71	0.09	0.04	0.58	0.16	0.06	0.030	0.80	0.38	0.05	0.28	1.83	0.86
6	F	210.8	1.97	0.83	7.61	3.63	1.67	0.79	0.07	0.03	0.31	0.15	0.04	0.019	0.89	0.42	0.35	0.26	1.89	0.89
7	F	229.9	1.96	0.86	8.16	3.55	1.48	0.65	0.11	0.05	0.32	0.17	0.06	0.026	0.76	0.33	0.54	0.21	2.00	0.87
8	F	211.3	1.71	0.83	7.78	3.68	1.53	0.72	0.06	0.03	0.30	0.18	0.05	0.029	0.63	0.44	0.37	0.21	1.95	0.92
9	F	211.6	1.56	0.74	6.85	3.23	1.45	0.68	0.08	0.04	0.38	0.18	0.06	0.020	0.76	0.36	0.46	0.22	2.02	0.93
10	F	227.1	1.45	0.64	6.21	3.61	1.46	0.64	0.07	0.03	0.41	0.18	0.06	0.030	0.66	0.29	0.61	0.27	1.95	0.86
Mean		230.30	1.73	0.78	7.42	3.54	1.56	0.71	0.075	0.04	0.47	0.21	0.06	0.026	0.80	0.36	0.55	0.25	1.91	0.87
S.D.		13.43	0.18	0.09	1.16	0.38	0.12	0.04	0.016	0.008	0.14	0.06	0.010	0.005	0.11	0.05	0.06	0.03	0.07	0.054

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APPENDIX - 7

SHIRAM INSTITUTE

TOX-199
BT-COTTON SEEDS (NATHSEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS
TABLE - 7.1
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN CONTROL (GROUNDNUT OIL ONLY)
GROUP OF MALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNGS	LIVER	HEART	GONADS	SPLEEN	KIDNEY	TRIAT	ADRENAL	GASTRO-INTESTINAL TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development

SHIRAM INSTITUTE

TOX-299
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 7.2
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN CONTROL (GROUNDNUT OIL ONLY)
GROUP OF FEMALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development

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SHRI RAM INSTITUTE

TOX-290
BT-COTTON SEEDS (NATI SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 7.3
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN NON TRANSGENIC COTTON SEEDS GROUP
(500 mg/kg,B.wt.) OF MALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GLANDS	SPLIES	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL L-TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development

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TOX-298
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 7.4
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN NON TRANSGENIC COTTON SEEDS GROUP
(500 mg/kg.B.wt.) OF FEMALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO- INTESTINAL TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development

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TOX-290
BT₁-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 7.5
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN NON TRANSGENIC COTTON SEEDS GROUP
(1000 mg/kg.B.wt.) OF MALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development

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TOX-290
BT-COTTON SEEDS (NATH 5SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 7.6
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN NON TRANSGENIC COTTON SEEDS GROUP
(1000 mg/kg B.wt) OF FEMALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)TABLE - 7.7
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN BT. COTTON SEEDS (NATH SEEDS) GROUP
(500 mg/kg.B.wt.) OF MALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development

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BL-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 7.8
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN BL COTTON SEEDS (NATH SEEDS) GROUP
(500 mg/kg.B.wt.) OF FEMALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLENES	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL L-TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development

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BT-COTTON SEEDS (NATH SEEDS)

SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 7.9
 INTENSITY OF GROSS PATHOLOGICAL LESIONS IN BL COTTON SEEDS (NATH SEEDS) GROUP
 (1000 mg/kg,B.WL) OF MALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LONG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development

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BT-COTTON SEEDS (NATH SEEDS)

SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 7.10
 INTENSITY OF GROSS PATHOLOGICAL LESIONS IN BT-COTTON SEEDS (NATH SEEDS) GROUP
 (1000 mg/kg B.wt.) OF FEMALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development

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APPENDIX - 8

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BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 8.1
INTENSITY OF HISTO PATHOLOGICAL LESIONS IN CONTROL (GROUNDNUT OIL ONLY) GROUP
OF MALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	Foci of MNCells NAD	NAD	NAD	NAD	NAD	Slight congestion	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	Slight congestion NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	Foci of MN cells
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development, MNCells : Mononuclear Cells

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TOX-250
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TONICITY STUDY IN RATS

TABLE - 8.2
INTENSITY OF HISTO PATHOLOGICAL LESIONS IN CONTROL (GROUNDNUT OIL ONLY) GROUP
OF FEMALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	Foci of M.N.Cells	Slight fatty changes	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	Slight congestion	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	Foci of M.N.Cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development, M.N.Cells : Mononuclear Cells

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TOX-290
Bt-COTTON SEEDS (MATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS
TABLE - 8.3
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN NON TRANSGENIC COTTON SEEDS GROUP
(500 mg/kg B.wt.) OF MALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLIEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	Slight congestion	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	Foci of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development; MN Cells : Micromucular Cells

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TON²⁹⁰
BT COTTON SEEDS (Bt SEEDS)
SUB-CHRONIC ORAL TONICITY STUDY IN RATS

TABLE - 8.4
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN NON TRANSGENIC COTTON SEEDS GROUP
(500 mg/kg.B.wt) OF FEMALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	Foci of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development, MN Cells : Mononuclear Cells

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TOX-250
BT-COTTON SEEDS (NATI SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 8.5
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN NON TRANSGENIC COTTON SEEDS GROUP
(1000 mg/kg,B.wt) OF MALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	MALE	Foci of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	Slight congestion	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	Foci of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	Foci of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development; MN Cells : Micromitotic Cells

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TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 8.6
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN NON TRANSGENIC COTTON SEEDS GROUP
(1000 mg/kg B.wt) OF FEMALE RATS AT TERMINAL SACRIFICE

ANIMAL NO	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	FEMALE	NAD	Slight fatty changes	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	Foci of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	Slight congestion	NAD	NAD	NAD

NAD : No Abnormal Development, MN Cells : Mononuclear Cells

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TOX-390
BT-COTTON SEEDS (NATH SEEDS)

TABLE - 8.7
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN BT COTTON SEEDS (NATH SEEDS)
GROUP (500 mg/kg-B.wt) OF MALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLIEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	MALE	Foci of MN Cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	Slight congestion	NAD	NAD	NAD	NAD	NAD	NAD	NAD	Foci of MN cells
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development; MN Cells : Mononuclear Cells

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SHRI RAM INSTITUTE

TOX-290
BT-COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS
TABLE - 8.8
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN BT COTTON SEEDS (NATH SEEDS)
GROUP (500 mg/kg.B.wt.) OF FEMALE RATS AT TERMINAL SACRIFICE

ANIMAL NO.	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	FEMALE	Foci of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	FEMALE	NAD	NAD	NAD	NAD	NAD	Slight congestion	NAD	NAD	NAD
9	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	FEMALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development, MN Cells : Mononuclear Cells

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SHRIRAM INSTITUTE

TOX-390
BT- COTTON SEEDS (NATH SEEDS)
SUB-CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 8.9
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN BL COTTON SEEDS (NATH SEEDS)
GROUP (1000 mg/kg.B.wt) OF MALE RATS AT TERMINAL SACRIFICE

ANIMAL NO	SEX	LUNG	LIVER	HEART	GONADS	SPLEEN	KIDNEY	BRAIN	ADRENAL	GASTRO-INTESTINAL TRACT
1	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
2	MALE	Foci of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
3	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
5	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
6	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
7	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
8	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
9	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	Foci of MN cells	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD : No Abnormal Development. MN Cells : Mononuclear Cells

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