



SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

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PROJECT NO. : TOX- 346C
PRODUCT : Bt COTTONSEEDS
STUDY : SUB CHRONIC ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000046374
DATE : 14.05.2007

SUB CHRONIC ORAL TOXICITY STUDY IN RATS

WITH

Bt COTTONSEEDS

Report for:

**METAHELIX LIFE SCIENCES PRIVATE LIMITED
PLOT NO. 3, KIADB 4th PHASE, BOMMASANDRA,
BANGALORE- 560 099, INDIA**

Guidelines:

**‘DBT, Guidelines for Toxicity and Allergenicity Evaluation of Transgenic
Seeds, Plants and Plant parts’**

Prepared by:

**DEPARTMENT OF TOXICOLOGY
SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH**

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QUALITY ASSURANCE STATEMENT

This is to certify that the work described in the study report entitled 'Sub chronic oral toxicity study in wistar rats' with 'Bt Cottonseeds' has been audited and examined with respect to the study protocol and the Standard Operating Procedures in accordance to 'DBT, Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant parts' in compliance with Good laboratory Practices (G.L.P) for non clinical laboratory studies.

The report provides true and accurate record of results obtained.

The dates of inspections & dates on which findings were reported to the study director & SRI management are given below:

<u>Phases of study</u>	<u>Dates of Inspection</u>	<u>Dates of Reporting</u>
Protocol	21.11.2006	21.11.2006
Conduct	29.11.2006	29.11.2006
	15.12.2006	15.12.2006
	20.01.2007	20.01.2007
	27.02.2007	27.02.2007
	Records/ Raw data	15.04.2007
Report	05.05.2007	15.04.2007

Binnu Bhat
 Sr. SCIENTIST
 QUALITY ASSURANCE



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STATEMENT OF COMPLIANCE WITH GOOD LABORATORY PRACTICE

We, the undersigned take overall responsibility to conduct the work described in the study entitled 'Sub chronic oral toxicity study in Wistar rats' with Bt Cottonseeds performed with respect to the study protocol and the Standard Operating Procedures in accordance to 'DBT, Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant parts' for non-clinical laboratory studies.

All the raw data, documentation, protocol and copy of final report are retained in the archives at Shriram Institute for Industrial Research, Delhi.


STUDY DIRECTOR


SCIENTIST PATHOLOGY


HEAD, DEPT. OF TOXICOLOGY

Approved for issue


DEPUTY DIRECTOR
(MANAGEMENT)



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SCIENTIFIC PERSONNEL INVOLVED IN THE STUDY

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SUMMARY

This study was designed to investigate the toxicological effects of 90 days (5 days/week) repeated oral administration of 'Bt Cottonseeds' 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.

Three groups of 20 rats each (10 males and 10 females) were made. First group was kept as control, which was given vehicle only i.e. corn oil. Second and third group was administered with 'Non-Bt Cottonseeds (Sample-I)' in powdered form at the dose level of 1000 mg/kg b.wt. and powdered 'Bt Cottonseeds (Sample-II)' at the dose level of 1000 mg/kg b.wt. respectively.

The powdered 'Non-Bt Cottonseeds and Bt Cottonseeds' samples were prepared daily in corn oil (vehicle) for oral administration.

Under the conditions of this study, the 90 days repeated oral administration of 'Non-Bt Cottonseeds' and 'Bt Cottonseeds' at the dose level of 1000 mg/kg b.wt to wistar rats did not induce any observable toxic effects, when compared to its control counterpart. Hence, **No Observable Adverse Effect Level (N.O.A.E.L) > 1000 mg/kg b.wt.**



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INTRODUCTION

This study was aimed to determine the sub-acute oral toxicity in laboratory animal model.

The given study was carried out with the dose level of 1000 mg/kg b.wt. of powdered 'Non-Bt Cottonseeds (Sample-I)' and 'Bt Cottonseeds (Sample-II)' along with the vehicle control as per the 'DBT guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts'.



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OBJECTIVES

To assess the toxicological effects of 90 days oral administration of ‘Non-Bt Cottonseeds (Sample-I)’ and ‘Bt Cottonseeds (Sample-II)’ in comparison to the control in 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 ‘DBT guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts’.

CHARACTERIZATION OF TEST AND CONTROL COTTONSEEDS

The test and control cottonseeds were characterized by the sponsor prior to their use in the study.



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TEST SUBSTANCE

The sponsor is responsible for necessary characterization and evaluation of the test substance. The details of the test substance provided by the sponsor are as follows:

PRODUCT NAME : NON-Bt COTTONSEEDS (SAMPLE -I)
& Bt COTTONSEEDS (SAMPLE -II)

SPONSOR : METAHELIX LIFE SCIENCES
PRIVATE LIMITED

MATERIAL DESCRIPTION : YELLOWISH BROWN COLOURED
POWDER

PACKED IN : BROWN COLOURED PAPER
CARTONS

DATE OF COMMENCEMENT : 29.11.2006
OF STUDY

DATE OF COMPLETION : 28.02.2007
OF STUDY

Note: For characterization details of test samples, see Annexure-I provided by the sponsor.



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EXPERIMENTAL DESIGN

STUDY LABORATORY

Dept. of Toxicology
Shriram Institute for Industrial Research
19, University Road, Delhi-110007 (INDIA)

STRAIN AND SPECIES

Wistar (albino) rats

ANIMAL SOURCE

Lab animal facility, SRI, Delhi

SEX

Male & Female

WEIGHT RANGE

120 ± 20 gms

HUSBANDRY

All animals were caged in a group of 5 according to sex in plastic cages fitted with wire mesh tops and having sterilized paddy husk bedding. Water and standard rat diet were provided *ad libitum*.

ENVIRONMENTAL

Room temperature : 22 ± 3°C

CONDITIONS

Relative humidity : 30 – 70 %

Air exchange : 15 air change s / hour

Lighting condition : 12 hours light / 24 hours

AGE OF ANIMALS

6-8 weeks

ACCLIMATIZATION PERIOD

7 days

DURATION OF STUDY

90 days



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EXPERIMENTAL PROCEDURE

Sample preparation

Powdered samples were freshly prepared everyday in corn oil (vehicle) for repeated oral administration for 90 days of 'Non-Bt Cottonseeds (Sample-I)' and 'Bt Cottonseeds (Sample-II)'.

Total 60 healthy adult male and female (30+30) 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 3 groups of 10 male and 10 female rats each and identified by cage tag.

The first group was kept as control given only the vehicle i.e. corn oil. Second and third group was administered with 'Non-Bt Cottonseeds (Sample-I)' and 'Bt Cottonseeds (Sample-II)' at the dose level of 1000 mg/kg b.wt. respectively.

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



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Animal Group And Dosage Level

Group	Dose mg/kg b.wt	No. of animals Male +Female
1. Control	0.0	10 +10
2. Sample-I (Non-Bt Cottonseeds)	1000.0	10 +10
3. Sample-II (Bt Cottonseeds)	1000.0	10 +10

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

Feed Consumption : Recorded individually at weekly intervals, thereafter group mean feed consumption were recorded.

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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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The following clinical laboratory determinations were made in all the animals of each group after termination of the experiment. 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. 45 ml of blood was withdrawn under carbon dioxide anesthesia prior to sacrifice.

Haematology

Following haematological estimations were performed on control and treated group of animals:

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



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Serum

Following estimation were performed on control and treated rats using Roche diagnostic kits:

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



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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, ovaries, uterus and brain.

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

Stomach	Brain
Intestine	Heart
Lungs	Kidneys
Liver	Adrenals
Spleen	Testis
Uterus	Ovaries

Any other macroscopically abnormal tissue.

BIOSTATISTICAL METHOD USED: Student's t-test



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OBSERVATIONS

Mortality and toxic signs

No mortality was observed in any of the test groups including the control group of animals. No toxic signs and symptoms were noticed in any of the two dose groups and the control group of animals.

Mean body weights

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

Haematological evaluations

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

Clinical Biochemistry evaluations

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



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Organ Weight

Absolute organ weights and their ratios (relative organ weights) with their respective body weights are shown in Appendix-5. As there were no significant changes in the organ weights of the test animals, when compared with organ weights of control group animals, the test substance ('Non-Bt Cottonseeds' and 'Bt Cottonseeds') was failing to suggest any specific target organ.

Necropsy examinations

Necropsy examination of animals did not reveal any significant changes in both the test groups i.e. Non-Bt Cottonseeds (Sample-I) and Bt Cottonseeds (Sample-II) dosed at 1000 mg/kg B.wt when compared to its control counterparts, as shown in appendix 6.

Histopathological examination

No significant histopathological changes (Appendix-7) were noticed in the animals of Non-Bt Cottonseeds (Sample-I) and Bt Cottonseeds (Sample-II) dosed at 1000 mg/kg b.wt when compared to its control counterparts.



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RESULT WITH CONCLUSION

Under the conditions of this study, the 90 days repeated oral administration of powdered 'Bt Cottonseeds (Sample-II)' at the dose level of 1000 mg/kg b.wt. for five days/ week to wistar rats did not induce any treatment related observable toxic effects, when compared to its corresponding 'Non-Bt Cottonseeds (Sample-I)' in powdered form and the control group of animals treated with corn oil (vehicle) only.

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

The sample has been conducted as per DBT, Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant parts.



TABLE - 1.01
 MEAN PERCENTILE 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 Sacrifice
Control (Corn Oil Only)	100.0 ± 0.0	109.56 ± 1.14	118.87 ± 1.79	127.79 ± 2.45	136.23 ± 2.79	143.44 ± 3.49	153.45 ± 4.04	159.72 ± 4.48	164.87 ± 4.80	170.35 ± 5.22	174.66 ± 5.56	178.27 ± 6.07	181.02 ± 6.39	183.14 ± 6.75
Non-Bt Cottonseeds (Sample –I)	100.0 ± .0	109.26 ± 1.46	118.12 ± 2.03	126.75 ± 2.70	134.90 ± 3.02	141.98 ± 3.35	151.32 ± 4.12	157.46 ± 4.16	162.23 ± 4.29	167.63 ± 4.87	171.72 ± 5.28	175.27 ± 5.83	177.90 ± 6.05	179.60 ± 6.34
Bt Cottonseeds (Sample –II)	100.0 ± 0.0	109.97 ± 1.17	119.15 ± 1.73	127.53 ± 2.17	135.62 ± 2.32	143.04 ± 2.26	151.97 ± 3.12	159.41 ± 2.65	164.24 ± 2.72	169.87 ± 3.01	174.15 ± 3.22	177.79 ± 3.51	180.65 ± 3.65	182.55 ± 3.76

* P = 0.05



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TABLE - 1.02
MEAN PERCENTILE 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 Sacrifice
Control (Corn Oil Only)	100.0 ± 0.0	109.30 ± 1.50	118.20 ± 2.02	126.64 ± 2.69	134.55 ± 3.28	142.27 ± 4.97	151.48 ± 5.44	157.61 ± 5.35	162.50 ± 6.08	167.76 ± 6.66	171.79 ± 7.10	175.29 ± 7.46	177.95 ± 7.59	179.70 ± 7.66
Non-Bt Cottonseeds (Sample -I)	100.0 ± 0.0	109.37 ± 1.34	118.17 ± 1.80	126.78 ± 3.12	134.75 ± 3.99	141.93 ± 4.41	151.20 ± 5.14	157.22 ± 5.44	161.62 ± 5.70	167.17 ± 5.87	171.20 ± 6.34	174.91 ± 6.70	177.61 ± 6.98	179.39 ± 7.16
Bt Cottonseeds (Sample -II)	100.0 ± 0.0	109.78 ± 1.21	118.78 ± 2.03	127.54 ± 2.48	134.37 ± 2.96	140.95 ± 3.23	149.55 ± 3.81	155.98 ± 4.07	160.85 ± 4.22	166.28 ± 4.48	170.23 ± 4.74	174.49 ± 4.95	177.60 ± 5.31	179.54 ± 5.52

* P = 0.05



TABLE - 1.03
MEAN 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 Sacrifice
Control (Corn Oil Only)	128.20 ± 6.51	140.40 ± 5.91	152.30 ± 5.79	163.70 ± 5.48	174.50 ± 5.54	183.70 ± 5.25	196.50 ± 4.97	204.50 ± 4.81	211.10 ± 5.07	218.10 ± 5.00	223.60 ± 4.86	228.20 ± 4.29	231.70 ± 4.14	234.40 ± 3.81
Non-Bt Cottonseeds (Sample -I)	130.20 ± 6.27	142.20 ± 5.63	153.70 ± 5.36	164.90 ± 5.36	175.50 ± 5.58	184.70 ± 5.62	196.80 ± 5.07	204.80 ± 5.31	211.00 ± 5.46	218.00 ± 5.23	223.30 ± 5.08	227.90 ± 4.75	231.30 ± 4.47	233.50 ± 4.30
Bt Cottonseeds (Sample -II)	126.50 ± 4.25	139.10 ± 4.33	150.70 ± 4.50	161.30 ± 5.06	171.50 ± 4.58	180.90 ± 5.17	192.20 ± 6.21	201.60 ± 5.50	207.70 ± 5.40	214.80 ± 5.16	220.20 ± 4.96	224.80 ± 4.64	228.40 ± 4.43	230.80 ± 4.26

* P = 0.05



TABLE - 1.04
MEAN 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 Sacrifice
Control (Corn Oil Only)	131.90 ± 6.77	144.10 ± 5.97	155.80 ± 6.01	166.90 ± 5.78	177.30 ± 5.87	187.40 ± 5.48	199.50 ± 5.06	207.60 ± 5.58	214.00 ± 5.06	220.90 ± 5.04	226.20 ± 5.29	230.80 ± 5.31	234.30 ± 5.50	236.60 ± 5.25
Non-Bt Cottonseeds (Sample-I)	129.90 ± 6.87	142.00 ± 5.93	153.40 ± 5.97	164.50 ± 4.88	174.80 ± 4.39	184.10 ± 4.31	196.10 ± 3.81	203.90 ± 3.96	209.60 ± 3.98	216.80 ± 4.13	222.00 ± 4.03	226.80 ± 3.82	230.30 ± 3.80	232.60 ± 3.75
Bt Cottonseeds (Sample-II)	129.30 ± 5.36	141.90 ± 4.72	153.50 ± 4.09	164.80 ± 3.99	173.60 ± 3.60	182.10 ± 3.60	193.20 ± 3.99	201.50 ± 4.09	207.80 ± 4.29	214.80 ± 4.39	219.90 ± 4.43	225.40 ± 4.53	229.40 ± 4.22	231.90 ± 3.93

* P = 0.05



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TABLE - 1.05
 WEEKLY PERCENTILE DATA OF MALE RATS

DURATION : 90 DAYS

GROUP : CONTROL (Vehicle- Corn oil)

Body Weights on															
Animal 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 Sacrifice
1		00.0	110.16	119.53	128.91	137.50	146.09	155.47	161.72	167.19	173.44	178.13	181.25	184.38	186.72
2	M	100.0	109.84	119.67	129.51	138.52	147.54	158.20	165.57	172.13	177.87	181.97	186.07	188.52	190.16
3	M	100.0	110.57	119.51	129.27	138.21	145.53	156.10	161.79	167.48	173.17	178.05	182.11	185.37	188.62
4	M	100.0	107.25	115.94	123.19	131.88	137.68	147.10	152.90	157.97	162.32	165.94	168.84	170.29	171.74
5	M	100.0	109.38	118.75	128.13	135.94	142.97	153.13	159.38	163.28	168.75	173.44	177.34	179.69	182.03
6		00.0	110.66	121.31	130.33	137.70	145.90	156.56	163.11	168.03	173.77	177.87	182.79	186.07	188.52
7	M	100.0	108.57	117.14	125.00	132.14	138.57	147.14	152.14	157.14	162.14	165.71	168.57	171.43	172.86
8	M	100.0	110.08	118.60	127.91	136.43	142.64	152.71	158.91	164.34	169.77	174.42	177.52	179.84	181.40
9	M	100.0	108.46	116.92	125.38	133.85	140.77	150.77	157.69	162.31	167.69	171.54	174.62	177.69	180.00
10	M	100.0	110.66	121.31	130.33	140.16	146.72	157.38	163.93	168.85	174.59	179.51	183.61	186.89	189.34
Mean		100.0	109.56	118.87	127.79	136.23	143.44	153.45		164.87	170.35	174.66	178.27	181.02	183.14
± S.D.		± 0.0	± 1.14	± 1.79	± 2.45	± 2.79	± 3.49	± 4.04	± 159.72	± 4.80	± 5.22	± 5.56	± 6.07	± 6.39	± 6.75
									± 4.48						



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TABLE - 1.06
 WEEKLY PERCENTILE DATA OF FEMALE RATS

DURATION : 90 DAYS

GROUP : CONTROL (Vehicle- Corn oil)

Body Weights on															
Animal 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 Sacrifice
1		100.0	107.19	115.83	124.46	130.94	137.41	146.04	152.52	156.83	161.87	166.19	169.78	171.94	173.38
2	F	100.0	109.38	118.75	127.34	134.38	142.19	152.34	158.59	163.28	167.97	171.88	175.00	177.34	179.69
3	F	100.0	107.97	115.94	123.91	131.16	136.96	144.93	151.45	155.80	160.14	163.04	165.94	168.12	169.57
4	F	100.0	110.53	118.80	127.82	136.09	143.61	152.63	158.65	163.91	169.92	174.44	177.44	180.45	181.95
5	F	100.0	110.29	119.12	127.21	136.03	144.12	152.21	158.09	162.50	167.65	172.06	175.74	178.68	180.15
6		100.0	109.45	117.32	125.98	134.65	141.73	151.97	157.48	162.99	168.50	173.23	177.17	179.53	181.89
7	F	100.0	111.57	121.49	131.40	139.67	147.93	157.85	163.64	170.25	176.86	180.99	185.12	188.43	190.08
8	F	100.0	110.57	121.14	130.08	139.02	152.03	161.79	168.29	173.98	179.67	184.55	188.62	191.06	192.68
9	F	100.0	108.96	117.16	125.37	133.58	140.30	150.00	155.97	160.45	165.67	168.66	172.39	175.37	177.61
10	F	100.0	107.14	116.43	122.86	130.00	136.43	145.00	151.43	155.00	159.29	162.86	165.71	168.57	170.00
Mean		100.0	109.30	118.20	126.64	134.55	142.27	151.48	157.61	162.50	167.76	171.79	175.29	177.95	179.70
± S.D.		± 0.0	± 1.50	± 2.02	± 2.69	± 3.28	± 4.97	± 5.44	± 5.35	± 6.08	± 6.66	± 7.10	± 7.46	± 7.59	± 7.66



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TABLE - 1.07
 WEEKLY PERCENTILE DATA OF MALE RATS
 DURATION : 90 DAYS GROUP : SAMPLE-I, NON-Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on															
Animal 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 Sacrifice
1		00.0	108.96	117.91	124.63	132.09	139.55	148.51	155.22	159.70	164.18	167.91	171.64	174.63	176.12
2	M	100.0	111.67	120.83	130.83	140.00	147.50	158.33	165.00	170.00	176.67	181.67	185.83	188.33	190.83
3	M	100.0	109.42	117.39	126.09	134.06	141.30	148.55	154.35	158.70	164.49	167.39	170.29	171.74	173.19
4	M	100.0	111.38	121.14	130.89	139.02	146.34	156.91	162.60	167.48	173.98	178.86	183.74	186.99	188.62
5	M	100.0	110.32	119.84	129.37	137.30	144.44	154.76	161.11	165.87	171.43	175.40	179.37	181.75	184.13
6	M	100.0	108.53	117.83	124.81	132.56	139.53	148.84	155.04	160.47	165.89	169.77	173.64	176.74	178.29
7	M	100.0	108.27	116.54	125.56	133.08	139.85	149.62	154.89	160.15	164.66	168.42	171.43	173.68	175.19
8	M	100.0	107.19	114.39	123.02	130.94	136.69	145.32	151.80	156.12	161.15	165.47	168.35	170.50	171.94
9	M	100.0	109.02	118.05	126.32	135.34	142.11	151.13	157.14	162.41	166.92	171.43	174.44	177.44	178.95
10	M	100.0	107.87	117.32	125.98	134.65	142.52	151.18	157.48	161.42	166.93	170.87	174.02	177.17	178.74
Mean ± S.D.		100.0 ± 0.0	109.26 ± 1.46	118.12 ± 2.03	126.75 ± 2.70	134.90 ± 3.02	141.98 ± 3.35	151.32 ± 4.12	157.46 ± 4.16	162.23 ± 4.29	167.63 ± 4.87	171.72 ± 5.28	175.27 ± 5.83	177.90 ± 6.05	179.60 ± 6.34



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TABLE - 1.08
 WEEKLY PERCENTILE DATA OF FEMALE RATS

DURATION : 90 DAYS GROUP : SAMPLE-I, NON-Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on															
Animal 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 Sacrifice
1		00.0	109.76	119.51	129.27	137.40	145.53	155.28	161.79	166.67	171.54	175.61	179.67	182.93	184.55
2	F	100.0	110.48	119.35	129.03	137.90	145.97	155.65	162.10	167.74	173.39	178.23	182.26	185.48	187.90
3	F	100.0	107.30	115.33	121.90	128.47	135.04	144.53	149.64	154.01	159.12	162.04	165.69	167.88	169.34
4	F	100.0	107.97	116.67	123.91	130.43	137.68	145.65	152.17	156.52	160.87	165.22	168.12	171.01	172.46
5	F	100.0	110.48	119.35	129.03	138.71	145.97	156.45	162.90	166.94	172.58	176.61	181.45	184.68	186.29
6	F	100.0	108.96	116.42	124.63	132.84	139.55	148.51	153.73	157.46	163.43	167.91	170.90	173.13	175.37
7	F	100.0	107.86	116.43	122.86	130.00	136.43	144.29	150.00	154.29	160.00	162.86	166.43	168.57	170.00
8	F	100.0	109.16	118.32	127.48	135.11	141.98	150.38	156.49	160.31	166.41	170.23	174.05	177.10	178.63
9	F	100.0	110.57	120.33	130.08	139.02	146.34	156.91	162.60	167.48	173.17	178.05	182.11	184.55	186.18
10	F	100.0	111.20	120.00	129.60	137.60	144.80	154.40	160.80	164.80	171.20	175.20	178.40	180.80	183.20
Mean ± S.D.		100.0 ± 0.0	109.37 ± 1.34	118.17 ± 1.80	126.78 ± 3.12	134.75 ± 3.99	141.93 ± 4.41	151.20 ± 5.14	157.22 ± 5.44	161.62 ± 5.70	167.17 ± 5.87	171.20 ± 6.34	174.91 ± 6.70	177.61 ± 6.98	179.39 ± 7.16



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TABLE - 1.09
 WEEKLY PERCENTILE DATA OF MALE RATS
 DURATION : 90 DAYS GROUP : SAMPLE-II, Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on															
Animal 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 Sacrifice
1		00.0	109.38	118.75	126.56	134.38	141.41	150.78	157.81	161.72	167.97	171.88	175.78	178.91	180.47
2	M	100.0	110.00	119.23	128.46	135.38	143.08	153.08	159.23	163.85	168.46	173.08	176.15	178.46	180.00
3	M	100.0	108.33	117.50	128.33	135.83	142.50	151.67	158.33	163.33	170.00	175.00	179.17	182.50	185.00
4	M	100.0	111.57	121.49	125.62	137.19	145.45	155.37	162.81	168.60	174.38	179.34	183.47	185.95	187.60
5	M	100.0	110.40	119.20	128.00	134.40	141.60	151.20	157.60	163.20	168.00	172.00	176.00	179.20	181.60
6	M	100.0	111.11	119.84	129.37	137.30	143.65	146.03	160.32	165.08	170.63	175.40	178.57	181.75	183.33
7	M	100.0	108.46	116.15	123.85	132.31	140.00	150.77	157.69	162.31	167.69	172.31	175.38	178.46	180.00
8	M	100.0	109.02	118.05	126.32	133.83	142.11	150.38	156.39	160.90	166.17	169.92	172.93	175.19	177.44
9	M	100.0	111.38	121.95	131.71	140.65	147.97	157.72	165.04	169.11	175.61	179.67	183.74	186.99	189.43
10	M	100.0	110.08	119.38	127.13	134.88	142.64	152.71	158.91	164.34	169.77	172.87	176.74	179.07	180.62
Mean ± S.D.		100.0 ± 0.0	109.97 ± 1.17	119.15 ± 1.73	127.53 ± 2.17	135.62 ± 2.32	143.04 ± 2.26	151.97 ± 3.12	159.41 ± 2.65	164.24 ± 2.72	169.87 ± 3.01	174.15 ± 3.22	177.79 ± 3.51	180.65 ± 3.65	182.55 ± 3.76



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TABLE - 1.10
 WEEKLY PERCENTILE DATA OF FEMALE RATS

DURATION : 90 DAYS; GROUP : SAMPLE-II, Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on															
Animal 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 Sacrifice
1		00.0	109.68	119.35	129.03	137.10	144.35	152.42	159.68	164.52	170.16	174.19	178.23	181.45	183.06
2	F	100.0	109.02	117.29	124.81	131.58	139.10	145.86	151.88	157.14	161.65	166.17	169.92	172.93	174.44
3	F	100.0	109.52	119.05	129.37	135.71	142.06	148.41	154.76	159.52	165.87	169.05	173.81	177.78	180.16
4	F	100.0	109.02	117.29	124.81	131.58	137.59	146.62	153.38	158.65	163.16	165.41	169.17	171.43	173.68
5	F	100.0	110.77	120.00	128.46	134.62	141.54	150.77	156.92	161.54	166.92	171.54	175.38	178.46	180.00
6	F	100.0	111.02	119.69	128.35	135.43	141.73	151.97	158.27	162.99	167.72	171.65	176.38	179.53	181.89
7	F	100.0	107.14	114.29	122.86	128.57	134.29	142.14	147.86	152.14	157.86	162.14	166.43	169.29	170.71
8	F	100.0	109.85	118.94	128.03	134.85	140.91	150.00	156.82	162.12	168.18	171.21	175.76	178.03	179.55
9	F	100.0	111.11	120.63	129.37	135.71	142.86	152.38	158.73	162.70	167.46	172.22	176.19	179.37	181.75
10	F	100.0	110.66	121.31	130.33	138.52	145.08	154.92	161.48	167.21	173.77	178.69	183.61	187.70	190.16
Mean ± S.D.		100.0 ± 0.0	109.78 ± 1.21	118.78 ± 2.03	127.54 ± 2.48	134.37 ± 2.96	140.95 ± 3.23	149.55 ± 3.81	155.98 ± 4.07	160.85 ± 4.22	166.28 ± 4.48	170.23 ± 4.74	174.49 ± 4.95	177.60 ± 5.31	179.54 ± 5.52



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TABLE - 1.11

WEEKLY BODY WEIGHT DATA (in gms) OF MALE RATS
GROUP : CONTROL (Vehicle - Corn Oil)

DURATION : 90 DAYS

Body Weights on															
Animal 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 Sacrifice
1		128	141	153	165	176	187	199	207	214	222	228	232	236	239
2	M	122	134	146	158	169	180	193	202	210	217	222	227	230	232
3	M	123	136	147	159	170	179	192	199	206	213	219	224	228	232
4	M	138	148	160	170	182	190	203	211	218	224	229	233	235	237
5	M	128	140	152	164	174	183	196	204	209	216	222	227	230	233
6	M	122	135	148	159	168	178	191	199	205	212	217	223	227	230
7	M	140	152	164	175	185	194	206	213	220	227	232	236	240	242
8	M	129	142	153	165	176	184	197	205	212	219	225	229	232	234
9	M	130	141	152	163	174	183	196	205	211	218	223	227	231	234
10	M	122	135	148	159	171	179	192	200	206	213	219	224	228	231
Mean ± S.D		128.20 ± 6.51	140.40 ± 5.91	152.30 ± 5.79	163.70 ± 5.48	174.50 ± 5.54	183.70 ± 5.25	196.50 ± 4.97	204.50 ± 4.81	211.10 ± 5.07	218.10 ± 5.00	223.60 ± 4.86	228.20 ± 4.29	231.70 ± 4.14	234.40 ± 3.81



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TABLE - 1.12
 WEEKLY BODY WEIGHT DATA (in gms) OF FEMALE RATS
 DURATION : 90 DAYS GROUP : CONTROL (Vehicle- Corn Oil)

Body Weights on															
Animal 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 Sacrifice
1		139	149	161	173	182	191	203	212	218	225	231	236	239	241
2	F	128	140	152	163	172	182	195	203	209	215	220	224	227	230
3	F	138	149	160	171	181	189	200	209	215	221	225	229	232	234
4	F	133	147	158	170	181	191	203	211	218	226	232	236	240	242
5	F	136	150	162	173	185	196	207	215	221	228	234	239	243	245
6	F	127	139	149	160	171	180	193	200	207	214	220	225	228	231
7	F	121	135	147	159	169	179	191	198	206	214	219	224	228	230
8	F	123	136	149	160	171	187	199	207	214	221	227	232	235	237
9	F	134	146	157	168	179	188	201	209	215	222	226	231	235	238
10	F	140	150	163	172	182	191	203	212	217	223	228	232	236	238
Mean ± S.D.		131.90 ± 6.77	144.10 ± 5.97	155.80 ± 6.01	166.90 ± 5.78	177.30 ± 5.87	187.40 ± 5.48	199.50 ± 5.06	207.60 ± 5.58	214.00 ± 5.06	220.90 ± 5.04	226.20 ± 5.29	230.80 ± 5.31	234.30 ± 5.50	236.60 ± 5.25



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TABLE - 1.13
WEEKLY BODY WEIGHT DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : SAMPLE-I, NON-Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on															
Animal 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 Sacrifice
1		134	146	158	167	177	187	199	208	214	220	225	230	234	236
2	M	120	134	145	157	168	177	190	198	204	212	218	223	226	229
3	M	138	151	162	174	185	195	205	213	219	227	231	235	237	239
4	M	123	137	149	161	171	180	193	200	206	214	220	226	230	232
5	M	126	139	151	163	173	182	195	203	209	216	221	226	229	232
6	M	129	140	152	161	171	180	192	200	207	214	219	224	228	230
7	M	133	144	155	167	177	186	199	206	213	219	224	228	231	233
8	M	139	149	159	171	182	190	202	211	217	224	230	234	237	239
9	M	133	145	157	168	180	189	201	209	216	222	228	232	236	238
10	M	127	137	149	160	171	181	192	200	205	212	217	221	225	227
Mean ± S.D.		130.20 ± 6.27	142.20 ± 5.63	153.70 ± 5.36	164.90 ± 5.36	175.50 ± 5.58	184.70 ± 5.62	196.80 ± 5.07	204.80 ± 5.31	211.00 ± 5.46	218.00 ± 5.23	223.30 ± 5.08	227.90 ± 4.75	231.30 ± 4.47	233.50 ± 4.30



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TABLE - 1.14
WEEKLY BODY WEIGHT DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : SAMPLE-I, NON-Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on															
Animal 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 Sacrifice
1		123	135	147	159	169	179	191	199	205	211	216	221	225	227
2	F	124	137	148	160	171	181	193	201	208	215	221	226	230	233
3	F	137	147	158	167	176	185	198	205	211	218	222	227	230	232
4	F	138	149	161	171	180	190	201	210	216	222	228	232	236	238
5	F	124	137	148	160	172	181	194	202	207	214	219	225	229	231
6	F	134	146	156	167	178	187	199	206	211	219	225	229	232	235
7	F	140	151	163	172	182	191	202	210	216	224	228	233	236	238
8	F	131	143	155	167	177	186	197	205	210	218	223	228	232	234
9	F	123	136	148	160	171	180	193	200	206	213	219	224	227	229
10	F	125	139	150	162	172	181	193	201	206	214	219	223	226	229
Mean ± S.D		129.90 ± 6.87	142.00 ± 5.93	153.40 ± 5.97	164.50 ± 4.88	174.80 ± 4.39	184.10 ± 4.31	196.10 ± 3.81	203.90 ± 3.96	209.60 ± 3.98	216.80 ± 4.13	222.00 ± 4.03	226.80 ± 3.82	230.30 ± 3.80	232.60 ± 3.75



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TABLE - 1.15
WEEKLY BODY WEIGHT DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : SAMPLE-II, Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on															
Animal 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 Sacrifice
1		128	140	152	162	172	181	193	202	207	215	220	225	229	231
2	M	130	143	155	167	176	186	199	207	213	219	225	229	232	234
3	M	120	130	141	154	163	171	182	190	196	204	210	215	219	222
4	M	121	135	147	152	166	176	188	197	204	211	217	222	225	227
5	M	125	138	149	160	168	177	189	197	204	210	215	220	224	227
6	M	126	140	151	163	173	181	184	202	208	215	221	225	229	231
7	M	130	141	151	161	172	182	196	205	211	218	224	228	232	234
8	M	133	145	157	168	178	189	200	208	214	221	226	230	233	236
9	M	123	137	150	162	173	182	194	203	208	216	221	226	230	233
10	M	129	142	154	164	174	184	197	205	212	219	223	228	231	233
Mean ± S.D.		126.50 ± 4.25	139.10 ± 4.33	150.70 ± 4.50	161.30 ± 5.06	171.50 ± 4.58	180.90 ± 5.17	192.20 ± 6.21	201.60 ± 5.50	207.70 ± 5.40	214.80 ± 5.16	220.20 ± 4.96	224.80 ± 4.64	228.40 ± 4.43	230.80 ± 4.26



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TABLE - 1.16
WEEKLY BODY WEIGHT DATA (in gms) OF FEMALE RATS
DURATION : 90 DAYS GROUP : SAMPLE-II, Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on															
Animal 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 Sacrifice
1		124	136	148	160	170	179	189	198	204	211	216	221	225	227
2	F	133	145	156	166	175	185	194	202	209	215	221	226	230	232
3	F	126	138	150	163	171	179	187	195	201	209	213	219	224	227
4	F	133	145	156	166	175	183	195	204	211	217	220	225	228	231
5	F	130	144	156	167	175	184	196	204	210	217	223	228	232	234
6	F	127	141	152	163	172	180	193	201	207	213	218	224	228	231
7	F	140	150	160	172	180	188	199	207	213	221	227	233	237	239
8	F	132	145	157	169	178	186	198	207	214	222	226	232	235	237
9	F	126	140	152	163	171	180	192	200	205	211	217	222	226	229
10	F	122	135	148	159	169	177	189	197	204	212	218	224	229	232
Mean ± S.D		129.30 ± 5.36	141.90 ± 4.72	153.50 ± 4.09	164.80 ± 3.99	173.60 ± 3.60	182.10 ± 3.60	193.20 ± 3.99	201.50 ± 4.09	207.80 ± 4.29	214.80 ± 4.39	219.90 ± 4.43	225.40 ± 4.53	229.40 ± 4.22	231.90 ± 3.93

* P = 0.05



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TABLE - 1.17
MEAN WEEKLY BODY WEIGHT 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 (Corn Oil Only)	12.20 ± 1.03	24.10 ± 1.37	35.50 ± 1.72	46.30 ± 1.64	55.50 ± 2.17	68.30 ± 2.11	76.30 ± 2.31	82.90 ± 2.60	89.90 ± 2.88	95.40 ± 3.06	100.00 ± 3.30	103.50 ± 3.57	106.20 ± 3.85
Non-Bt Cottonseeds (Sample -I)	12.00 ± 1.49	23.50 ± 1.78	34.70 ± 2.21	45.30 ± 2.31	54.30 ± 2.36	66.60 ± 2.63	74.60 ± 2.37	80.80 ± 2.35	87.80 ± 2.70	93.10 ± 2.96	97.70 ± 3.37	101.10 ± 3.41	103.30 ± 3.65
Bt Cottonseeds (Sample -II)	12.60 ± 1.35	24.20 ± 1.93	35.30 ± 2.16	45.00 ± 2.31	54.40 ± 2.41	66.70 ± 2.58	75.10 ± 2.73	81.20 ± 2.62	88.30 ± 2.58	93.70 ± 2.54	98.30 ± 2.50	101.90 ± 2.42	104.30 ± 2.36



TABLE - 1.18
 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
Contr ol (Corn Oil Only)	12.20 ± 1.55	23.90 ± 1.73	35.00 ± 2.11	45.40 ± 2.59	55.50 ± 4.33	67.60 ± 4.25	75.70 ± 3.92	82.10 ± 4.38	89.00 ± 4.85	94.30 ± 5.31	98.9 ± 5.57	102.4 ± 5.66	104.70 ± 5.56
Non-Bt Cottonseeds (Sample -I)	12.10 ± 1.20	23.50 ± 1.27	34.60 ± 2.41	44.90 ± 3.03	54.20 ± 3.08	66.20 ± 3.33	74.00 ± 3.37	79.70 ± 3.40	86.90 ± 3.28	92.10 ± 3.73	96.90 ± 3.90	100.40 ± 4.14	102.70 ± 4.27
Bt Cottonseeds (Sample -II)	12.60 ± 1.26	24.20 ± 1.87	35.50 ± 2.01	44.30 ± 2.21	52.80 ± 2.25	63.90 ± 2.85	72.20 ± 2.94	78.50 ± 3.00	85.50 ± 3.10	90.60 ± 3.24	96.10 ± 3.35	100.10 ± 3.51	102.60 ± 3.57

* P = 0.05



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TABLE - 1.19
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF MALE RATS

DURATION : 90 DAYS

GROUP : CONTROL (Vehicle- Corn Oil)

Body Weights on														
Animal No.	Sex	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	13	25	37	48	59	71	79	86	94	100	104	108	111
2	M	12	24	36	47	58	71	80	88	95	100	105	108	110
3	M	13	24	36	47	56	69	76	83	90	96	101	105	109
4	M	10	22	32	44	52	65	73	80	86	91	95	97	99
5	M	12	24	36	46	55	68	76	81	88	94	99	102	105
6	M	13	26	37	46	56	69	77	83	90	95	101	105	108
7	M	12	24	35	45	54	66	73	80	87	92	96	100	102
8	M	13	24	36	47	55	68	76	83	90	96	100	103	105
9	M	11	22	33	44	53	66	75	81	88	93	97	101	104
10	M	13	26	37	49	57	70	78	84	91	97	102	106	109
Mean		12.20	24.10	35.50	46.30	55.50	68.30	76.30	82.90	89.90	95.40	100.00	103.50	106.20
± S.D.		± 1.03	± 1.37	± 1.72	± 1.64	± 2.17	± 2.11	± 2.31	± 2.60	± 2.88	± 3.06	± 3.30	± 3.57	± 3.85



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TABLE - 1.20
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF FEMALE RATS

DURATION : 90 DAYS GROUP : CONTROL (Vehicle- Corn Oil)

Body Weights on														
Animal No.	Sex	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	10	22	34	43	52	64	73	79	86	92	97	100	102
2	F	12	24	35	44	54	67	75	81	87	92	96	99	102
3	F	11	22	33	43	51	62	71	77	83	87	91	94	96
4	F	14	25	37	48	58	70	78	85	93	99	103	107	109
5	F	14	26	37	49	60	71	79	85	92	98	103	107	109
6	F	12	22	33	44	53	66	73	80	87	93	98	101	104
7	F	14	26	38	48	58	70	77	85	93	98	103	107	109
8	F	13	26	37	48	64	76	84	91	98	104	109	112	114
9	F	12	23	34	45	54	67	75	81	88	92	97	101	104
10	F	10	23	32	42	51	63	72	77	83	88	92	96	98
Mean		12.20	23.90	35.00	45.40	55.50	67.60	75.70	82.10	89.00	94.30	98.9	102.4	104.70
± S.D.		± 1.55	± 1.73	± 2.11	± 2.59	± 4.33	± 4.25	± 3.92	± 4.38	± 4.85	± 5.31	± 5.57	± 5.66	± 5.56



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TABLE - 1.21
WEEKLY BODY WEIGHT GAIN DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : SAMPLE-I, NON-Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on														
Animal No.	Sex	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	12	24	33	43	53	65	74	80	86	91	96	100	102
2	M	14	25	37	48	57	70	78	84	92	98	103	106	109
3	M	13	24	36	47	57	67	75	81	89	93	97	99	101
4	M	14	26	38	48	57	70	77	83	91	97	103	107	109
5	M	13	25	37	47	54	69	77	83	90	95	100	103	106
6	M	11	23	32	42	51	63	71	78	85	90	95	99	101
7	M	11	22	34	44	53	66	73	80	86	91	95	98	100
8	M	10	20	32	43	51	63	72	78	85	91	95	98	100
9	M	12	24	35	47	56	68	76	83	89	95	99	103	105
10	M	10	22	33	44	54	65	73	78	85	90	94	98	100
Mean		12.00	23.50	34.7	45.3	54.3	66.6	74.6	80.8	87.8	93.1	97.7	101.1	103.30
± S.D.		± 1.49	± 1.78	± 2.21	± 2.31	± 2.36	± 2.63	± 2.37	± 2.35	± 2.70	± 2.96	± 3.37	± 3.41	± 3.65



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TABLE - 1.22

WEEKLY BODY WEIGHT GAIN DATA (in gms) OF FEMALE RATS
 DURATION : 90 DAYS GROUP : SAMPLE-I, NON-Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on														
Animal No.	Sex	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	12	24	36	46	56	68	76	82	88	93	98	102	104
2	F	13	24	36	47	57	69	77	84	91	97	102	106	109
3	F	10	21	30	39	48	61	68	74	81	85	90	93	95
4	F	11	23	33	42	52	63	72	78	84	90	94	98	100
5	F	13	24	36	48	57	70	78	83	90	95	101	105	107
6	F	12	22	33	44	53	65	72	77	85	91	95	98	101
7	F	11	23	32	42	51	62	70	76	84	88	93	96	98
8	F	12	24	36	46	55	66	74	79	87	92	97	101	103
9	F	13	25	37	48	57	70	77	83	90	96	101	104	106
10	F	14	25	37	47	56	68	76	81	89	94	98	101	104
Mean		12.1	23.5	34.6	44.9	54.2	66.2	74.00	79.7	86.9	92.1	96.9	100.4	102.70
± S.D.		± 1.20	± 1.27	± 2.41	± 3.03	± 3.08	± 3.33	± 3.37	± 3.40	± 3.28	± 3.73	± 3.90	± 4.14	± 4.27



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TABLE - 1.23

WEEKLY BODY WEIGHT GAIN DATA (in gms) OF MALE RATS
DURATION : 90 DAYS GROUP : SAMPLE-II, Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on														
Animal No.	Sex	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	12	24	34	44	53	65	74	79	87	92	97	101	103
2	M	13	25	37	46	56	69	77	83	89	95	99	102	104
3	M	10	21	34	43	51	62	70	76	84	90	95	99	102
4	M	14	26	36	45	55	67	76	83	90	96	101	104	106
5	M	13	24	35	43	52	64	72	79	85	90	95	99	102
6	M	14	25	37	47	55	68	76	82	89	95	99	103	105
7	M	11	21	31	42	52	66	75	81	88	94	98	102	104
8	M	12	24	35	45	56	67	75	81	88	93	97	100	103
9	M	14	27	39	50	59	71	80	85	93	98	103	107	110
10	M	13	25	35	45	55	68	76	83	90	94	99	102	104
Mean		12.6	24.2	35.3	45.0	54.4	66.7	75.1	81.2	88.3	93.7	98.3	101.9	104.30
±		±	±	±	±	±	±	±	±	±	±	±	±	±
S.D.		1.35	1.93	2.16	2.31	2.41	2.58	2.73	2.62	2.58	2.54	2.50	2.42	2.36



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TABLE - 1.24

WEEKLY BODY WEIGHT GAIN DATA (in gms) OF FEMALE RATS

DURATION : 90 DAYS GROUP : SAMPLE-II, Bt COTTONSEEDS (1000 mg/ kg.b.wt.)

Body Weights on														
Animal No.	Sex	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	12	24	36	46	55	65	74	80	87	92	97	101	103
2	F	12	23	33	42	52	61	69	76	82	88	93	97	99
3	F	12	24	37	45	53	61	69	75	83	87	93	98	101
4	F	12	23	33	42	50	62	71	78	84	87	92	95	98
5	F	14	26	37	45	54	66	74	80	87	93	98	102	104
6	F	14	25	36	45	53	66	74	80	86	91	97	101	104
7	F	10	20	32	40	48	59	67	73	81	87	93	97	99
8	F	13	25	37	46	54	66	75	82	90	94	100	103	105
9	F	14	26	37	45	54	66	74	79	85	91	96	100	103
10	F	13	26	37	47	55	67	75	82	90	96	102	107	110
Mean ± S.D.		12.6 ± 1.26	24.2 ± 1.87	35.5 ± 2.01	44.3 ± 2.21	52.8 ± 2.25	63.9 ± 2.85	72.2 ± 2.94	78.5 ± 3.00	85.5 ± 3.10	90.6 ± 3.24	96.1 ± 3.35	100.1 ± 3.51	102.60 ± 3.57



TABLE - 2.01
AVERAGE FEED CONSUMPTION DATA OF MALE AND FEMALE RATS

Dose Levels	MALE (Average feed consumption in gm)	FEMALE (Average feed consumption in gm)
Control	153.50 ± 3.72	153.57 ± 3.09
Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	153.40 ± 2.97	153.96 ± 3.04
Sample-II, Bt Cottonseeds (1000 mg/kg)	153.27 ± 3.53	153.69 ± 3.04

* P = 0.05



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TABLE - 2.02
FEED CONSUMPTION DATA OF MALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Vehicle only)	Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	Sample-II, Bt Cottonseeds (1000 mg/kg)
0	175.0	157.3	159.4	161.4
1	175.0	156.2	157.8	158.2
2	175.0	158.3	152.8	153.3
3	175.0	152.6	159.9	151.8
4	175.0	153.8	156.6	150.2
5	175.0	152.9	157.4	154.2
6	175.0	155.8	149.9	156
7	175.0	152.2	153	153.6
8	175.0	151.7	152.4	152.6
9	175.0	153.5	155	157
10	175.0	152	160.2	155.1
11	175.0	147	153.3	151.8
12	175.0	152	154.2	149.7
13	175.0	157	150.7	150.3
14	175.0	149.9	154.2	152.8
15	175.0	157	148.8	154.8
16	175.0	160	150.2	155.2
17	175.0	161.3	153.2	150
18	175.0	149.4	151.8	154.2
19	175.0	154.7	159.2	153.8
20	175.0	160.2	156.4	153.8



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TABLE - 2.03
FEED CONSUMPTION DATA OF MALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Vehicle only)	Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	Sample-II, Bt Cottonseeds (1000 mg/kg)
21	175.0	154	156.2	155.4
22	175.0	160.2	154.4	150.3
23	175.0	154.6	152.2	144.9
24	175.0	153	156.2	160
25	175.0	159.9	153.3	156.2
26	175.0	154.9	154.4	159.3
27	175.0	153.8	156	153
28	175.0	160	155.2	158
29	175.0	158.5	156	154.3
30	175.0	157.4	153.3	156.6
31	175.0	153.8	158	153.2
32	175.0	149.9	154.2	156.6
33	175.0	148.8	156.2	153.3
34	175.0	150.2	156.8	152.2
35	175.0	152.2	152.2	153
36	175.0	156.6	160	159.4
37	175.0	158	153.4	154.4
38	175.0	153.6	156	152.2
39	175.0	156.3	153.7	153.6
40	175.0	154	152.8	153.8
41	175.0	156.6	153.3	154.8



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TABLE - 2.04
FEED CONSUMPTION DATA OF MALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Vehicle only)	Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	Sample-II, Bt Cottonseeds (1000 mg/kg)
42	175.0	153	154.6	156.4
43	175.0	148.8	156.2	153.3
44	175.0	156	149.9	159
45	175.0	152.9	153.2	146.6
46	175.0	155.3	151.9	153.3
47	175.0	149.9	152.6	156
48	175.0	158.4	153.2	151.9
49	175.0	152.4	156	152.2
50	175.0	159	153.7	156
51	175.0	148.2	151.4	149.9
52	175.0	153	154.6	152
53	175.0	149.2	153	154.5
54	175.0	153	156.2	159
55	175.0	159.7	156	151.4
56	175.0	158.4	153.2	152.9
57	175.0	153.9	154.7	147.9
58	175.0	149.2	155.8	152.6
59	175.0	148.6	147.7	153.4
60	175.0	150.6	154.8	151.7
61	175.0	148.7	151.2	149.9
62	175.0	150.6	153.6	150.6



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TABLE - 2.05
FEED CONSUMPTION DATA OF MALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Vehicle only)	Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	Sample-II, Bt Cottonseeds (1000 mg/kg)
63	175.0	148.8	150.3	153.8
64	175.0	149.7	151.2	150.3
65	175.0	150.1	149.8	149.6
66	175.0	153.6	154.3	150.7
67	175.0	154.8	149.1	160.3
68	175.0	148.3	150.6	161.5
69	175.0	151.4	152.7	154.3
70	175.0	152.3	151.8	155.2
71	175.0	156.1	155.2	151.1
72	175.0	151.8	154.8	148.9
73	175.0	152.3	151.3	152.6
74	175.0	159.2	152.6	153.7
75	175.0	148.5	152.1	151.6
76	175.0	156.2	150	148.6
77	175.0	154.3	151.6	151.6
78	175.0	149.6	148.6	146
79	175.0	145.9	152	151.8
80	175.0	156.7	144.6	147.4
81	175.0	154.6	152.6	151
82	175.0	146.7	148.2	149.9
83	175.0	156.9	151.6	153.3



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TABLE - 2.06
FEED CONSUMPTION DATA OF MALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Vehicle only)	Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	Sample-II, Bt Cottonseeds (1000 mg/kg)
84	175.0	154.6	155.8	153.8
85	175.0	148.8	147.6	152.2
86	175.0	152.6	153	157
87	175.0	150	154.6	160.2
88	175.0	149.8	150.4	143.8
89	175.0	148.8	149.9	149
90	175.0	156	149.8	153.6
Mean	175.0	153.50	153.40	153.27
±	±	±	±	±
S.D.	0.00	3.72	2.97	3.53



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TABLE - 2.07
FEED CONSUMPTION DATA OF FEMALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Vehicle only)	Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	Sample-II, Bt Cottonseeds (1000 mg/kg)
0	175.0	158.8	160.2	159.9
1	175.0	154.4	154.2	154.4
2	175.0	153.8	155	156.6
3	175.0	157.1	149.9	157.2
4	175.0	153.4	153.3	154.3
5	175.0	156.7	154.4	156
6	175.0	154.8	156	157.2
7	175.0	156.6	154.8	158.2
8	175.0	153.9	155.6	150.2
9	175.0	154.4	158	149.9
10	175.0	153.3	160	153.3
11	175.0	152.2	158.2	152.8
12	175.0	150.8	157.4	156.6
13	175.0	159.4	159.9	153.8
14	175.0	152.2	157.7	154.2
15	175.0	153.3	158.8	154.2
16	175.0	149.9	159.9	158
17	175.0	151.8	160.2	152.9
18	175.0	159.9	159.2	154.9
19	175.0	153.4	158.8	156.6
20	175.0	156.6	154.4	158



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TABLE - 2.08
FEED CONSUMPTION DATA OF FEMALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Vehicle only)	Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	Sample-II, Bt Cottonseeds (1000 mg/kg)
21	175.0	149.9	153.3	154.2
22	175.0	153.2	154.9	152.8
23	175.0	154	156.6	156
24	175.0	155.2	157.8	157.8
25	175.0	156	160.2	156.4
26	175.0	155.2	153.3	154.5
27	175.0	154.3	155	153.1
28	175.0	156	154.2	156.9
29	175.0	152.3	156.6	156.6
30	175.0	154.4	152.7	159.9
31	175.0	156.2	156.6	156.6
32	175.0	155.2	152.4	154.4
33	175.0	159.9	153.3	152.2
34	175.0	157.8	159.9	149.9
35	175.0	152.8	157	156.6
36	175.0	152.9	153.2	154.2
37	175.0	156.2	158	150.2
38	175.0	152.8	152.8	152.8
39	175.0	156.4	155.2	158.2
40	175.0	157.7	154.6	152.2
41	175.0	154.4	152.2	153.2



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TABLE - 2.09
FEED CONSUMPTION DATA OF FEMALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Vehicle only)	Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	Sample-II, Bt Cottonseeds (1000 mg/kg)
42	175.0	154.9	156.3	158.2
43	175.0	156	152.8	152.8
44	175.0	151.4	153.8	153.4
45	175.0	154.2	154.2	156
46	175.0	151	152.9	153.8
47	175.0	153.3	155.2	151.6
48	175.0	155.4	152.7	154.2
49	175.0	158	156.6	152.8
50	175.0	149.2	153.5	156.6
51	175.0	152.2	149.7	154
52	175.0	151.4	151	152
53	175.0	153	156	154.9
54	175.0	150.4	152	153.2
55	175.0	155.3	152.2	148.9
56	175.0	153.4	154.9	156.8
57	175.0	155.3	155	156.4
58	175.0	151.1	153.1	152.3
59	175.0	150.6	153.4	154.8
60	175.0	149.3	148.5	150.3
61	175.0	148.9	150.6	149.2
62	175.0	155.7	151.8	150.1



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TABLE - 2.10
FEED CONSUMPTION DATA OF FEMALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Vehicle only)	Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	Sample-II, Bt Cottonseeds (1000 mg/kg)
63	175.0	150.3	149.5	153.4
64	175.0	150.9	151.7	153.2
65	175.0	156.2	153.5	155.1
66	175.0	157.3	151.8	155.2
67	175.0	159.6	153.2	157.3
68	175.0	158.3	154.5	155.9
69	175.0	153.6	161.1	159.1
70	175.0	156.2	152.3	156.3
71	175.0	152.3	156.6	149.8
72	175.0	154.6	155.2	150.3
73	175.0	155.2	153.1	151.6
74	175.0	152.1	151.7	152.3
75	175.0	151.6	157.2	155.4
76	175.0	153.1	156.3	151.3
77	175.0	155.2	157.4	150.2
78	175.0	153.6	152.3	151.3
79	175.0	154	141.8	152
80	175.0	149.9	148.3	147.2
81	175.0	153	147.1	149.9
82	175.0	148.2	144	153.4
83	175.0	151	149.1	149.4



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TABLE - 2.11
FEED CONSUMPTION DATA OF FEMALE RATS 90 DAYS ORAL STUDY

DAYS	FEED WT. (In gms.)	CONTROL (Vehicle only)	Sample-I, Non-Bt Cottonseeds (1000 mg/kg)	Sample-II, Bt Cottonseeds (1000 mg/kg)
84	175.0	148.2	142.8	152
85	175.0	151.6	156.1	147.2
86	175.0	149.39	148.4	149.2
87	175.0	153	151.4	147.6
88	175.0	147	147.4	150.2
89	175.0	144.2	149.9	152.8
90	175.0	146	144.8	146.8
Mean	175.0	153.57	153.96	153.69
±	±	±	±	±
S.D.	0.00	3.09	3.93	3.04



TABLE - 3.01
MEAN HAEMATOLOGY DATA OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal Group	WBC Count (x10 ³)	DIFFERENTIAL					RBC count (x10 ⁶)	Hb gm %	HCT %	Platelets Count
		L%	N%	E%	M%	B%				
Control (Corn Oil)	7.44 ± 1.57	85.00 ± 4.11	13.80 ± 3.82	0.60 ± 0.52	0.60 ± 0.52	0.00 ± 0.00	8.54 ± 0.33	15.43 ± 0.48	46.27 ± 1.61	10.91 ± 1.62
Non-Bt Cottonseeds (Sample -I)	7.64 ± 1.74	79.90 ± 6.85	18.40 ± 6.64	0.90 ± 0.57	0.80 ± 0.42	0.00 ± 0.00	8.33 ± 0.37	15.36 ± 0.66	45.85 ± 2.47	9.49 ± 2.13
Bt Cottonseeds (Sample -II)	8.04 ± 1.32	84.50 ± 3.03	14.30 ± 2.98	0.80 ± 0.42	0.40 ± 0.52	0.00 ± 0.00	8.53 ± 0.33	15.91 ± 0.59	47.73 ± 1.77	10.44 ± 2.20

* P = 0.05



TABLE - 3.02
MEAN HAEMATOLOGY DATA OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal Group	WBC Count (x10 ³)	DIFFERENTIAL					RBC count (x10 ⁶)	Hb gm %	HCT % L%	Platelets Count N%
		L%	N%	E%	M%	B%				
Control (Corn Oil)	8.37 ± 1.93	84.10 ± 5.00	14.60 ± 4.30	0.80 ± 0.63	0.50 ± 0.53	0.00 ± 0.00	7.95 ± 0.35	15.02 ± 0.28	44.56 ± 1.24	10.72 ± 1.10
Non-Bt Cottonseeds (Sample -I)	7.77 ± 1.82	84.00 ± 3.77	14.70 ± 3.86	0.90 ± 0.32	0.40 ± 0.52	0.00 ± 0.00	7.46 ± 0.20	14.65 ± 0.43	41.51 ± 1.28	9.65 ± 1.43
Bt Cottonseeds (Sample -II)	7.01 ± 0.44	84.70 ± 3.50	13.80 ± 3.61	0.80 ± 0.42	0.70 ± 0.48	0.00 ± 0.00	7.58 ± 0.43	14.80 ± 0.69	41.96 ± 2.68	10.37 ± 1.22

* P = 0.05



TABLE - 3.03
HAEMATOLOGY DATA OF MALE RATS (CONTOL GROUP) AT TERMINAL SACRIFICE

Animal No.	Sex	WBC Count (x10 ³)	DIFFERENTIAL					RBC count (x10 ⁶)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%	M%	B%				
1	M	11.6	85.0	14.0	1.0	0.0	0.0	8.8	15.3	45.9	9.9
2	M	7.3	86.0	13.0	0.0	1.0	0.0	8.6	15.1	45.3	8.0
3	M	7.2	91.0	9.0	0.0	0.0	0.0	8.5	14.7	44.1	13.5
4	M	6.9	88.0	10.0	1.0	1.0	0.0	8.3	14.9	44.7	10.5
5	M	7.8	83.0	16.0	0.0	1.0	0.0	8.9	16.2	48.6	11.1
6	M	6.3	89.0	11.0	0.0	0.0	0.0	8.9	16.0	48.0	9.0
7	M	7.8	78.0	20.0	1.0	1.0	0.0	7.8	15.2	44.4	11.6
8	M	6.9	79.0	20.0	1.0	0.0	0.0	8.7	15.8	47.4	11.2
9	M	6.5	86.0	12.0	1.0	1.0	0.0	8.4	15.5	47.5	12.2
10	M	6.1	85.0	13.0	1.0	1.0	0.0	8.5	15.6	46.8	12.1
Mean		7.44	85.00	13.80	0.60	0.60	0.00	8.54	15.43	46.27	10.91
±		±	±	±	±	±	±	±	±	±	±
S.D		1.57	4.11	3.82	0.52	0.52	0.00	0.33	0.48	1.61	1.62



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TABLE -3.04
HAEMATOLOGY DATA OF FEMALE RATS (CONTROL GROUP) AT TERMINAL SACRIFICE

Animal No.	Sex	WBC Count (x10 ³)	DIFFERENTIAL					RBC count (x10 ⁶)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%	M%	B%				
1	F	8.4	85.0	14.0	1.0	0.0	0.0	7.9	14.9	43.0	11.5
2	F	7.8	89.0	11.0	0.0	0.0	0.0	7.6	14.6	43.5	9.3
3	F	6.9	84.0	14.0	1.0	1.0	0.0	7.5	14.9	43.5	11.8
4	F	13.4	86.0	13.0	1.0	0.0	0.0	7.7	15.1	44.1	10.6
5	F	8.2	88.0	11.0	0.0	1.0	0.0	7.6	15.0	43.8	12.6
6	F	7.4	85.0	15.0	0.0	0.0	0.0	8.5	15.0	45.6	9.8
7	F	7.9	80.0	18.0	1.0	1.0	0.0	8.3	15.4	46.2	10.8
8	F	8.1	77.0	21.0	1.0	1.0	0.0	8.3	15.5	46.5	10.6
9	F	6.4	91.0	8.0	1.0	0.0	0.0	8.0	15.1	45.3	11.1
10	F	9.2	76.0	21.0	2.0	1.0	0.0	8.1	14.7	44.1	9.1
Mean		8.37	84.10	14.60	0.80	0.50	0.00	7.95	15.02	44.56	10.72
±		±	±	±	±	±	±	±	±	±	±
S.D		1.93	5.00	4.30	0.63	0.53	0.00	0.35	0.28	1.24	1.10



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TABLE - 3.05
HAEMATOLOGY DATA OF MALE RATS (SAMPLE-I, NON-Bt COTTONSEEDS) AT TERMINAL SACRIFICE

Animal No.	Sex	WBC Count (x10 ³)	DIFFERENTIAL					RBC count (x10 ⁶)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%	M%	B%				
1	M	6.6	85.0	13.0	2.0	0.0	0.0	8.9	15.7	47.1	6.6
2	M	6.8	78.0	21.0	0.0	1.0	0.0	8.7	16.4	49.2	9.5
3	M	7.5	73.0	25.0	1.0	1.0	0.0	8.7	16.0	48.0	11.5
4	M	6.5	76.0	22.0	1.0	1.0	0.0	8.5	15.8	47.4	10.8
5	M	7.4	86.0	13.0	0.0	1.0	0.0	8.1	14.8	44.4	10.1
6	M	6.9	90.0	9.0	1.0	0.0	0.0	7.9	14.9	43.7	12.0
7	M	12.2	72.0	26.0	1.0	1.0	0.0	7.9	14.2	41.3	6.2
8	M	6.4	88.0	10.0	1.0	1.0	0.0	8.4	15.5	47.5	11.5
9	M	8.7	72.0	26.0	1.0	1.0	0.0	8.3	15.4	46.2	7.2
10	M	7.4	79.0	19.0	1.0	1.0	0.0	7.9	14.9	43.7	9.5
Mean		7.64	79.90	18.40	0.90	0.80	0.00	8.33	15.36	45.85	9.49
±		±	±	±	±	±	±	±	±	±	±
S.D		1.74	6.85	6.64	0.57	0.42	0.00	0.37	0.66	2.47	2.13



TABLE - 3.06
HAEMATOLOGY DATA OF FEMALE RATS (SAMPLE-I, NON-BT COTTONSEEDS) AT TERMINAL SACRIFICE

Animal No.	SEX	WBC Count (x10 ³)	DIFFERENTIAL					RBC count (x10 ⁶)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%	M%	B%				
1	F	10.2	86.0	13.0	1.0	0.0	0.0	7.5	14.6	42.5	8.0
2	F	11.2	88.0	11.0	1.0	0.0	0.0	7.3	14.7	42.1	9.1
3	F	6.2	84.0	15.0	1.0	0.0	0.0	7.4	14.6	41.1	10.2
4	F	7.1	84.0	15.0	0.0	1.0	0.0	7.1	13.6	38.3	9.9
5	F	6.3	80.0	19.0	1.0	0.0	0.0	7.7	15.2	42.9	9.1
6	F	9.2	86.0	12.0	1.0	1.0	0.0	7.4	14.6	42.4	8.4
7	F	7.5	90.0	8.0	1.0	1.0	0.0	7.3	14.6	41.2	10.5
8	F	6.3	78.0	20.0	1.0	1.0	0.0	7.5	15.1	41.6	8.1
9	F	7.6	84.0	15.0	1.0	0.0	0.0	7.7	14.7	41.4	12.7
10	F	6.1	80.0	19.0	1.0	0.0	0.0	7.7	14.8	41.6	10.5
Mean		7.77	84.00	14.70	0.90	0.40	0.00	7.46	14.65	41.51	9.65
±		±	±	±	±	±	±	±	±	±	±
S.D		1.82	3.77	3.86	0.32	0.52	0.00	0.20	0.43	1.28	1.43



TABLE - 3.07
HAEMATOLOGY DATA OF MALE RATS (SAMPLE-II, Bt COTTONSEEDS) AT TERMINAL SACRIFICE

Animal No.	SEX	WBC Count (x10 ³)	DIFFERENTIAL					RBC count (x10 ⁶)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%	M%	B%				
1	M	7.2	86.0	13.0	0.0	1.0	0.0	8.6	16.1	48.3	10.1
2	M	6.3	80.0	18.0	1.0	1.0	0.0	8.8	16.6	49.8	8.2
3	M	6.5	84.0	14.0	1.0	1.0	0.0	9.1	17.0	51.0	10.2
4	M	6.9	85.0	14.0	1.0	0.0	0.0	8.1	15.1	45.3	8.8
5	M	9.2	86.0	12.0	1.0	1.0	0.0	8.8	16.0	48.0	9.8
6	M	7.9	84.0	16.0	0.0	0.0	0.0	8.3	15.8	47.4	12.1
7	M	9.2	87.0	12.0	1.0	0.0	0.0	8.3	15.2	45.6	8.8
8	M	9.8	85.0	14.0	1.0	0.0	0.0	8.7	15.9	47.7	15.9
9	M	7.8	89.0	10.0	1.0	0.0	0.0	8.5	16.0	48.0	10.0
10	M	9.6	79.0	20.0	1.0	0.0	0.0	8.1	15.4	46.2	10.5
Mean		8.04	84.50	14.30	0.80	0.40	0.00	8.53	15.91	47.73	10.44
±		±	±	±	±	±	±	±	±	±	±
S.D		1.32	3.03	2.98	0.42	0.52	0.00	0.33	0.59	1.77	2.20



TABLE - 3.08
HAEMATOLOGY DATA OF FEMALE RATS (SAMPLE-II, Bt COTTONSEEDS) AT TERMINAL SACRIFICE

Animal No.	SEX	WBC Count (x10 ³)	DIFFERENTIAL					RBC count (x10 ⁶)	Hb gm %	HCT %	Platelets Count
			L%	N%	E%	M%	B%				
1	F	6.2	80.0	18.0	1.0	1.0	0.0	7.8	15.1	42.9	11.3
2	F	7.2	84.0	15.0	1.0	0.0	0.0	7.6	14.7	41.5	10.9
3	F	7.8	85.0	14.0	0.0	1.0	0.0	7.1	14.1	39.9	8.8
4	F	7.1	88.0	10.0	1.0	1.0	0.0	7.6	14.6	41.6	11.7
5	F	6.9	78.0	21.0	1.0	0.0	0.0	7.3	14.0	39.9	8.3
6	F	6.9	89.0	9.0	1.0	1.0	0.0	7.2	14.8	40.1	11.2
7	F	7.4	86.0	13.0	0.0	1.0	0.0	7.8	14.8	42.1	11.2
8	F	6.7	85.0	13.0	1.0	1.0	0.0	7.1	14.2	40.2	11.3
9	F	6.7	88.0	11.0	1.0	0.0	0.0	7.8	15.4	42.5	9.6
10	F	7.2	84.0	14.0	1.0	1.0	0.0	8.5	16.3	48.9	9.4
Mean		7.01	84.70	13.80	0.80	0.70	0.00	7.58	14.80	41.96	10.37
±		±	±	±	±	±	±	±	±	±	±
S.D		0.44	3.50	3.61	0.42	0.48	0.00	0.43	0.69	2.68	1.22



TABLE - 4.01
MEAN BIOCHEMISTRY DATA OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal Group	Blood Urea (mg %)	Glucose (mg %)	Total Protein (gm%)	S.G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	Cholesterol (mg%)	SAP U/L
Control (Corn Oil)	40.03 ± 5.48	120.70 ± 51.00	7.50 ± 0.22	60.85 ± 16.27	62.67 ± 11.16	4.29 ± 0.18	51.50 ± 9.48	101.80 ± 13.59
Non-Bt Cottonseeds (Sample -I)	33.39 ± 4.79	126.70 ± 39.92	7.48 ± 0.48	57.11 ± 13.56	62.57 ± 9.19	4.22 ± 0.23	49.80 ± 7.10	97.60 ± 16.23
Bt Cottonseeds (Sample -II)	33.72 ± 3.64	105.00 ± 22.08	7.85 ± 0.33	53.09 ± 12.90	55.71 ± 6.10	4.49 ± 0.11	59.70 ± 9.26	76.20 ± 17.96

* P = 0.05



TABLE - 4.02
MEAN BIOCHEMISTRY DATA OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal Group	Blood Urea (mg %)	Glucose (mg %)	Total Protein (gm%)	S.G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	Cholesterol (mg%)	SAP U/L
Control (Corn Oil)	35.37 ± 7.66	121.50 ± 30.07	8.10 ± 0.40	53.42 ± 8.95	68.93 ± 13.71	4.34 ± 0.24	61.20 ± 10.45	87.20 ± 18.59
Non-Bt Cottonseeds (Sample -I)	30.80 ± 4.90	148.70 ± 38.10	8.30 ± 0.43	43.35 ± 10.94	63.37 ± 8.14	4.47 ± 0.39	59.50 ± 6.67	77.79 ± 19.77
Bt Cottonseeds (Sample -II)	28.43 ± 3.09	115.60 ± 12.03	8.26 ± 0.34	42.63 ± 12.26	55.98 ± 10.20	4.87 ± 0.27	67.30 ± 11.16	69.30 ± 20.78

* P = 0.05



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TABLE - 4.03
BIOCHEMISTRY DATA OF CONTROL GROUP OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal No.	Sex	Blood Urea (mg %)	Glucose (mg %)	Total Protein (gm%)	S.G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	Cholesterol (mg%)	SAP U/L
1	M	47.0	93.0	7.6	81.8	77.1	4.1	50.0	83.0
2	M	44.6	74.0	7.8	62.5	73.6	4.5	55.0	111.0
3	M	43.1	81.0	7.5	57.5	74.9	4.1	42.0	118.0
4	M	35.0	100.0	7.2	59.7	56.9	4.0	43.0	106.0
5	M	34.5	210.0	7.3	41.0	56.4	4.4	45.0	111.0
6	M	40.1	113.0	7.7	72.9	52.2	4.5	56.0	102.0
7	M	34.0	84.0	7.2	60.0	57.8	4.2	68.0	83.0
8	M	48.2	142.0	7.7	87.7	75.2	4.3	66.0	83.0
9	M	39.4	99.0	7.6	44.8	48.0	4.4	46.0	111.0
10	M	34.4	211.0	7.4	40.6	54.6	4.4	44.0	110.0
Mean		40.03	120.70	7.50	60.85	62.67	4.29	51.50	101.80
±		±	±	±	±	±	±	±	±
S.D		5.48	51.00	0.22	16.27	11.16	0.18	9.48	13.59



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PROJECT NO. : TOX-346C
PRODUCT : Bt COTTONSEEDS
STUDY : SUB CHRONIC ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000046374
DATE : 14.05.2007

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TABLE 4.04
BIOCHEMISTRY DATA OF CONTROL GROUP OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal No.	Sex	Blood Urea (mg %)	Glucose (mg %)	Total Protein (gm%)	S.G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	Cholesterol (mg%)	SAP U/L
1		40.4	131.0	8.3	44.3	83.9	4.3	58.0	93.0
2	F	43.2	110.0	7.8	72.8	46.1	4.1	56.0	102.0
3	F	32.2	177.0	8.9	47.9	75.3	4.8	55.0	79.0
4	F	46.8	158.0	7.5	56.5	74.1	4.2	45.0	112.0
5	F	43.5	134.0	8.0	53.4	59.1	4.5	61.0	115.0
6	F	34.2	120.0	8.3	59.0	55.7	4.1	82.0	87.0
7	F	25.9	83.0	7.8	42.7	91.7	4.6	67.0	55.0
8	F	24.9	91.0	8.3	52.1	60.7	4.4	69.0	76.0
9	F	30.7	91.0	7.8	46.7	73.4	4.3	67.0	74.0
10	F	31.9	120.0	8.3	58.8	69.3	4.1	52.0	79.0
Mean		35.37	121.50	8.10	53.42	68.93	4.34	61.20	87.20
± S.D		± 7.66	± 30.07	± 0.40	± 8.95	± 13.71	± 0.24	± 10.45	± 18.59



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STUDY : SUB CHRONIC ORAL TOXICITY STUDY IN RATS
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DATE : 14.05.2007

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TABLE - 4.05
BIOCHEMISTRY DATA OF SAMPLE-I (NON-Bt COTTONSEEDS) OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal No.	Sex	BLOOD UREA (mg %)	Glucose (mg %)	Total Protein (gm%)	S.G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	Cholesterol (mg%)	SAP U/L
1		37.9	101.0	7.5	65.5	77.1	4.2	48.0	85.0
2	M	33.6	85.0	7.4	43.1	54.8	4.5	42.0	101.0
3	M	26.4	189.0	7.7	58.8	55.4	4.5	55.0	97.0
4	M	28.6	177.0	7.0	45.6	72.1	4.3	49.0	96.0
5	M	28.2	111.0	7.4	85.3	68.7	3.9	41.0	89.0
6	M	37.6	97.0	7.7	57.5	52.8	3.9	45.0	107.0
7	M	29.8	178.0	7.0	48.1	59.2	4.3	49.0	71.0
8	M	35.4	95.0	7.0	40.1	73.1	4.0	62.0	99.0
9	M	40.0	134.0	8.6	62.0	58.6	4.2	60.0	134.0
10	M	36.4	100.0	7.5	65.1	53.9	4.4	47.0	97.0
Mean		33.39	126.70	7.48	57.11	62.57	4.22	49.80	97.60
± S.D		± 4.79	± 39.92	± 0.48	± 13.56	± 9.19	± 0.23	± 7.10	± 16.23



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TABLE - 4.06
BIOCHEMISTRY DATA OF SAMPLE -I (NON-Bt COTTONSEEDS) OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal No.	Sex	BLOOD UREA (mg %)	Glucose (mg %)	Total Protein (gm%)	S.G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	Cholesterol (mg%)	SAP U/L
1		26.3	170.0	8.5	55.6	62.8	5.3	73.0	61.7
2	F	32.2	188.0	8.8	37.8	52.0	4.4	55.0	98.2
3	F	24.1	106.0	8.5	31.5	66.9	4.8	51.0	59.4
4	F	34.9	172.0	7.7	35.3	52.2	4.5	68.0	103.6
5	F	31.1	135.0	7.8	35.9	54.2	4.6	55.0	88.0
6	F	25.4	92.0	8.6	55.1	72.3	4.3	63.0	97.0
7	F	37.4	134.0	8.5	62.7	73.0	4.2	59.0	62.0
8	F	36.4	193.0	7.9	35.1	65.5	3.8	58.0	63.0
9	F	33.8	188.0	8.8	37.1	71.6	4.4	56.0	93.0
10	F	26.4	109.0	7.9	47.4	63.2	4.4	57.0	52.0
Mean		30.80	148.70	8.30	43.35	63.37	4.47	59.50	77.79
± S.D		± 4.90	± 38.10	± 0.43	± 10.94	± 8.14	± 0.39	± 6.67	± 19.77



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TABLE - 4.07
BIOCHEMISTRY DATA OF SAMPLE-II (Bt COTTONSEEDS) OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal No.	Sex	BLOOD UREA (mg %)	Glucose (mg %)	Total Protein (gm%)	S.G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	Cholesterol (mg%)	SAP U/L
1		32.8	99.0	8.0	62.1	58.3	4.5	73.0	108.0
2	M	31.8	113.0	7.9	64.7	59.0	4.5	51.0	103.0
3	M	31.6	116.0	7.8	47.7	52.2	4.6	75.0	69.0
4	M	37.9	107.0	8.0	52.8	49.9	4.3	54.0	68.0
5	M	36.5	87.0	8.5	69.9	70.1	4.6	69.0	57.0
6	M	29.4	80.0	7.6	38.1	55.2	4.3	60.0	64.0
7	M	40.7	108.0	7.3	43.2	50.8	4.5	57.0	56.0
8	M	34.2	90.0	7.7	69.6	54.3	4.5	50.0	77.0
9	M	29.7	158.0	8.1	34.3	49.8	4.6	54.0	73.0
10	M	32.6	92.0	7.6	48.5	57.5	4.5	54.0	87.0
Mean		33.72	105.00	7.85	53.09	55.71	4.49	59.70	76.20
±		±	±	±	±	±	±	±	±
S.D		3.64	22.08	0.33	12.90	6.10	0.11	9.26	17.96



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TABLE - 4.08
BIOCHEMISTRY DATA OF SAMPLE-II (Bt COTTONSEEDS) OF FEMALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Animal No.	Sex	BLOOD UREA (mg %)	Glucose (mg %)	Total Protein (gm%)	S.G.P.T I.U	S.G.O.T I.U	Albumin (gm%)	Cholesterol (mg%)	SAP U/L
1	F	25.5	107.0	8.2	28.8	56.9	4.7	68.0	70.0
2	F	27.6	115.0	8.2	51.4	52.0	4.7	50.0	65.0
3	F	28.2	118.0	8.6	44.5	62.4	5.0	73.0	78.0
4	F	33.4	118.0	8.5	49.6	50.3	4.8	74.0	52.0
5	F	29.7	130.0	8.6	69.9	82.4	4.9	61.0	57.0
6	F	30.2	106.0	8.2	38.0	47.9	5.0	56.0	53.0
7	F	31.9	117.0	8.6	42.2	51.2	5.4	67.0	56.0
8	F	23.9	139.0	7.6	34.3	50.0	4.5	69.0	52.0
9	F	29.2	108.0	7.8	29.2	55.7	5.1	64.0	110.0
10	F	24.7	98.0	8.3	38.4	51.0	4.6	91.0	100.0
Mean		28.43	115.60	8.26	42.63	55.98	4.87	67.30	69.30
±		±	±	±	±	±	±	±	±
S.D		3.09	12.03	0.34	12.26	10.20	0.27	11.16	20.78



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TABLE - 5.01
MEAN PERCENTILE ORGAN WEIGHT DATA OF MALE RATS AT TERMINAL SACRIFICE

DOSAGE GROUP			
Organs	Control (Corn Oil Only)	Non-Bt Cottonseeds (Sample -I)	Bt Cottonseeds (Sample- II)
Lung	0.72 ± 0.03	0.72 ± 0.03	0.72 ± 0.05
Liver	3.00 ± 0.26	3.07 ± 0.24	3.09 ± 0.27
Kidney	0.76 ± 0.03	0.76 ± 0.03	0.77 ± 0.07
Testis	1.14 ± 0.05	1.13 ± 0.09	1.11 ± 0.13
Adrenal	0.03 ± 0.01	0.03 ± 0.01	0.03 ± .004
Heart	0.31 ± 0.02	0.32 ± 0.03	0.31 ± 0.03
Spleen	0.23 ± 0.02	0.24 ± 0.03	0.26 ± 0.06
Brain	0.79 ± 0.03	0.78 ± 0.03	0.81 ± 0.05

* P = 0.05



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TABLE - 5.02
MEAN PERCENTILE ORGAN WEIGHT DATA OF FEMALE RATS AT TERMINAL SACRIFICE
DOSAGE GROUP

Organs	Control (Corn Oil Only)	Non-Bt Cottonseeds (Sample -I)	Bt Cottonseeds (Sample -II)
Lung	0.70 ± 0.04	0.71 ± 0.04	0.72 ± 0.07
Liver	2.93 ± 0.10	3.04 ± 0.27	3.00 ± 0.22
Kidney	0.75 ± 0.04	0.75 ± 0.05	0.74 ± 0.06
Ovaries	0.06 ± 0.01	0.06 ± 0.01	0.07 ± 0.01
Uterus	0.11 ± 0.03	0.10 ± 0.02	0.11 ± 0.01
Adrenal	0.03 ± .004	0.03 ± .004	0.03 ± 0.01
Heart	0.29 ± 0.03	0.31 ± 0.02	0.30 ± 0.03
Spleen	0.22 ± 0.03	0.24 ± 0.03	0.25 ± 0.05
Brain	0.77 ± 0.02	0.78 ± 0.02	0.77 ± 0.03

* P = 0.05



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TABLE -5.03
AVERAGE ORGAN WEIGHT DATA OF MALE RATS AT TERMINAL SACRIFICE

DOSAGE GROUP			
Organs	Control (Corn Oil Only)	Non-Bt Cottonseeds (Sample -I)	Bt Cottonseeds (Sample -II)
Lung	1.69 ± 0.06	1.68 ± 0.06	1.67 ± 0.12
Liver	7.02 ± 0.60	7.17 ± 0.59	7.12 ± 0.60
Kidney	1.79 ± 0.07	1.76 ± 0.05	1.77 ± 0.15
Testis	2.66 ± 0.14	2.64 ± 0.20	2.57 ± 0.30
Adrenal	0.07 ± 0.01	0.06 ± 0.01	0.07 ± 0.01
Heart	0.72 ± 0.05	0.75 ± 0.06	0.73 ± 0.06
Spleen	0.55 ± 0.04	0.57 ± 0.06	0.59 ± 0.14
Brain	1.85 ± 0.08	1.83 ± 0.03	1.87 ± 0.11

* P = 0.05



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TABLE - 5.04
AVERAGE ORGAN WEIGHT DATA OF FEMALE RATS AT TERMINAL SACRIFICE
DOSAGE GROUP

Organs	Control (Corn Oil Only)	Non-Bt Cottonseeds (Sample -I)	Bt Cottonseeds (Sample -II)
Lung	1.66 ± 0.07	1.65 ± 0.09	1.66 ± 0.16
Liver	6.93 ± 0.26	7.08 ± 0.63	6.97 ± 0.54
Kidney	1.76 ± 0.07	1.75 ± 0.11	1.72 ± 0.15
Ovaries	0.13 ± 0.02	0.15 ± 0.02	0.17 ± 0.02
Uterus	0.26 ± 0.07	0.24 ± 0.04	0.25 ± 0.03
Adrenal	0.06 ± 0.01	0.07 ± 0.01	0.06 ± 0.01
Heart	0.70 ± 0.08	0.72 ± 0.04	0.70 ± 0.07
Spleen	0.53 ± 0.08	0.55 ± 0.08	0.57 ± 0.11
Brain	1.82 ± 0.04	1.81 ± 0.05	1.79 ± 0.07

* P = 0.05



TABLE - 5.05
 ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF CONTROL GROUP OF MALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Testis		Adrenal		Heart		Spleen		Brain	
			Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.
1	M	239	1.68	0.70	7.4	3.10	1.72	0.72	2.64	1.10	0.07	0.03	0.67	0.28	0.55	0.23	1.85	0.77
2	M	232	1.71	0.74	6.34	2.73	1.80	0.78	2.43	1.05	0.06	0.03	0.7	0.30	0.46	0.20	1.86	0.80
3	M	232	1.55	0.67	6.48	2.79	1.69	0.73	2.7	1.16	0.05	0.02	0.69	0.30	0.53	0.23	1.8	0.78
4	M	237	1.75	0.74	7.50	3.16	1.78	0.75	2.80	1.18	0.06	0.03	0.70	0.30	0.52	0.22	1.91	0.81
5	M	233	1.73	0.74	7.66	3.29	1.87	0.80	2.64	1.13	0.09	0.04	0.68	0.29	0.60	0.26	1.70	0.73
6	M	230	1.74	0.76	6.18	2.69	1.76	0.77	2.50	1.09	0.06	0.03	0.71	0.31	0.55	0.24	1.8	0.78
7	M	242	1.64	0.68	6.37	2.63	1.82	0.75	2.81	1.16	0.09	0.04	0.71	0.29	0.62	0.26	1.92	0.79
8	M	234	1.71	0.73	7.26	3.10	1.85	0.79	2.74	1.17	0.07	0.03	0.79	0.34	0.57	0.24	1.95	0.83
9	M	234	1.73	0.74	7.41	3.17	1.68	0.72	2.84	1.21	0.06	0.03	0.81	0.35	0.56	0.24	1.81	0.77
10	M	231	1.66	0.72	7.61	3.29	1.88	0.81	2.54	1.10	0.05	0.02	0.77	0.33	0.53	0.23	1.94	0.84
Mean		234.40	1.69	0.72	7.02	3.00	1.79	0.76	2.66	1.14	0.07	0.03	0.72	0.31	0.55	0.23	1.85	0.79
±		±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±
S.D.		3.81	0.06	0.03	0.60	0.26	0.07	0.03	0.14	0.05	0.01	0.01	0.05	0.02	0.04	0.02	0.08	0.03



TABLE - 5.06

ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF CONTROL GROUP OF FEMALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Ovaries		Uterus		Adrenal		Heart		Spleen		Brain	
			Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.
1	F	241	1.65	0.68	7.33	3.04	1.78	0.74	0.14	0.06	0.45	0.19	0.07	0.03	0.75	0.31	0.62	0.26	1.8	0.75
2	F	230	1.66	0.72	6.84	2.97	1.81	0.79	0.11	0.05	0.22	0.10	0.07	0.03	0.68	0.30	0.59	0.26	1.79	0.78
3	F	234	1.75	0.75	6.67	2.85	1.60	0.68	0.16	0.07	0.25	0.11	0.08	0.03	0.72	0.31	0.61	0.26	1.78	0.76
4	F	242	1.59	0.66	7.05	2.91	1.74	0.72	0.11	0.05	0.21	0.09	0.06	0.02	0.8	0.33	0.63	0.26	1.85	0.76
5	F	245	1.65	0.67	6.70	2.73	1.71	0.70	0.13	0.05	0.25	0.10	0.06	0.02	0.56	0.23	0.51	0.21	1.76	0.72
6	F	231	1.76	0.76	6.81	2.95	1.76	0.76	0.12	0.05	0.24	0.10	0.05	0.02	0.74	0.32	0.45	0.19	1.86	0.81
7	F	230	1.52	0.66	6.70	2.91	1.79	0.78	0.13	0.06	0.20	0.09	0.07	0.03	0.57	0.25	0.41	0.18	1.76	0.77
8	F	237	1.68	0.71	7.03	2.97	1.82	0.77	0.10	0.04	0.26	0.11	0.06	0.03	0.76	0.32	0.54	0.23	1.87	0.79
9	F	238	1.60	0.67	7.39	3.11	1.86	0.78	0.16	0.07	0.3	0.13	0.05	0.02	0.73	0.31	0.49	0.21	1.85	0.78
10	F	238	1.70	0.71	6.80	2.86	1.76	0.74	0.15	0.06	0.26	0.11	0.06	0.03	0.65	0.27	0.46	0.19	1.86	0.78
Mean		236.60	1.66	0.70	6.93	2.93	1.76	0.75	0.13	0.06	0.26	0.11	0.06	0.03	0.70	0.29	0.53	0.22	1.82	0.77
±		±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±
S.D.		5.25	0.07	0.04	0.26	0.10	0.07	0.04	0.02	0.01	0.07	0.03	0.04	0.004	0.08	0.03	0.08	0.03	0.04	0.02



TABLE - 5.07

ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF SAMPLE-I (NON-Bt COTTONSEEDS) OF MALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Testis		Adrenal		Heart		Spleen		Brain	
			Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.
1	M	236	1.66	0.70	7.82	3.31	1.72	0.73	2.3	0.97	0.04	0.02	0.72	0.31	0.53	0.22	1.86	0.79
2	M	229	1.68	0.73	6.44	2.81	1.8	0.79	2.61	1.14	0.06	0.03	0.69	0.30	0.46	0.20	1.75	0.76
3	M	239	1.72	0.72	7.37	3.08	1.64	0.69	3.00	1.26	0.07	0.03	0.74	0.31	0.54	0.23	1.76	0.74
4	M	232	1.76	0.76	6.84	2.95	1.80	0.78	2.68	1.16	0.08	0.03	0.78	0.34	0.56	0.24	1.81	0.78
5	M	232	1.60	0.69	7.47	3.22	1.77	0.76	2.52	1.09	0.07	0.03	0.75	0.32	0.66	0.28	1.86	0.80
6	M	230	1.65	0.72	7.96	3.46	1.74	0.76	2.84	1.23	0.05	0.02	0.87	0.38	0.64	0.28	1.93	0.84
7	M	233	1.69	0.73	7.00	3.00	1.77	0.76	2.46	1.06	0.07	0.03	0.68	0.29	0.55	0.24	1.87	0.80
8	M	239	1.6	0.67	6.65	2.78	1.83	0.77	2.65	1.11	0.06	0.03	0.77	0.32	0.58	0.24	1.80	0.75
9	M	238	1.72	0.72	7.79	3.27	1.80	0.76	2.56	1.08	0.05	0.02	0.71	0.30	0.56	0.24	1.82	0.76
10	M	227	1.75	0.77	6.35	2.80	1.76	0.78	2.82	1.24	0.07	0.03	0.78	0.34	0.62	0.27	1.85	0.81
Mean		233.50	1.68	0.72	7.17	3.07	1.76	0.76	2.64	1.13	0.06	0.03	0.75	0.32	0.57	0.24	1.83	0.78
±		±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±
S.D.		4.30	0.06	0.03	0.59	0.24	0.05	0.03	0.20	0.09	0.01	0.01	0.06	0.03	0.06	0.03	0.05	0.03



TABLE - 5.08

ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF SAMPLE-I (NON-Bt COTTONSEEDS) OF FEMALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Ovaries		Uterus		Adrenal		Heart		Spleen		Brain	
			Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.
1	F	227	1.52	0.67	7.95	3.50	1.68	0.74	0.16	0.07	0.26	0.11	0.08	0.04	0.75	0.33	0.55	0.24	1.8	0.79
2	F	233	1.80	0.77	7.32	3.14	1.86	0.80	0.17	0.07	0.23	0.10	0.07	0.03	0.8	0.34	0.47	0.20	1.79	0.77
3	F	232	1.54	0.66	5.94	2.56	1.86	0.80	0.15	0.06	0.20	0.09	0.06	0.03	0.67	0.29	0.52	0.22	1.78	0.77
4	F	238	1.54	0.65	7.63	3.21	1.62	0.68	0.14	0.06	0.24	0.10	0.06	0.03	0.75	0.32	0.53	0.22	1.85	0.78
5	F	231	1.69	0.73	6.51	2.82	1.76	0.76	0.16	0.07	0.22	0.10	0.07	0.03	0.69	0.30	0.53	0.23	1.76	0.76
6	F	235	1.60	0.68	7.02	2.99	1.68	0.71	0.15	0.06	0.31	0.13	0.05	0.02	0.73	0.31	0.52	0.22	1.86	0.79
7	F	238	1.64	0.69	7.24	3.04	1.56	0.66	0.16	0.07	0.25	0.11	0.07	0.03	0.70	0.29	0.50	0.21	1.76	0.74
8	F	234	1.73	0.74	7.69	3.29	1.91	0.82	0.16	0.07	0.24	0.10	0.06	0.03	0.69	0.29	0.6	0.26	1.87	0.80
9	F	229	1.71	0.75	7.06	3.08	1.75	0.76	0.10	0.04	0.28	0.12	0.07	0.03	0.73	0.32	0.74	0.32	1.85	0.81
10	F	229	1.68	0.73	6.39	2.79	1.77	0.77	0.12	0.05	0.16	0.07	0.06	0.03	0.68	0.30	0.51	0.22	1.75	0.76
Mean		232.60	1.65	0.71	7.08	3.04	1.75	0.75	0.15	0.06	0.24	0.10	0.07	0.03	0.72	0.31	0.55	0.24	1.81	0.78
±		±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±
S.D.		3.75	0.09	0.04	0.63	0.27	0.11	0.05	0.02	0.01	0.04	0.02	0.01	.004	0.04	0.02	0.08	0.03	0.05	0.02



TABLE - 5.09

ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF SAMPLE-II (Bt COTTONSEEDS) OF MALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Testis		Adrenal		Heart		Spleen		Brain	
			Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.
1	M	231	1.58	0.68	7.45	3.23	1.72	0.74	2.74	1.19	0.08	0.03	0.65	0.28	0.56	0.24	1.92	0.83
2	M	234	1.84	0.79	6.61	2.82	1.62	0.69	2.73	1.17	0.07	0.03	0.76	0.32	0.48	0.21	1.73	0.74
3	M	222	1.65	0.74	7.06	3.18	1.82	0.82	2.31	1.04	0.07	0.03	0.68	0.31	0.39	0.18	1.90	0.86
4	M	227	1.79	0.79	7.56	3.33	1.75	0.77	2.57	1.13	0.06	0.03	0.81	0.36	0.59	0.26	1.99	0.88
5	M	227	1.56	0.69	7.46	3.29	1.89	0.83	2.78	1.22	0.07	0.03	0.71	0.31	0.55	0.24	1.78	0.78
6	M	231	1.75	0.76	7.49	3.24	1.98	0.86	3.18	1.38	0.05	0.02	0.78	0.34	0.59	0.26	1.85	0.80
7	M	234	1.51	0.65	7.64	3.26	1.77	0.76	2.22	0.95	0.07	0.03	0.79	0.34	0.84	0.36	1.66	0.71
8	M	236	1.72	0.73	7.62	3.23	1.72	0.73	2.48	1.05	0.06	0.03	0.76	0.32	0.69	0.29	1.87	0.79
9	M	233	1.76	0.76	5.92	2.54	1.50	0.64	2.45	1.05	0.05	0.02	0.65	0.28	0.48	0.21	1.97	0.85
10	M	233	1.53	0.66	6.42	2.76	1.97	0.85	2.23	0.96	0.07	0.03	0.67	0.29	0.76	0.33	2.00	0.86
Mean		230.80	1.67	0.72	7.12	3.09	1.77	0.77	2.57	1.11	0.07	0.03	0.73	0.31	0.59	0.26	1.87	0.81
±		±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±
S.D.		4.26	0.12	0.05	0.60	0.27	0.15	0.07	0.30	0.13	0.01	.004	0.06	0.03	0.14	0.06	0.11	0.05



TABLE - 5.10

ABSOLUTE & RELATIVE ORGAN WEIGHT DATA OF SAMPLE-II (Bt COTTONSEEDS) OF FEMALE RATS AT TERMINAL SACRIFICE

Animal No	Sex	Body Weight in gms	Lung		Liver		Kidney		Ovaries		Uterus		Adrenal		Heart		Spleen		Brain	
			Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.	Wt. In gm	% Body wt.
1	F	227	1.55	0.68	6.25	2.75	1.44	0.63	0.15	0.07	0.27	0.12	0.06	0.03	0.64	0.28	0.52	0.23	1.79	0.79
2	F	232	1.38	0.59	6.69	2.88	1.7	0.73	0.16	0.07	0.23	0.10	0.05	0.05	0.56	0.24	0.56	0.24	1.78	0.77
3	F	227	1.76	0.78	6.36	2.80	1.62	0.71	0.16	0.07	0.21	0.09	0.08	0.04	0.76	0.33	0.40	0.18	1.84	0.81
4	F	231	1.86	0.81	6.92	3.00	1.75	0.76	0.17	0.07	0.3	0.13	0.06	0.03	0.81	0.35	0.50	0.22	1.78	0.77
5	F	234	1.69	0.72	6.59	2.82	1.79	0.76	0.18	0.08	0.2	0.09	0.08	0.03	0.70	0.30	0.66	0.28	1.79	0.76
6	F	231	1.77	0.77	7.45	3.23	1.83	0.79	0.18	0.08	0.21	0.09	0.05	0.02	0.74	0.32	0.57	0.25	1.71	0.74
7	F	239	1.40	0.59	6.88	2.88	1.78	0.74	0.17	0.07	0.26	0.11	0.07	0.03	0.71	0.30	0.48	0.20	1.75	0.73
8	F	237	1.69	0.71	7.94	3.35	1.77	0.75	0.12	0.05	0.24	0.10	0.06	0.03	0.74	0.31	0.8	0.34	1.89	0.80
9	F	229	1.70	0.74	7.55	3.30	1.54	0.67	0.17	0.07	0.28	0.12	0.05	0.02	0.66	0.29	0.59	0.26	1.66	0.72
10	F	232	1.77	0.76	7.02	3.03	1.96	0.84	0.20	0.09	0.26	0.11	0.07	0.03	0.70	0.30	0.65	0.28	1.89	0.81
Mean		231.90	1.66	0.72	6.97	3.00	1.72	0.74	0.17	0.07	0.25	0.11	0.06	0.03	0.70	0.30	0.57	0.25	1.79	0.77
±		±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±	±
S.D.		3.93	0.16	0.07	0.54	0.22	0.15	0.06	0.02	0.01	0.03	0.01	0.01	0.01	0.07	0.03	0.11	0.05	0.07	0.03



SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

PROJECT NO. : TOX-346C
PRODUCT : Bt COTTONSEEDS
STUDY : SUB CHRONIC ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000046374
DATE : 14.05.2007

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TABLE - 6.01
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN CONTROL
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	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	Slight enlargement	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	Thickening of mucosa
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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TABLE - 6.02
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN CONTROL
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	Mild congestion	NAD	NAD	NAD	NAD	NAD	NAD	NAD	Thickening of mucosa
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



TABLE - 6.03
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN SAMPLE-I, NON-Bt COTTONSEEDS
(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	Mild congestion	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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TABLE - 6.04
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN SAMPLE-I, NON-Bt COTTONSEEDS
(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	Slight enlargement	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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TABLE - 6.05
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN SAMPLE-II, Bt COTTONSEEDS
(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	Mild congestion	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	Mild thickening of mucosa
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

NAD: No Abnormal Development



TABLE - 6.06
INTENSITY OF GROSS PATHOLOGICAL LESIONS IN SAMPLE-II, Bt COTTONSEEDS
(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	Mild thickening of mucosa
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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TABLE - 7.01
INTENSITY OF HISTO PATHOLOGICAL LESIONS IN CONTROL 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	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
4	MALE	NAD	Mild fatty changes	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	Mucinous enteritis
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, M.N.Cells : Mononuclear Cells



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TABLE - 7.02
INTENSITY OF HISTO PATHOLOGICAL LESIONS IN CONTROL 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	Congested blood vessel	NAD	NAD	NAD	NAD	NAD	NAD	NAD	Inflammation with oedema
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, M.N.Cells: Mononuclear Cells



SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

PROJECT NO. : TOX-346C
PRODUCT : Bt COTTONSEEDS
STUDY : SUB CHRONIC ORAL TOXICITY STUDY IN RATS
REPORT NO. : 000046374
DATE : 14.05.2007

Confidential

TABLE - 7.03
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN SAMPLE-I, NON -Bt COTTONSEEDS
(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	Congested blood vessel	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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



SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

PROJECT NO. : TOX-346C
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Confidential

TABLE - 7.04
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN SAMPLE-I, NON-Bt COTTONSEEDS
(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	Mild fatty changes with degeneration	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, M.N.Cells: Mononuclear Cells



TABLE - 7.05
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN SAMPLE -II, Bt COTTONSEEDS
(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	Thickening of alveolar septa	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	Infiltration of M.N.Cells
10	MALE	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD	NAD

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



TABLE - 7.06
INTENSITY OF HISTOPATHOLOGICAL LESIONS IN SAMPLE -II, Bt COTTONSEEDS
(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	Inflammatory changes
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, M.N.Cells: Mononuclear Cells



SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

(A unit of Shriram Scientific and Industrial Research Foundation)

An ISO - 9001:2000 Certified Institute

TEST CERTIFICATE

000046374

Issued to :

METAHELIX LIFE SCIENCES PVT. LTD.
PLOT NO. 3, KIADB 4TH PHASE,
BOMMASANDRA
BANGALORE - 560099KARNATAKA

J.O.No. TOX 346C
Reg.No. 4612570
Date 15-05-2007
GC-01 (REV-04)

Your Ref.No. --

Kind Attn: DR. M.J. VASUDEVA RAO , PRESIDENT

Sample Particulars:

One sample of "Bt Cottonseeds" was received for Sub-chronic oral toxicity study in rats.

Date

TEST RESULTS

Material Description : Non-Bt Cottonseeds (Sample-I)- Yellowish brown coloured powder
Bt Cottonseeds (Sample-II)- Yellowish brown coloured powder

Sponsor : Metahelix Life Sciences Private Limited
Plot no.3, KIADB 4th Phase, Bommasandra,
Bangalore-560 099, India.

Result

Sub-Chronic oral toxicity study in rats

Under the conditions of this study, the 90 days repeated oral administration of Bt Cottonseeds (Sample-II) at the dose level of 1000 mg/kg B.wt for five days/ week to rats did not induce any treatment related observable toxic effects, when compared to its corresponding Non-Bt Cottonseeds (Sample-I) and the control group of animals treated with corn oil (vehicle) only.

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

The sample has been conducted as per DBT, Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant parts.

(Annexure enclosed)

DOR : 06-11-2006
DOC : 14-05-2007


AUTHORISED SIGNATORY
(EMPLOYEE CODE 6006)

PCR & ELISA CONFIRMATION OF BIOSAFETY COTTONSEED MATERIAL

Objective: Quality Control of the cottonseed material from cry1C-9124 based intrahirsutum hybrids to be used for the biosafety studies; despatched on 11th September 2006.

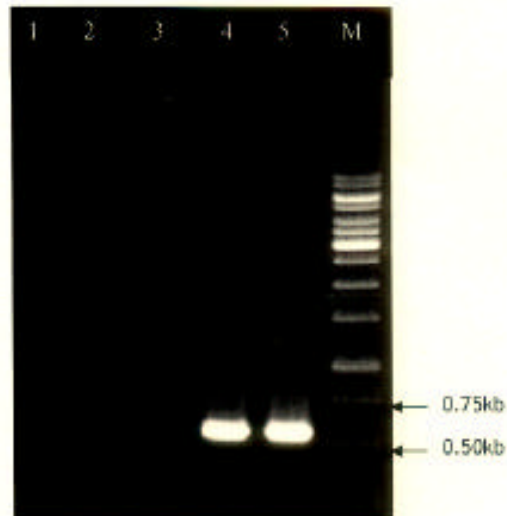
1. Confirmation of transgenic nature by PCR specific to the transgene
2. Confirmation of presence of Cry1C protein and its quantitation by ELISA

PCR confirmation

PCR was performed on Eppendorf Mastercycler Gradient machine with the following primers:

Upper: 5'-CCT CGC CAT TCT TCG TGA TTC C
 Lower: 5'-GGT TGG CCT CCC TTC CGT AGA TA

1. H₂O CONTROL
2. -VE CONTROL (LEAF)
3. NON TRANSGENIC SEED DNA
4. TRANSGENIC SEED DNA
5. +VE CONTROL



EXPECTATION- 0.58 KB

Results and conclusion

As expected amplification from cry1C was observed in case of transgenic and positive control proving the presence of the gene. Water and negative controls were clear indicating the absence of gene.

Metahelix Life Sciences Private Limited

Plot No. 3, KIADB 4th Phase, Bommasandra, Bangalore 560 099, India.
 Tel: +91-80-787 0236, 783 6086 Fax: +91-80-783 6084 www.meta-helix.com

ELISA confirmation

Quantitative ELISA for Cry1C protein was performed using the Quantiplate kit for Cry1C (Enviroligix, USA; Catalog No. AP 007) according to the manufacturer's protocol

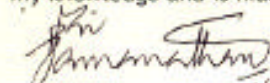
Sl no	Entry ID	A ₄₅₀	Cry1C concentration (µg/g on fresh wt)
1	Blank	0.09	NA
2	1 ppb standard	0.3	0.92
3	5 ppb standard	1.44	5.2
4	10 ppb standard	2.21	9.93
5	Nontransgenic	0.092	NA
6	Transgenic	2.9	13.08

Results

The absorbance value observed at 450nm for nontransgenic sample was nearly the same as blank and no colour development was observed in case of nontransgenic. Blue colour development was observed in case of transgenic samples indicating the presence of Cry1C protein.

Declaration

I hereby declare that the certificate of quality presented above is true to the best of my knowledge and is made on the basis of experiments carried out in our premises.



Val. Ramanathan

Head - Genomics



SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

Confidential

PROJECT NO. : TOX-346C
PRODUCT : Bt COTTONSEEDS
STUDY : ADDENDUM TO REPORT NO. 000046374 FOR SUB-
CHRONIC ORAL TOXICITY STUDY IN RATS

ADDENDUM TO REPORT NO. 000046374 FOR
SUB CHRONIC ORAL TOXICITY STUDY IN RATS
WITH
Bt COTTONSEEDS

Report for:

METAHELIX LIFE SCIENCES PRIVATE LIMITED
PLOT NO.3, KIADB 4th PHASE, BOMMASANDRA,
BANGALORE-560 099, INDIA

Guidelines:

**‘DBT, Guidelines for Toxicity and Allergenicity Evaluation of Transgenic
Seeds, Plants and Plant Parts’**

Prepared by:

DEPARTMENT OF TOXICOLOGY
SHRIRAM INSTITUTE FOR INDUSTRIAL RESEARCH

(A Unit of Shriram Scientific & Industrial Research Foundation)

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PROJECT NO. : TOX-346C
PRODUCT : Bt COTTONSEEDS
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CHRONIC ORAL TOXICITY STUDY IN RATS

QUALITY ASSURANCE STATEMENT

This is to certify that the work described in the study report entitled 'Addendum to Report No. 000046374 for Sub chronic oral toxicity study in rats' with 'Bt Cottonseeds' has been examined in accordance to the 'DBT, Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant parts' in compliance with Good laboratory Practices (G.L.P) for non-clinical laboratory studies.

The report provides true and accurate record of results obtained.

Binnu Bhat
Sr. SCIENTIST
QUALITY ASSURANCE



PROJECT NO. : TOX-346C
PRODUCT : Bt COTTONSEEDS
STUDY : ADDENDUM TO REPORT NO. 000046374 FOR SUB-
CHRONIC ORAL TOXICITY STUDY IN RATS

STATEMENT OF COMPLIANCE WITH GOOD LABORATORY PRACTICE

We, the undersigned take overall responsibility to conduct the work described in the study entitled 'Addendum to Report No. 000046374 for Sub chronic oral toxicity study in rats' with Bt Cottonseeds performed with respect to the Standard Operating Procedures in accordance to 'DBT, Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant parts' in compliance with Good laboratory Practices (G.L.P) for non-clinical laboratory studies.

All the raw data, documentation, protocol and copy of final report are retained in the archives at Shriram Institute for Industrial Research, Delhi.

M. Aggarwal
STUDY DIRECTOR *J. Sreeni*
SCIENTIST PATHOLOGY *M. Aggarwal*
HEAD, DEPT. OF TOXICOLOGY

Approved for issue

[Signature]
DEPUTY DIRECTOR
(MANAGEMENT)



PROJECT NO. : TOX-346C
PRODUCT : Bt COTTONSEEDS
STUDY : ADDENDUM TO REPORT NO. 000046374 FOR SUB-
CHRONIC ORAL TOXICITY STUDY IN RATS

TEST SUBSTANCE

The sponsor is responsible for necessary characterization and evaluation of the test substance. The details of the test substance provided by the sponsor are as follows:

PRODUCT NAME : NON-Bt COTTONSEEDS (SAMPLE -I)
& Bt COTTONSEEDS (SAMPLE -II)

SPONSOR : METAHELIX LIFE SCIENCES
PRIVATE LIMITED

MATERIAL DESCRIPTION : YELLOWISH BROWN COLOURED
POWDER

PACKED IN : BROWN COLOURED PAPER
CARTONS



PROJECT NO. : TOX-346C
PRODUCT : Bt COTTONSEEDS
STUDY : ADDENDUM TO REPORT NO. 000046374 FOR 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>	120 ± 20 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 : 22 ± 3°C Relative humidity : 30 – 70 % Air exchange : 15 air changes / hour Lighting condition : 12 hours light / 24 hours
<u>AGE OF ANIMALS</u>	6-8 weeks
<u>DURATION OF STUDY</u>	90 days
<u>DATE OF COMMENCEMENT OF STUDY</u>	01.10.2007
<u>DATE OF COMPLETION OF STUDY</u>	31.12.2007



PROJECT NO. : TOX-346C
 PRODUCT : Bt COTTONSEEDS
 STUDY : ADDENDUM TO REPORT NO. 000046374 FOR SUB-
 CHRONIC ORAL TOXICITY STUDY IN RATS

Animal Group And Dosage Level

Group	Dose mg/kg b.wt	No. of animals Male +Female
1. Control	0.0	10 +10
3. Sample-I (Non-Bt Cottonseeds)	1000.0	10 +10
3. Sample-II (Bt Cottonseeds)	1000.0	10 +10

Mortality and toxic signs / symptoms:

Mortality and clinical sign and symptoms were recorded during the observation period of 90 days after dose administration.



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CLINICAL LABORATORY STUDIES

Blood Sampling

Food was withdrawn overnight prior to collection of samples. 45 ml of blood was withdrawn under carbon dioxide anesthesia prior to sacrifice.

Haematology

Following haematological estimations were performed on control and treated group of animals using 'Fully Automatic Cell Counter (Inst.no. SRI/TOX/INST/19)':

- (a) Prothrombin Time
- (b) ESR

Biochemistry

Following estimation were performed on control and treated rats using 'Fully Automatic Biochemistry Analyser (Inst.no. SRI/TOX/INST/18)':

- (a) Bilirubin
- (b) Non-protein nitrogen
- (c) Histamine

BIOSTATISTICAL METHOD USED:

Student's t-test



PROJECT NO. : TOX-346C
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OBSERVATIONS

Mortality and toxic signs

No mortality was observed in any of the test groups including the control group of animals. No toxic signs and symptoms were noticed in any of the two dose groups and the control group of animals.

Haematological evaluations

No significant changes were noted among the test groups and control group of animals with respect to haematological findings (Table-1.01-1.04) as the parameters i.e. Prothrombin Time and ESR fell within the accepted limits of normal variations for albino rats.

Clinical Biochemistry evaluations

Biochemistry evaluations (Table-2.01-2.04) disclosed no significant differences in the tests as well as the control groups of animals, as the parameters i.e. Bilirubin, Non-protein Nitrogen, Histamine fell within the accepted limits of normal variations.



PROJECT NO. : TOX-346C
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RESULT WITH CONCLUSION

Under the conditions of this study, the 90 days repeated oral administration of powdered 'Non-Bt Cottonseeds (Sample-I)' and 'Bt Cottonseeds (Sample-II)' at the dose level of 1000 mg/kg b.wt. for five days/ week to wistar rats did not induce any treatment related observable toxic effects, with regards to the haematological parameters i.e. Prothrombin Time and ESR as well as the biochemical parameter i.e. Bilirubin, Non-protein nitrogen and Histamine when compared to its control group of animal treated with corn oil (vehicle) only.

The sample has been conducted as per DBT, Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant parts.



PROJECT NO. : TOX-346C
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 CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 1.01
MEAN HAEMATOLOGY DATA OF RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Parameter	Sex	Control (Vehicle only)	Non-Bt Cottonseeds (Sample I) 1000 mg /kg b.wt.	Bt Cottonseeds (Sample II) 1000 mg /kg b.wt.
Prothrombin Time (Sec.)	Male	19.10 ± 1.20	19.80 ± 1.62	18.70 ± 1.16
	Female	19.10 ± 1.66	18.50 ± 1.58	19.30 ± 1.64
ESR (mm/hr.)	Male	18.30 ± 1.34	18.30 ± 0.95	18.40 ± 1.17
	Female	18.80 ± 1.03	18.80 ± 1.03	19.30 ± 1.57



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TABLE - 1.02
HAEMATOLOGY DATA OF RATS AT TERMINAL SACRIFICE
GROUP: CONTROL

Animal No.	Prothrombin Time (Sec.)		ESR (mm/hr.)	
	Male	Female	Male	Female
1	19	19	20	20
2	21	21	18	19
3	20	22	19	18
4	18	20	17	17
5	19	18	16	19
6	20	17	17	18
7	18	19	19	20
8	17	20	18	19
9	20	17	20	18
10	19	18	19	20
Mean ± S.D	19.10 ± 1.20	19.10 ± 1.66	18.30 ± 1.34	18.80 ± 1.03



PROJECT NO. : TOX-346C
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TABLE - 1.03
HAEMATOLOGY DATA OF RATS AT TERMINAL SACRIFICE
GROUP: NON-Bt COTTONSEEDS (SAMPLE -I)

Animal No.	Prothrombin Time (Sec.)		ESR (mm/hr.)	
	Male	Female	Male	Female
1	22	19	18	18
2	20	17	17	20
3	21	20	19	19
4	22	21	18	20
5	19	18	20	19
6	17	17	19	17
7	20	16	18	18
8	18	20	17	20
9	19	19	18	18
10	20	18	19	19
Mean	19.80	18.50	18.30	18.80
± S.D	± 1.62	± 1.58	± 0.95	± 1.03



PROJECT NO. : TOX-346C
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TABLE - 1.04
HAEMATOLOGY DATA OF RATS AT TERMINAL SACRIFICE
GROUP: Bt COTTONSEEDS (SAMPLE II)

Animal No.	Prothrombin Time (Sec.)		ESR (mm/hr.)	
	Male	Female	Male	Female
1	20	20	17	22
2	19	18	19	21
3	17	19	20	20
4	18	17	18	19
5	20	20	17	18
6	19	22	19	20
7	18	17	17	20
8	17	19	18	18
9	19	20	19	17
10	20	21	20	18
Mean	18.70	19.30	18.40	19.30
± S.D	± 1.16	± 1.64	± 1.17	± 1.57



PROJECT NO. : TOX-346C
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TABLE - 2.01
MEAN BIOCHEMISTRY DATA OF MALE RATS
DURATION : 90 DAYS TIME : TERMINAL SACRIFICE

Parameter	Sex	Control (Vehicle only)	Non-Bt Cottonseeds (Sample I) 1000 mg /kg b.wt.	Bt Cottonseeds (Sample II) 1000 mg /kg b.wt.
T-Bil (mg/dl)	Male	0.10 ± 0.02	0.11 ± 0.02	0.09 ± 0.02
	Female	0.09 ± 0.02	0.11 ± 0.03	0.17 ± 0.17
D-Bil (mg/dl)	Male	0.05 ± 0.01	0.05 ± 0.01	0.05 ± 0.01
	Female	0.05 ± 0.01	0.06 ± 0.02	0.06 ± 0.01
Non- protein nitrogen (mg/dl)	Male	45.86 ± 1.28	46.30 ± 1.11	45.93 ± 1.05
	Female	44.82 ± 0.92	45.73 ± 0.86	45.38 ± 0.68

* Serum Histamine was present negligibly.



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 PRODUCT : Bt COTTONSEEDS
 STUDY : ADDENDUM TO REPORT NO. 000046374 FOR SUB-
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TABLE - 2.02
BIOCHEMISTRY DATA OF RATS AT TERMINAL SACRIFICE
GROUP: CONTROL

Animal No.	T-Bil (mg/dl)		D-Bil (mg/dl)		Non-protein nitrogen (mg/dl)	
	Male	Female	Male	Female	Male	Female
1	0.12	0.07	0.06	0.04	47.6	43.4
2	0.10	0.08	0.05	0.04	45.8	44.2
3	0.11	0.07	0.05	0.05	44.7	45.6
4	0.09	0.14	0.04	0.08	46.8	44.2
5	0.09	0.09	0.05	0.05	44.2	45.2
6	0.10	0.09	0.06	0.06	46.3	44.0
7	0.11	0.07	0.06	0.05	47.2	46.3
8	0.11	0.08	0.07	0.04	45.2	45.1
9	0.07	0.08	0.04	0.05	44.0	45.8
10	0.08	0.10	0.05	0.07	46.8	44.4
Mean	0.10	0.09	0.05	0.05	45.86	44.82
± S.D	± 0.02	± 0.02	± 0.01	± 0.01	± 1.28	± 0.92



PROJECT NO. : TOX-346C
 PRODUCT : Bt COTTONSEEDS
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 CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 2.03
BIOCHEMISTRY DATA OF RATS AT TERMINAL SACRIFICE
GROUP: NON-Bt COTTONSEEDS (SAMPLE -I)

Animal No.	T-Bil (mg/dl)		D-Bil (mg/dl)		Non-protein nitrogen (mg/dl)	
	Male	Female	Male	Female	Male	Female
1	0.08	0.13	0.05	0.06	45.6	46.7
2	0.10	0.11	0.06	0.05	46.4	44.6
3	0.08	0.08	0.04	0.04	44.8	45.6
4	0.11	0.14	0.06	0.07	48.2	45.7
5	0.13	0.08	0.06	0.04	46.2	45.4
6	0.09	0.14	0.04	0.07	47.6	46.8
7	0.15	0.09	0.07	0.04	45.6	45.2
8	0.11	0.08	0.05	0.04	47.4	44.4
9	0.09	0.16	0.04	0.08	45.2	46.7
10	0.12	0.12	0.06	0.06	46.0	46.2
Mean	0.11	0.11	0.05	0.06	46.30	45.73
± S.D	± 0.02	± 0.03	± 0.01	± 0.02	± 1.11	± 0.86



PROJECT NO. : TOX-346C
 PRODUCT : Bt COTTONSEEDS
 STUDY : ADDENDUM TO REPORT NO. 000046374 FOR SUB-
 CHRONIC ORAL TOXICITY STUDY IN RATS

TABLE - 2.04
BIOCHEMISTRY DATA OF RATS AT TERMINAL SACRIFICE
GROUP: Bt COTTONSEEDS (SAMPLE II)

Animal No.	T-Bil (mg/dl)		D-Bil (mg/dl)		Non-protein nitrogen (mg/dl)	
	Male	Female	Male	Female	Male	Female
1	0.09	0.64	0.05	0.08	46.4	46.3
2	0.08	0.10	0.04	0.05	45.2	45.6
3	0.11	0.17	0.06	0.08	46.6	44.2
4	0.11	0.10	0.05	0.05	45.5	46.1
5	0.10	0.14	0.05	0.07	44.8	44.8
6	0.12	0.11	0.06	0.05	46.4	45.6
7	0.08	0.12	0.05	0.06	45.2	45.2
8	0.07	0.11	0.04	0.05	46.6	45.4
9	0.09	0.12	0.05	0.06	48.0	46.0
10	0.09	0.09	0.06	0.04	44.6	44.6
Mean	0.09	0.27	0.05	0.06	45.93	45.38
± S.D	± 0.02	± 0.48	± 0.01	± 0.01	± 1.05	± 0.68