DRAFT STUDY REPORT

STUDY TITLE

ACUTE ORAL TOXICITY STUDY OF LIPOSOMAL VERSION THCV IN WISTAR RATS

TEST GUIDELINE: OECD TG No. 423
"ACUTE ORAL TOXICITY – ACUTE TOXIC CLASS METHOD", ADOPTED 17TH DECEMBER 2001

STUDY NO.: LBPL/G-1260 (TX)
STUDY CODE: AOTR

STUDY DIRECTOR
Mr. Raghu. N

SPONSOR
CURESUPPORT B V
THE NETHERLANDS.

TEST FACILITY
LIVEON BIOLABS PRIVATE LIMITED
PLOT NO.46 & 47, II PHASE, WATER TANK ROAD
KIADB INDUSTRIAL AREA, ANTHARASANAHALLI
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1. OBJECTIVE

The objective of this Acute Oral Toxicity Study is to assess the toxicological profile of the test item “Liposomal Version THCV” when administered to Wistar rats by a single oral gavage or in smaller fractions over a period not exceeding 24 hours. This study may provide a rational basis for risk assessment in humans. The results allow a substance to be ranked and classified according to Globally Harmonised System (GHS) for the classification of chemicals which cause acute toxicity.

2. STUDY DETAILS

Study Title	:	Acute Oral Toxicity Study of Liposomal Version THCV in Wistar Rats.
Study Number	:	LBPL/G-1260 (TX)
Study Code	:	AOTR
Sponsor	:	CURESUPPORT B V The Netherlands.
Test Facility	:	LIVEON BIOLABS PRIVATE LIMITED Plot No.46 & 47, II Phase Water Tank Road, KIADB Industrial Area Antharasanahalli, Tumakuru – 572106 Karnataka, India.

3. STUDY RESPONSIBILITIES

Study Director	:	Mr. Raghu N
Study Personnel -I	:	Ms. Sushma A. L.
Study Personnel -II	:	Mr. Shourie G. K.
Study Personnel -III	:	Ms. Savitha C
Study Veterinarian	:	Dr. Vidya. C. S.
Sponsor Representative & Monitoring Scientist	:	Dr. Preetha Balakrishnan

4. STUDY SCHEDULE

Study Initiation Date	:	11/05/2021
Experiment Start Date	:	11/05/2021
Acclimatization Start Date	:	11/05/2021
Acclimatization End Date	:	Step I : 16/05/2021 Step II: 18/05/2021 Step III : 20/05/2021
Treatment Start Date	:	Step I : 17/05/2021 Step II: 19/05/2021 Step III : 21/05/2021
Experiment End Date	:	02/06/2021
Draft Report to Sponsor	:	11/06/2021
Study Completion Date	:	Will be included

5. ABBREVIATIONS AND SYMBOLS

AAALAC	:	Association for Assessment and Accreditation of Laborat Animal Care
AOTR	:	Acute Oral Toxicity Rat
CPCSEA	:	Committee for the Purpose of Control and Supervision Experiments on Animals
dB	:	Decibel
g	:	Gram
GHS	:	Globally Harmonized System of Classification and Labelling of Chemicals
h/hr (s)	:	Hour (s)
IAEC	:	Institutional Animal Ethics Committee
LBPL	:	Liveon Biolabs Private Limited
LD_{50}	:	Lethal Dose 50
mg	:	Milligram
mL/kg	:	Millilitre per kilogram
mg/kg	:	Milligram per kilogram
mL	:	Millilitre
OECD	:	Organisation for Economic Co-operation and Development
SD	:	Standard Deviation
TFM	:	Test Facility Management
TIIS	:	Test Item Information Sheet
QAU	:	Quality Assurance Unit
%	:	Percentage
°C	:	Degree Celsius

6. STATEMENT OF STUDY COMPLIANCE

Study Number : LBPL/G-1260 (TX)

Study Title : Acute Oral Toxicity Study of Liposomal Version THCV in Wistar Rats.

This Study was performed on the lines of OECD Principles of Good Laboratory Practice for the testing of chemicals as specified by International [C (97) 186/Final] Legislation. This study was conducted in accordance with the standard operating procedures and the mutually agreed study plan signed by Study Director and sponsor Representative.

Study Plan / Amendment	Study Director	Sponsor
Study Plan	11/05/2021	14/05/2021
Amendment No.1	17/05/2021	

DECLARATION.

The Study Director hereby declares that the work was performed under his supervision and in accordance with the described procedures. It is assured that the reported results faithfully represent the raw data obtained during the experimental work. No circumstances have been left unreported which may have affected the quality or integrity of the data or which might have a potential bearing on the validity and reproducibility of this study.

The Study Director accepts overall responsibility for the technical conduct of the study as well as the interpretation, analysis, documentation, and reporting of the results.

_____

Study Director
Sign. and Date

7. STATEMENT OF QUALITY ASSURANCE UNIT

This is to state that the following study was audited and inspected by Quality Assurance Unit of Liveon Biolabs Private Limited on lines ofwith OECD Principles of GLP for testing of chemicals as specified by international [(C (97)186/Final] legislation.

Study Number : LBPL/G-1360 (TX)

Study Title : Acute Oral Toxicity Study of Liposomal Version THCV in Wistar Rats.

The study phases were inspected and findings were reported to the Management and Study Director on the dates shown below.

Sl. No.	Inspection Phase	Date		
		Inspection	SD	TFM
1	Draft study plan	30/04/2021	30/04/2021	30/04/2021
2	Study Plan Amendment No.1	17/05/2021	17/05/2021	17/05/2021
3	Dosing	17/05/2021	17/05/2021	17/05/2021
4	Draft Study Report	11/06/2021	11/06/2021	11/06/2021
5	Final Study Report	Xx/xx/2021	Xx/xx/2021	Xx/xx/2021

Inspections were performed according to the Standard Operating Procedures of the test facility's Quality Assurance Unit. The report was inspected against the approved study plan and pertinent raw data and accurately reflects the raw data.

Quality Assurance Unit
Sign. and Date

8. STATEMENT OF CONFIDENTIALITY

The information and data presented in this study report is considered as confidential and proprietary information of Curesupport B V. and will not be disclosed to anyone without the expressed or written approval of sponsor, except to the employees of this test facility wherever necessary and to persons authorized by law or judicial judgement.

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Test Facility Management
Sign. and Date

9. STATEMENT OF TEST FACILITY MANAGEMENT

Study Number : LBPL/NG-1360 (TX)

Study Title : Acute Oral Toxicity Study of Liposomal THCV in Wistar Rats.

This is to affirm that for above mentioned study, Test Facility Management has made available all the resources to the study director necessary for conduct of the present study as per the,OECD principles of GLP and mutually agreed study plan.

_____

Test Facility Management
Sign. and Date

10. STUDY SUMMARY

Acute Oral Toxicity Study of Acute Oral Toxicity Study of Liposomal Version THCV in Wistar Rats was conducted to assess the toxicological profile of the test item. This study provides a rational basis for risk assessment in humans. The results allow a substance to ranked and classified according to Globally Harmonised System (GHS) for the classification of chemicals which cause acute toxicity.

A total of 12 female Wistar rats were used (n=3/step) for acute oral toxicity study. 9 female rats were used for treatment and 3 rats were euthanized without any treatment.

For step I, the dose formulation was prepared at the dose of 300 mg/kg body weight (30 mg/mL) by vehicle (corn oil) administered as a single oral gavage for three female rats which were fasted overnight (about 16.5 hours) prior to dose and animals were fed about 3.5 hours after dosing). Since there were no clinical signs or mortalities / morbidity in the Step I, the Step II (confirmation dose) adminsration was done at the same dose (300 mg/kg) with 3 female rats to confirm the Step I results.

In step III, the dose formulation was prepared at the dose of 2000 mg/kg (200 mg/mL) body weight by vehicle (corn oil) and administered as a single oral gavage for three female rats which were fasted overnight (about 17 hours prior to dose and animals were fed about 3.5 hours after dosing). Since there were clinical signs of piloerection, dehydration, lethargy and perineum wet with urine and rats were found dead on Day 2 (2/3) and on Day Day 3 (1/3) in the Step III as the mortalities were observed in Step III rats, the further testing was stopped and there was no test item adminsration for step IV animals.

All the rats in the experiment were observed for mortality / morbidity and clinical signs till termination (Day 15). Body weights were recorded prior to dosing on Day 1, and on Days 8 and 15 of the observation period. Necropsy was performed for all the rats at termination (Day 15).

Based on the results of the present study, the test item,
The LD50 is 500 mg/kg body weight (Category 4) and LD50 cut-off value according to the Globally Harmonized System (GHS) for classification of chemicals.

11. STUDY COMPLIANCE

The study was performed with the following:

- This study was performed on lines of OECD Principles of Good Laboratory Practice [C (97)186/Final].
- The mutually agreed Study Plan and the Standard Operating Procedures (SOPs) of test facility.

12. STUDY GUIDELINE

The design of this study was based on the study objective(s) and procedures as detailed in the Study Plan, the overall product development strategy for the test item, and the below mentioned guidelines in principles as applicable.

- OECD Guideline for Testing of Chemicals, Section 4, No. 423, "Acute Oral Toxicity – Acute Toxic Class Method", adopted: 17th December 2001.

13. IAEC APPROVAL

The use of animals for this study has been approved by Liveon Biolabs Private Limited IAEC. IAEC approved Protocol No.: LBPL-IAEC-025-05-2021.

14. ANIMAL WELFARE AND VETERINARY CARE

Liveon Biolabs Private Limited is an Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) international accredited facility and registered with Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA), Ministry of Environment, Forests and Climate Change, Government of India. Also, Liveon Biolabs Private Limited ensures that animal experiments are performed in accordance with the recommendation of the guidelines for laboratory animal facility published in the gazette of India, 2018.
During the study none of the animals were get injured, ill or moribund.

15. SAFETY PRECAUTIONS

The personnel involved in study conduct was worne all necessary personnel protective equipment like gloves, head cap and face mask were used in addition to protective body garments and slippers/shoes to ensure adequate personnel health and safety and to avoid inhalation and skin contact with the test item.

16. PRINCIPLE

To determine the acute toxicity, a stepwise procedure was employed with the use of three animals of a single sex (female) at each step. Sufficient information was obtained on the acute toxicity of the test item for its classification. The test item was administered orally to a group of experimental animals at one of the defined doses (i.e., 300 mg/kg body weight) with a first step (Step I). Absence or presence of compound-related

mortality of the animals dosed at one step will determine the dose at the next step, i.e.;

- no further testing is needed,
- dosing of three additional animals with the same dose, or
- dosing of three additional animals at the next higher or the next lower dose level.

This method was enable a judgment with respect to classifying the test item to one of a series of toxicity classes defined by fixed LD50 cut-off values and the test item may also be classified by Globally Harmonized System.

17. AMENDMENT AND DEVIATION

This Study Plan has been amended once there were no deviations to the study plan during the course of the study.

18. MATERIALS

18.1. Test Item Information

The test item information provided by the sponsor to LBPL is furnished below:

Name of Test Item	:	Liposomal Version THCV.
Test Item Code by Test Facility	:	S 339/TI-002
Physical Appearance	:	Pinkish White Powder
Purity	:	30%
Storage of Test Item	:	Ambient (+18 to +36°C)
Expiry Date	:	January 2023 (2 year shelf life)
Test Item Supplied by	:	Biometas Clinical Research Organization 22 A, Triveny Junction Annanad, Chalakudy, Kerala India 680309.

18.2. Identity of the Test item

Refer to Annexure 2

The identity of the test item was provided by the study sponsor by a TIIS, which will be included in the raw data and reflected in the report. The test item will not be authenticated at the Test Facility. The responsibility for the correct identity and the purity of the test item rests with the Sponsor.

18.3. Test System

Animal Species	: Rat(*Rattus norvegicus*)
Strain	: Wistar
Justification for se species	: Rat is one of the recomme regulatory agencies f preclinical toxicological rodents
Source	: In-house bred animals
Body weight (at T	: 155.28 to 176.29g
Age (at Treatmen	: 8-9 weeks
Sex	: Females (Females were non-pregnant)
Number of animal	: 3 animals per stpe

18.4. Test System Management

1. Animal Room Preparation

Before placing animals, the experimental room (AF24) was decontaminated by fumigation and microbial load was checked by settle plates method. The copies of results were kept in the raw data file. The experimental room floor was mopped with disinfectant solutions daily once.

2. Husbandry Conditions

Animals were housed under standard laboratory conditions, air-conditioned with adequate fresh air supply (air changes 12-15 per hour), room temperature of 20.1 to 23.0°C and relative humidity of 45-67%, with 12 hours light and 12 hours dark cycle was maintained in the experimental room. The temperature and relative humidity was recorded once daily.

3. Housing

Refer Annexure 8

Maximum of three animals were housed in a standard polysulfone cages ages (cage size approximately: Length 425 x Breadth 266 x Height 185mm) with stainless steel mesh top grill having facilities for holding pelleted feed and drinking water. The water was provided in polycarbonate water bottles fitted with rubber cork and a stainless-steel sipping tube. Clean sterilized corn cob was provided as bedding material. The corn cob was analyzed periodically for any fungal and microbial contaminations.

4. Diet and Water

Refer Annexure 6 & 7

AF- 1000M R&M Diets manufactured by Krishna Valley Agrotech LLP will be provided ad libitum to Rats or others to specify in the report.

Deep bore-well water subjected to reverse osmosis and UV sterilized, will be provided ad libitum to Rats in polycarbonate bottles with stainless rubber corked steel sipper tubes.

The feed and water provided will be tested for contaminants. The latest analysis reports of feed and water will be included in Study Report and keptin the raw data file.

18.5. Preparation of Animals

1. Acclimatization

The animals were acclimatized for step I five days and step II seven and step III nine days to laboratory conditions. Animals were observed for clinical signs once daily during acclimatization period. Veterinary examination was performed before selecting the animals and only healthy and active animals were used in the study.

2. Animal Identification

During acclimatization period, each animal was identified by tail marking with marker pen and cage cards.
During Treatment Period, each animal was identified by body marking with turmeric soluition and cage cards indicating Study No., Study Code, Species, Strain, Sex, treatment and experiment end date.

3. Justification for Route of Administration

In the assessment and evaluation of toxic characteristics of the test item, determination of acute oral toxicity is usually an initial step. It provides information on health hazards likely to arise from short term exposure by the oral route.

18.6. Methods

1. Animal Selection

The body weight of all the animals were measured on the at receipt, last day of acclimatization for the respective step/group. The rats with close body weight range were randomly selected on the last day of acclimatization for each treatment step/group.

2. Vehicle Selection and Justification

A solubility test was performed to select vehicle for the preparation of the test item. The test item found miscible in the corn oil after melting the testing the test item around 50°C. hence corn oil used as a vehicle for this study.

19. EXPERIMENTAL DESIGN AND PROCEDURES

19.1. Starting Dose

Three female rats were used for each step. The Study was Conducted in 4 steps. In Step I and Step II three female rats were dosed with 300 mg/kg body weight. No mortality was observed in all the treated animals. Based on the results, the step III were dosed with 2000 mg/kg body weight were treated. As the mortalities observed at 2000 mg/kg body weight step iv animals were not treated and euthanized under CO_2 asphyixation.

19.2. Administration of Test Item

19.2.1. Preparation of Dose Formulations

Required quantity of the test item was weighed into a clean test tube and allowed to melt the test item in the shaker water bath at around 50°C for 5-10 minutes. To the melted test item small quantities of vehicle was added and vortex the mixture for 5-10 minutes. The formulation was transfered to measuring cylinder and the volume made up to the mark with the vehicle to attain the dose of required concentration.
The dose formulations were administered as a single oral gavage to overnight fasted rats (access to water was not interrupted)

Since it is a stepwise method, all the preparation details for subsequent steps and doses were recorded in the raw data and reflected in the report.

Step	Dose (g)	Test item weight (mg)	Concentration (mg/mL)
Step I	300	300.1	30
Step II	300	300.2	30
Step III	2000	2000.0	200

Homogeneity of the test item in the vehicle was maintained during treatment by constant stirring using a magnetic stirrer.

Each animal was administered orally by gavage using disposable plastic syringe attached with metal feeding canula. Animals were fed approximately 3 .5 hours after dosing.

19.2.2. Dose Volume

The dose volume were administrated 10 mL/kg body weight. Test item was administrated in constant volume over the ranges of doses to be tested by varying the concentration of dose preparation.

19.2.3. Dose Formulation

For step I and II, the dose formulation was prepared at the dose of 300 mg/ kg (30 mg/mL) body weight using vehicle (corn oil) and administered as a single oral gavage.

For step III the dose formulation was prepared at the dose of 2000 mg/kg (200 mg/mL) body weight by vehicle (corn oil) and administered as a single oral gavage.

19.2.4. Dosing

Animals were fasted for 16.5 hours prior to dosing (water was given *ad libitum*) The dose volume was calculated based on the fasted body weight of each animal and administrated in a single dose by using gavage. After Test item administration., feed was provided after 3rd hour observation.

20. OBSERVATIONS

20.1. Body Weight

Individual animal body weight were recorded at receipt, on Day 1 prior to test item administration and on Days 8 and day 15 during the observation period.The body weights were recorded for found dead rats on Day 2 and Day 3 for step III rats.

20.2. Clinical Signs Mortality and Morbididty

Animals were observed individually for toxic signs and mortality after dosing at least once during the first 30 min, 1, 2 and 4 (± 5 minutes at each point) hours and daily thereafter for a total of 15 days.
Animals were observed twice daily for mortality and morbidity throughout the experimental period.

21. GROSS PATHOLOGY

All the surviving and dead animlas were subjected to gross necropsy examination.

22. RESULTS

22.1. Mortality/Morbidity and Clinical signs

Refer to Table 2

300mg/kg b.wt

Step I and Step II, no clinicals signs of toxicity was observed in any of the treated animals during Day 1 at 30 min, 1st hour, 2nd hour, 3rd hour and 4th hour post-dose and throughout experimental period of 15 days.
2000mg/kg b.wt

In Step III, no clinicals signs of toxicity was observed in any of the treated animals during Day 1 at 30 min, 1st hour, 2nd hour, 3rd hour and 4th hour. Howevwer, clinical sign of piloerection (slight), dehydration, lethargy and perineum with urine were observed at all the rats from Day 2 morning and two rats were found dead during evening observation. The remaining rat continued with above clinical signs and found dead on Day 3 mornig observation.

22.2. Body Weight

Refer to Table 1

There were no changes in body weight in any of the treated animals and showed gain on day 8 and 15, as compared to day 1 body weight.

22.3. Gross Pathology

On the day of necropsy, no external and internal macroscopical lesions were observed for dead rats and terminal gross pathological examination.

The detail of individual gross pathological findings are presented in Table 3.

23. CONCLUSION

Based on the results of the present study, the test item,
The LD50 is 500 mg/kg body weight (Category 4) as per LD50 cut-off value according to the Globally Harmonized System (GHS) for classification of chemicals.

24. ANIMAL EUTHANASIA AND DISPOSAL

After the completion of the study, all the surviving animals were sacrificed by using carbon dioxide asphyxiation and the carcasses was stored in deep freezer until disposal and sent to incineration through Medicare Environment Management Private Limited

25. STUDY REPORT PREPARATION AND DISTRIBUTION

The final study report will be distributed as follows :

Test Facility : One signed study plan in original (Copy No. 1/1)

Sponsor : Electronic copy in PDF format (Copy No. 1/1).

26. ARCHIVING

All study related records, study plan, raw data and final report will be maintained in the archives of Liveon Biolabs Pvt. Ltd. for 5 years from the date of completion of the study, all the records will be handled according to OECD Guidelines for Testing of Chemicals No 423 Management System. After the completion of archiving period, the test facility management will co-ordinate with the sponsor for further course of action on archived material.

27. REFERENCES

- OECD, 1998. OECD Principles of Good Laboratory Practice, in OECD Environmental Health and Safety Publications, Series on Principles of Good Laboratory Practice and Compliance Monitoring, No. 1 ENV/MC/CHEM (98)17, Paris 1998.
- OECD, 2000. Guidance Document on the Recognition, Assessment and Use of Clinical Signs as Humane Endpoints for Experimental Animals Used in Safety Evaluation Environmental Health and Safety Monograph Series on Testing and Assessment No 19. (ENV/JM/MONO(2000)7).
- OECD, 2001. Guideline for Testing of Chemicals, Section 4, No. 423, “Acute Oral Toxicity- Acute Toxic Class Method”, adopted: 17th December 2001.
- OECD, 2001. Harmonised Integrated Classification System for Human health and Environmental Hazards of Chemical Substances and Mixtures. Number. 33; ENV/JM/MONO(2001)6.
- Regulation (EC) No 1272/2008 of the European Parliament and of the council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.
- Globally Harmonized System of Classification and Labelling of Chemicals (GHS) Eighth Revised Edition, United Nations (2019). ST/SG/AC.10/30/Rev.8.
- Committee for the Purpose of Control and Supervision on Experiments on Animals (CPCSEA) Guidelines for Laboratory Animal Facility.

Table 1. Individual Animal Body Weight (g)

Step	Dose (mg/kg body weight)	Sex	Animal No.	Volume Administered (ml)	Time of Dosing	Body Weight (g) Days		
						1	8	15
I	300	F	Ra2826	1.6	11:28 to 11:29	155.28	180.26	193.21
			Ra2827	1.6		164.36	183.28	196.96
			Ra2828	1.6		163.15	191.29	203.41
			Mean			**160.93**	**184.94**	**197.86**
			SD			**4.93**	**5.70**	**5.16**
II	300	F	Ra2829	1.7	10:01 to 10:03	168.21	192.16	202.31
			Ra2830	1.7		166.23	196.32	208.16
			Ra2831	1.7		169.71	186.18	193.12
			Mean			**168.05**	**191.55**	**201.20**
			SD			**1.75**	**5.10**	**7.58**

Step	Dose (mg/kg body weight)	Sex	Animal No.	Volume Administered (ml)	Time of Dosing	Body Weight (g) Days		
						1	*2	*3
III	2000	F	Ra2832	1.8	10:05 to 10:07	176.29	169.16	-
			Ra2833	1.7		173.28	-	169.23
			Ra2834	1.7		166.21	160.21	-
			Mean			**171.93**	**164.69**	**-**

			SD	**5.17**	**6.33**	**-**

Key :F: Female ,SD -Standard Deviation, *: At death

Table 2. Individual Animal Clinical Signs

Step	**Dose (mg/kg body wei**	**Animal No.**	**Sex**		**Days**																
				1					**2**		**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**	**13**	**14**	**15**
				30 Min	**1 hr**	**2 hr**	**3 hr**	**4 hr**															
I	300	Ra2	F	1	1	1	1	1	1	-	1	1	1	1	1	1	1	1	1	1	1	1	1
		Ra2		1	1	1	1	1	1	-	1	1	1	1	1	1	1	1	1	1	1	1	1
		Ra2		1	1	1	1	1	1	-	1	1	1	1	1	1	1	1	1	1	1	1	1
II	300	Ra2		1	1	1	1	1	1	-	1	1	1	1	1	1	1	1	1	1	1	1	1
		Ra2		1	1	1	1	1	1	-	1	1	1	1	1	1	1	1	1	1	1	1	1
		Ra2		1	1	1	1	1	1	-	1	1	1	1	1	1	1	1	1	1	1	1	1
III	2000	Ra2	F	1	1	1	1	1	44,52,	2	-	-	-	-	-	-	-	-	-	-	-	-	-
		Ra2		1	1	1	1	1	44,52,	44,52,	2	-	-	-	-	-	-	-	-	-	-	-	-
		Ra2		1	1	1	1	1	44,52,	2	-	-	-	-	-	-	-	-	-	-	-	-	-

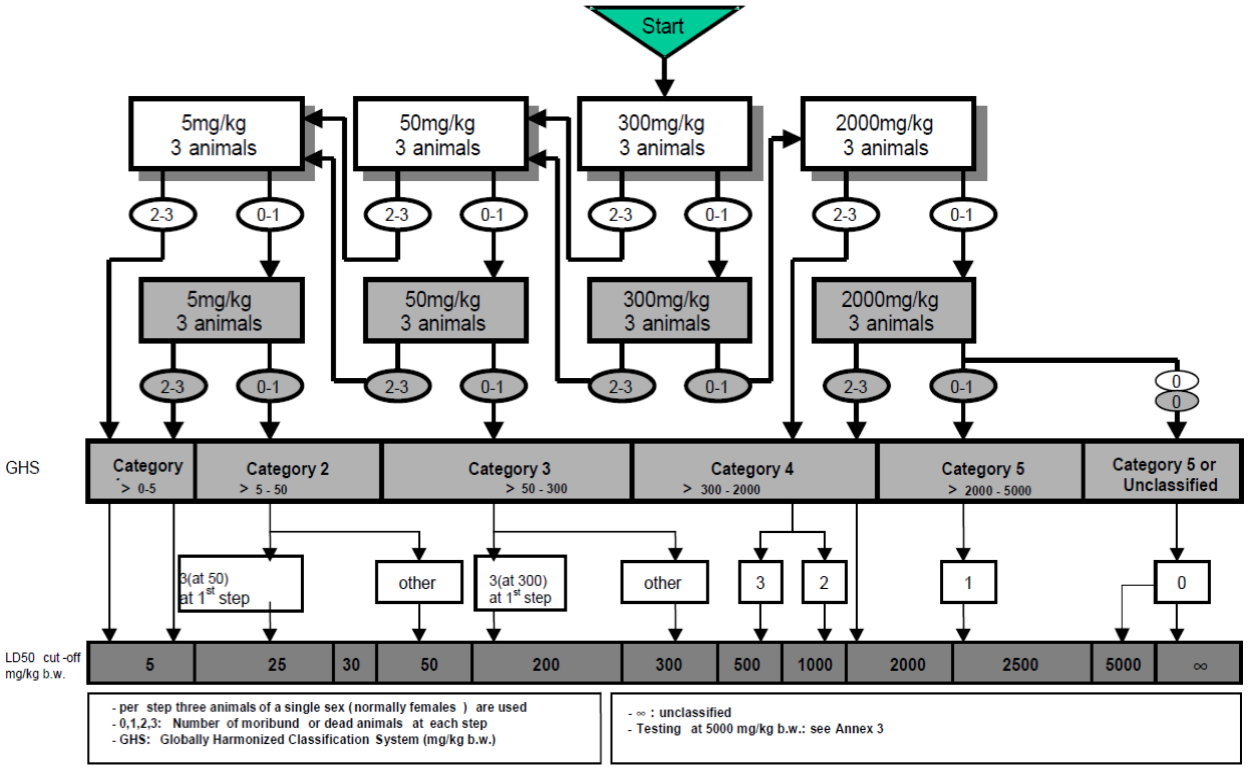
Key:1= Normal; F = Female; hr = Hour; min = Minutes, 44= Lethergy, 52 (piloerection slight), 19=dehydration, 76: perineum wet with urine.

Table 3. Individual Animal Gross Pathological Findings

Step	Dose (mg/kg Body weight)	Animal No.	Sex	Gross Pathological Findings	
				External	Internal
I	300	Ra2826	F	NAD	NAD
		Ra2827		NAD	NAD
		Ra2888		NAD	NAD
II	300	Ra2829		NAD	NAD
		Ra2830		NAD	NAD
		Ra2831		NAD	NAD
III	2000	Ra2832		NAD	NAD
		Ra2833		NAD	NAD
		Ra2834		NAD	NAD

Key: NAD: No Abnormalities Detected; F: Female.

Annexure 1. Test Procudure With A Starting Dose of 300 mg/kg Body Weight



Annexure 2.Test Item Information Sheet

Sl no.	Particulars	Details
1	Sponsor Name and Address: (As in Study Plan and/or Study Report)	**Curesupport B V** **The Netherlands**
2	Manufactured by (name and address) (Specify "same as study sponsor", if applicable. Otherwise provide details).	**Curesupport B V** **The Netherlands**
3	Supplied by (name and address) (Specify "same as study sponsor", if applicable. Otherwise provide details).	Biometas Clinical research organization 22 A, Triveny Junction Annanad, Chalakudy, Kerala India 680309
4	Address for Communication with Email:	Biometas Clinical research organization 22 A, Triveny Junction Annanad, Chalakudy, Kerala India 680309
5	Sponsor Representative Name:	**Dr. Preetha Balakrishnan**
6	Monitoring Scientist Name:	**Dr. Preetha Balakrishnan**
7	Address for Invoicing:	Biometas Clinical research organization 22 A, Triveny Junction Annanad, Chalakudy, Kerala India 680309
8	(Put ✓ mark, as applicable) **Test item:** ✓ **Placebo:** □ **Others to Specify:** **Reference**	
9	**Test/reference item name** (if applicable)	*Liposomal version* (−)-(6aR,10aR)-6,6,9-trimethyl- 3-pentyl-6a,7,8,10a-tetrahydro- 6H-benzo[c]chromen-1-ol
10	CAS No. (if applicable)	NA
11	Chemical name (IUPAC) (if applicable)	NA
12	Physical appearance	Pinkish white powder
13	Purity as per certificate of analysis	30%
14	Batch No. / Lot No. / Sample No. (strikeout whichever is not applicable)	NA
15	**Expiry date** **Retest date:** _____ (when stored as detailed below) (fillup expiry date and/or retest date, whichever is applicable)	**January 2023** **(2 year shelf life)**
16	**Retest date**	

Annexure 2(Contd.,). Test Item Information Sheet

17	**Recommended storage condition** (Put ✓ mark to any one temperature condition, as applicable) Note: 1) The condition recommended in this TIIS shall be adopted, even if it varies from that in MSDS. 2) In case, the recommended storage condition does not fall in any of the given temperature ranges/conditions, the item will be stored at the nearest lower temperature condition.	✓ **Ambient (+18 to +36°C)** □ Ambient (+15 to +25°C) □ Refrigeration (+2 to +8°C) □ Deep frozen (-10 to -30°C) □ Deep frozen (-60 to -80°C) □ Any other_____ (e.g.: protection from light/humidity, etc.)
18	Number of packages dispatched (Net quanity x No. of packets/containers/vials/ampoules, etc)	
19	Material safety data sheet attached (MSDS)	✓ **Yes** □ No
20	Certificate of analysis attached (COA)	✓ **Yes** □ No
21	Photosensitive	□ Yes ✓ **No**
22	Authenticity (identity) of test /item at test facility (if authenticity/characterization is required, sponsor may provide the reference standard & method of analysis)	□ Required (tick, if required) **Not required**
23	Physico-chemical properties	pH: Density: Specific gravity:
24	Any additional information (optional)	

Annexure 2(Contd.,). Test Item Information Sheet

List out the test to be conducted:

Sl. No.	Test / Study Name	Test Guideline
1	ACUTE ORAL TOXICITY STUDY OF TEST ITEM IN WISTAR RATS	OECD TG No. 423,

Sponsor's Authorization:

As a Sponsor or Sponsor representative of these studies, I agree with below points:

- The studies requested are to meet the regulatory requirements of test item.
- The animal usage is necessary for requested studies as per guideline requirements. The species chosen is appropriate to the study and as per guidelines requirements.
- The studies requested are not an unnecessary duplication of previous work.

Dr. Preetha Balakrishnan 08/03/2021

Sponsor or Sponsor Representative: **Sign. and Date**

Instructions for filling Test Item / Reference Item / Vehicle Information Sheet:

- Fill the information sheet with available information.
- Either strike off or delete inappropriate content.
- If the information is not available mentioned as NA and if section or column is not applicable for test item, reference item or vehicle, mention as NA (Not Applicable).
- Add column or rows as per requirements.

Annexure 3. GLP Certificate

GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT

NO: DCD/SPL.CI-I/CR-397/2020-21
GSC NO : DD099-00000-19332

Office of the Drugs Controller
for the State of Karnataka
Palace Road, Bangalore -01
Date: 28 JUL 2020

GLP CERTIFICATE

This is to certify that **M/s Liveon Biolabs Pvt Ltd., situated at Plot No.46 & 47, II phase, Road No.8, Water Tank road, KIADB Industrial area, Antharasanahalli, Tumkur-572106** have been granted approval in Form-37 bearing no. KTK/37/29/2012 dated: 19.10.2012 with validity up to 18.10.2022, under the provisions of Drugs & Cosmetics Act, 1940 and Rules there under.

It is further certified that:

The approved drug testing laboratory is subjected to inspection at regular intervals by competent authority appointed under the said Act, and having regard to the nature and extent of Good Laboratory Practices; the approved drug testing laboratory observes **Good Laboratory Practices** as per **Schedule L-1** under the provisions of Drugs & Cosmetics Act, 1940 and Rules there under.

This Certificate is valid for period of one year from the date of issue.

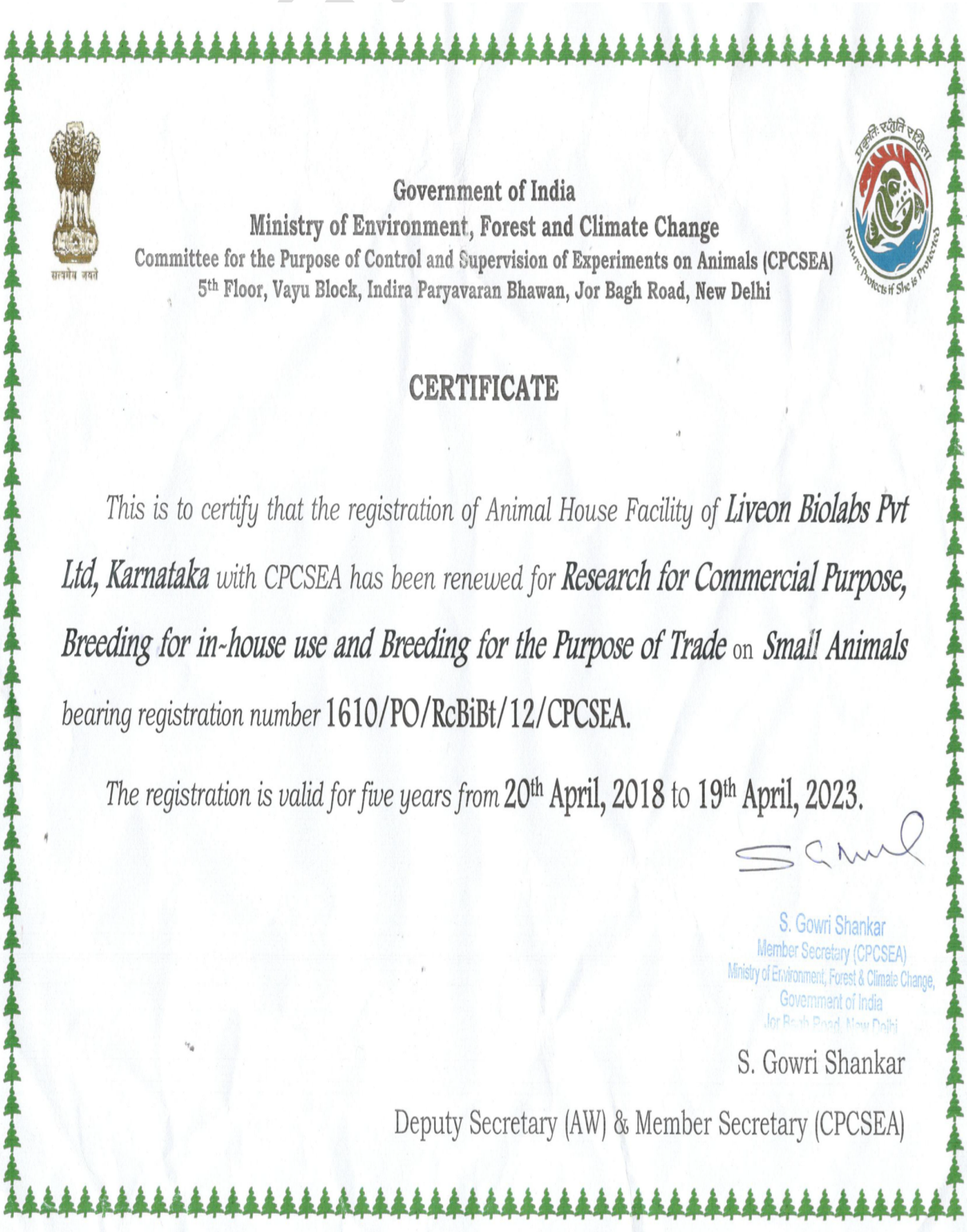
DRUGS CONTROLLER FOR THE STATE OF KARNATAKA

(BHAGOJI.T.KHANAPURE)
Drugs Controller for the
State of Karnataka

To,

M/s Liveon Biolabs Pvt Ltd.,
Plot No.46 & 47, II phase,
Road No.8, Water Tank road,
KIADB Industrial area,
Antharasanahalli, Tumkur-572106

Annexure 4. CPCSEA Certificate



Government of India
Ministry of Environment, Forest and Climate Change
Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA)
5th Floor, Vayu Block, Indira Paryavaran Bhawan, Jor Bagh Road, New Delhi

CERTIFICATE

This is to certify that the registration of Animal House Facility of ***Liveon Biolabs Pvt Ltd, Karnataka*** *with CPCSEA has been renewed for* ***Research for Commercial Purpose, Breeding for in-house use and Breeding for the Purpose of Trade*** on ***Small Animals*** *bearing registration number* 1610/PO/RcBiBt/12/CPCSEA.

The registration is valid for five years from 20th April, 2018 to 19th April, 2023.

S. Gowri Shankar
Member Secretary (CPCSEA)
Ministry of Environment, Forest & Climate Change,
Government of India
Jor Bagh Road, New Delhi

S. Gowri Shankar

Deputy Secretary (AW) & Member Secretary (CPCSEA)

Annexure 5. AAALAC Certificate

aaalac

5205 Chairman's Court, Suite 300
Frederick, MD USA 21703

October 29, 2019

R. Rajesh, M.Sc.
Scientist In-Charge
Animal Facility
Liveon Biolabs Private Limited
#46 & 47 Water Tank Road
KIADB Industrial Area
Karnataka 572106
India

Dear Mr. Rajesh:

The AAALAC International Council on Accreditation has reviewed the report of the recent site visit to Liveon Biolabs Private Limited, Karnataka, India. The Council commends you and the staff for providing and maintaining an excellent program of laboratory animal care and use. Especially noteworthy were the very involved Institutional Official and all staff members during the entire site visit; the clean and refabricated animal rooms and corridors; the well established traffic flow and personal protective equipment; and the good water and feed quality reports. The Council is pleased to inform you that the program conforms with AAALAC International standards as set forth by the *Guide for the Care and Use of Laboratory Animals*, NRC 2011 and the Guidelines of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA). Therefore, **FULL ACCREDITATION** shall continue.

Council acknowledges receipt of the correspondence dated September 13 and August 12, 2019 detailing actions taken relative to concerns expressed by the site visitors during the exit briefing. Specifically, the items addressed satisfactorily included: ensuring social housing of mice and rabbits when possible or unless otherwise justified and providing resting boards for rabbits housed on wire-bottom cages.

Council has no further recommendations to offer for improvement of the animal care and use program at this time. We look forward to following your program activities and wish you continued success.

AAALAC International requires an Annual Report detailing changes made during the year in accredited units. In the interim, AAALAC International expects to be apprised in a timely manner of significant programmatic changes or concerns should they occur. Please note that, at your request, AAALAC International will provide your institution with a separate letter simply verifying that your animal care and use program is accredited. Should you also wish to distribute an electronic copy of this letter to program staff, a Portable Document Format (pdf) version will be sent upon request.

Council acknowledges the September 13, 2019 correspondence describing the previous use of poultry and wishes to clarify that per the AAALAC International Rules of Accreditation … "All animals used or to be used in research, teaching, or testing at accreditable units are to be included and evaluated in accordance with the standards…". If poultry studies are conducted in the future, the AAALAC International Executive Office must be notified and an updated Program Description must be submitted.

Sincerely,

Bart Carter, D.V.M., M.S.
President, Council on Accreditation

BC:cma
001655

tel: 301.696.9626
fax: 301.696.9627

accredit@aaalac.org
www.aaalac.org

Annexure 6. Water Analysis Report

COPY No.: 949
Date : 02/03/2021
DOCUMENT CONTROL OFFICE

ANNEXURE 2: REPORT ON MICROBIAL MONITORING OF WATER SAMPLES

Date of Sampling: 04/05/2021 Date of Reporting: 06/05/2021

Sl. No.	Source	Results		Remarks
		Coliform counts / 100 mL	*E. coli* count / 100 mL	
01	RO Water collection point 1	00	NP	–
02	RO Water collection point 2	00	NP	–

Presumptive Test

Quality of Water	*Coliform* count / 100 mL
Excellent	0
Satisfactory	1 – 3
Intermediate	4 – 9
Unsatisfactory	10 *Coliforms* or any *Coliform* organism present in consecutive samples or presence of any *Coliform* organism in more than 5% of routine samples.

Analyzed by: 06/05/2021 (Sign. and Date)

Approved by: Lakshmi 06/05/2021 (Sign. and Date)

Verified by Sagar. C 07/05/2021

Note – NP- Not Performed Lakshmi 06/05/2021

LBPLSOP-MIC-004
Version No.: 03
Page 18 of 29

Authorized by Lakshmi 07/05/2021

CONTROLLED COPY

Annexure 7. Feed Analysis Report

Krishna Valley Agrotech LLP
An ISO 9001:2015 & GMP Certified Company
Corporate Office: 422, Amanora Chambers, Magarpatta Road, Hadapsar, Pune 411028
Customer Care No.: 020 67274107, Website: www.kvat.co.in

Factory address: E-43 & E3/14, MIDC, Kupwad block, Sangli, Maharashtra-416436

AF-1000M Rat & Mice Diets (Autoclavable)

CERTIFICATE OF ANALYSIS

Lot No : 171

Date of manufacture: 18.03.2021

Expiry date: 17.09.2021

Report date: 19.03.2021

KRISHNA VALLEY AGROTECH LLP

Authorized signatory

Proximate analysis	
Analysis	Result %
Crude Protein	17.45
Ether extract	3.85
Crude Fiber	4.06
Moisture	8.90
Calcium	0.91
Phosphorus	0.69
Total ash	8.80
Gross Energy	3.0 Kcal/gm

Consolidated results obtained from one or more independent testing laboratories.

Analysis	Result	Units	Established Maximum concentration
Heavy Metals			
Arsenic	0.15	ppm	1.00
Cadmium	0.05	ppm	0.50
Lead	0.10	ppm	1.50
Mercury	0.02	ppm	0.20
Mycotoxins			
Aflatoxin B1,B2, G1, G2	<5.00	ppb	5.00
Chlorinated Hydrocarbons	<0.01	ppm	0.05
Organophosphates	<0.10	ppm	0.5
Phytoestrogen	Complies	µg/g	12
Microbial Examination			
Total Aerobic Count	Complies	CFU/gm	$<1x10^3$CFU/gm
Mold Count	Absent	CFU/gm	Absent/10 gm
Escherichia coli	Absent	CFU/gm	Absent/10 gm
Salmonella	Absent	CFU/gm	Absent/10 gm
Shigella	Absent	CFU/gm	Absent/10 gm
Pseudomonas aeruginosa	Absent	CFU/gm	Absent/10 gm

QC/F/ 05,00,1.1.2020

Annexure 7. Feed Analysis Report (Contd.,)

ROBUST MATERIALS TECHNOLOGY PVT. LTD.

(Recognised by MoEF&CC, DSIR-Government of India & Notified by FSSAI)
(Approved by Drug Control Department-GoK ; Certified by OHSAS-ISO 45001:2018)

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Email : info@robustmaterials.com **Website :** www.robustmaterials.com

TEST REPORT

M/s. Liveon Biolabs Pvt Ltd. Plot No. 46 & 47, 2nd Phase, Water Tank Road, KIADB Industrial Area, Antharasanahalli, Tumakuru-572 106.	Report No. : RCA/2020/08029 Report date : 11/12/2020 Ref. : Test Request Form Ref. Date : 04/12/2020 Job Order No : RCA/2020/08029 Date : 04/12/2020 Date of Analysis : 04/12/2020 to 10/12/2020
Sample Particulars: One Sample of **Rat & Mice Feed**	**Sample Qty** : 500 g

Sl. No.	Tests	Results	Acceptable Limits	Test Method
Description: Brown colored pellets				
1	Energy, Kcal/kg	3649.0	3000 - 4000	F/WP/029
2	Carbohydrates, %	60.5	60 – 70	F/WP/030
3	Crude Fat, %	5.3	5 - 6	AOAC 21st Edition
4	Crude protein, %	18.8	18 - 21	AOAC 21st Edition
5	Crude Fibre, %	4.3	3.8 - 5	IS:10226 (Part 1)-1982,Reaff 2005
6	Total Ash, %	6.3	5 - 8	AOAC 21st Edition
7	Moisture, %	9.1	NMT 10	AOAC 21st Edition
8	Calcium, %	1.05	1.0 – 1.6	AOAC 21st Edition
9	Iron as Fe, ppm	250.0	250.0	AOAC 21st Edition
10	Potassium, %	0.69	0.68 – 1.0	AOAC 21st Edition
11	Sodium, %	0.24	0.23 – 0.25	AOAC 21st Edition
12	Magnesium, %	0.20	0.20	AOAC 21st Edition
13	Zinc as Zn, ppm	79.0	77 - 80	AOAC 21st Edition
14	Manganese as Mn, ppm	100.0	100.0	AOAC 21st Edition

Note: NMT- Not More Than.

11/12/2020
Verified By

11/12/2020
Authorized By

Annexure 8. Bedding Material Report

ANNEXURE 9: MICROBIAL MONITORING REPORT OF AUTOCLAVED BEDDING MATERIAL

(Paddy Husk / Corn Cob)

Date of Sampling: 20/05/2021 Date of Reporting: 22/05/2021

Sl. No.	Source	Results	Remarks
01	LBPL-CC-0023 Corn cob Bedding material	No Bacterial growth on Nutrient agar plate	—

Report Prepared by Lavesh 22/05/2021
Sign. and Date

Approved by NH 22/05/2021
Sign. and Date

Authorized by NH 22/05/2021

Annexure 9. Contaminant Analysis for RO Water

ROBUST MATERIALS TECHNOLOGY PVT. LTD.

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TEST REPORT

TC-6165

M/s. Liveon Biolabs Pvt Ltd. Plot No. 46 & 47, 2nd Phase, Water Tank Road, KIADB Industrial Area, Antharasanahalli, Tumakuru-572 106.	Report No. : RCA/2020/08027 Report date : 11/12/2020 Ref. : Test Request Form Ref. Date : 04/12/2020 Job Order No : RCA/2020/08027 Date : 04/12/2020 Date of Analysis : 04/12/2020 to 10/12/2020
Sample Particulars: One sample of **RO Water.**	**Sample Qty:** 2 Ltrs

Sl. No.	Test	Results	Maximum Permissible Limit IS 10500 : 2012	Protocol
Description: Colorless liquid.				
1	Color (hazen units)	<2.0	15	IS 3025 (Part – 4) : 1983 Reaff 2017
2	Odour	Agreeable	Agreeable	IS 3025 (Part – 5) : 1983 Reaff.2018
3	pH Value	6.5	6.5 – 8.5	IS 3025 (Part – 11) : 1983 Reaff 2017
4	Turbidity, NTU	0.2	5	IS 3025 (Part – 10) : 1984 Reaff 2017
5	Chloride as Cl, mg/L	14.4	1000	IS 3025 (Part – 32) : 1988 Reaff 2019
6	Total hardness as $CaCO_3$, mg/L	19.8	600	IS 3025 (Part – 21) : 2009 Reaff. 2019
7	Calcium as Ca, mg/L	4.8	200	IS 3025 (Part – 40) : 1991 Reaff. 2019
8	Magnesium as Mg, mg/L	1.85	100	IS 3025 (Part – 46) : 1994 Reaff.2019
9	Total dissolved Solids, mg/L	46.0	2000	IS 3025 (Part – 16) : 1984 Reaff. 2017
10	Sulphate as SO_4, mg/L	BDL	400	IS 3025 (Part – 24) : 1986 Reaff. 2019
11	Fluoride as F, mg/L	Nil	1.5	APHA 23rd Edition
12	Residual, Free Chlorine, mg/L	<0.2	1	IS 3025 (Part – 26) : 1986 Reaff. 2019
13	Alkalinity as $CaCO_3$, mg/L	21.0	600	IS 3025 (Part – 23) : 1986 Reaff. 2019
14	Nitrates as NO_3, mg/L	5.4	45.0	APHA 23rd Edition
15	Copper as Cu, mg/L	BDL	1.5	APHA 23rd Edition
16	Iron as Fe, mg/L	BDL	0.3	APHA 23rd Edition
17	Manganese as Mn, mg/L	BDL	0.3	APHA 23rd Edition
18	Cadmium as Cd, mg/L	BDL	0.003	APHA 23rd Edition
19	Lead as Pb, mg/L	BDL	0.01	IS 3025 (Part – 47) : 1994 Reaff 2019
20	Zinc as Zn, mg/L	BDL	15	IS 3025 (Part – 49) : 1994 Reaff 2019
21	Aluminum as Al, mg/L	BDL	0.2	APHA 23rd Edition

11/12/2020
Verified By

11/12/2020
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Page 1 of 3

Note :1.The results listed refer only to the tested samples and applicable parameters. 2. Test certificate should not be reproduced except in full, without written approval of the laboratory. 3. The submitted samples are drawn by the laboratory unless otherwise specified. 4. Endorsement of product is neither inferred nor implied. 5. Samples will be destroyed after 15days from the date of issue of test report unless otherwise specified. 6. This report cannot be used as evidence in the court of law & should not be used in any advertising media without our permission in writing. 7. Total liability of our lab is limited to the invoice amount and any disputes arising out of this report are subject to Bangalore jurisdiction only. 8. Laboratory is not responsible for the authenticity of photocopied test reports.

RMT-QP26-F01/R0/10.03.2021

Annexure 9. Contaminant Analysis for RO Water (Contd.,)

ROBUST MATERIALS TECHNOLOGY PVT. LTD.

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Nagarabhavi, Bengaluru - 560 072. **Tel** : 080 2318 6230
Email : info@robustmaterials.com **Website** : www.robustmaterials.com

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TEST REPORT

M/s. Liveon Biolabs Pvt Ltd. Plot No. 46 & 47, 2nd Phase, Water Tank Road, KIADB Industrial Area, Antharasanahalli, Tumakuru-572 106.	Report No. : RCA/2020/08027 Report date : 11/12/2020 Ref. : Test Request Form Ref. Date : 04/12/2020 Job Order No : RCA/2020/08027 Date : 04/12/2020 Date of Analysis : 04/12/2020 to 10/12/2020
Sample Particulars: One sample of **RO Water.**	**Sample Qty**: 2 Ltrs

Sl. No.	Test	Results	Maximum Permissible Limit IS 10500: 2012	Protocol
22	Taste	Agreeable	Agreeable	IS 3025 (Part – 8): 1984 Reaff.1996
23	Phenolic compounds as C_6H_5OH, mg/L	Absent	0.002	IS 3025 (Part – 43): 1992
24	Mercury as Hg, mg/L	BDL	0.001	IS 3025 (Part – 48): 1994
25	Selenium as Se, mg/L	BDL	0.01	IS 3025 (Part – 56): 2003
26	Arsenic as As, mg/L	BDL	0.01	IS 3025 (Part – 37): 1988
27	Cyanide as CN	Absent	0.05	APHA 23rd Edition
28	Anionic detergents as MBAS, mg/L	Absent	1.0	Annex K of IS: 13428: 2005
29	Chromium as Cr, mg/L	BDL	0.05	APHA 23rd Edition
30	Boron as B, mg/L	BDL	1.0	APHA 23rd Edition
31	Ammonia (as NH3), mg/L	Nil	<0.5	IS 3025(part-34):1988
32	Pesticides, mg/L	Absent	Nil	GCMS
33	Mineral oil, mg/L	Absent	0.5	IS 3025 (Part – 39) : 1991
34	PAH, mg/L	Absent	0.0001	GCMS
35	Alpha Emitter, Bq/L	BDL	0.1	Instrumental
36	Beta Emitter, Bq/L	BDL	1.0	Instrumental

11/12/2020
Verified By

Authorized By 11/12/2020

Page 2 of 3

Note:1. The results listed refer only to the tested samples and applicable parameters. **2.** Test certificate should not be reproduced except in full, without written approval of the laboratory. **3.** The submitted samples are drawn by the laboratory unless otherwise specified. **4.** Endorsement of product is neither inferred nor implied. **5.** Samples will be destroyed after 15days from the date of issue of test report unless otherwise specified. **6.** This report cannot be used as evidence in the court of law & should not be used in any advertising media without our permission in writing. **7.** Total liability of our lab is limited to the invoice amount and any disputes arising out of this report are subject to Bangalore jurisdiction only. **8.** Laboratory is not responsible for the authenticity of photocopied test reports.

RMT-QP26-1.0/1/R-/10.03.2021

Annexure 9. Contaminant Analysis for RO Water (Contd.,)

ROBUST MATERIALS TECHNOLOGY PVT. LTD.

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(Approved by Drug Control Department-GoK ; Certified by OHSAS-ISO 45001:2018)

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Email : info@robustmaterials.com Website : www.robustmaterials.com

TEST REPORT

M/s. Liveon Biolabs Pvt Ltd.
Plot No. 46 & 47, 2nd Phase,
Water Tank Road, KIADB Industrial Area,
Antharasanahalli,
Tumakuru-572 106.

Report No.	: RCA/2020/08027
Report date	: 11/12/2020
Ref.	: Test Request Form
Ref. Date	: 04/12/2020
Job Order No	: RCA/2020/08027
Date	: 04/12/2020
Date of Analysis	: 04/12/2020 to 10/12/2020

Sample Particulars: One sample of **RO Water.** **Sample Qty**: 2 Ltrs

Sl. No.	Test	Results	Permissible Limit	Protocol
37	Staphylococcus aureus/250 ml	Absent	Absent	IS:5887(P-2) 1976
38	Salmonella/250 ml	Absent	Absent	IS:15187 Reaff 2016
39	Aspergillus niger/250 ml	Absent	Absent	IS:5403 - 1999 Reaff 2018
40	Escherichia coli /250ml	Absent	Absent	IS:15185 Reaff 2016
41	Pseudomonas sp /250 ml	Absent	Absent	Annex D of IS:13428-2002
42	Total microbial count, cfu/ml	<1	<100	IS:5402-2012 Reaff 2018

----------END OF THE REPORT----------

Verified By 11/12/2020

Authorized By 11/12/2020

Page 3 of 3

Note :1. The results listed refer only to the tested samples and applicable parameters. **2.** Test certificate should not be reproduced except in full, without written approval of the laboratory. **3.** The submitted samples are drawn by the laboratory unless otherwise specified. **4.** Endorsement of product is neither inferred nor implied. **5.** Samples will be destroyed after 15days from the date of issue of test report unless otherwise specified. **6.** This report cannot be used as evidence in the court of law & should not be used in any advertising media without our permission in writing. **7.** Total liability of our lab is limited to the invoice amount and any disputes arising out of this report are subject to Bangalore jurisdiction only. **8.** Laboratory is not responsible for the authenticity of photocopied test reports.

RMT-QP26-F01/R1/10.03.2021

Annexure 10. Contaminant Analysis for Feed

ROBUST MATERIALS TECHNOLOGY PVT. LTD.

(Recognised by MoEF&CC, DSIR-Government of India & Notified by FSSAI)
(Approved by Drug Control Department-GoK ; Certified by OHSAS-ISO 45001:2018)

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Nagarabhavi, Bengaluru - 560 072. **Tel :** 080 2318 6230
Email : info@robustmaterials.com **Website :** www.robustmaterials.com

TEST REPORT

M/s. Liveon Biolabs Pvt Ltd. Plot No. 46 & 47, 2nd Phase, Water Tank Road, KIADB Industrial Area, Antharasanahalli, Tumakuru-572 106.	Report No. : RCA/2020/08029 Report date : 11/12/2020 Ref. : Test Request Form Ref. Date : 04/12/2020 Job Order No : RCA/2020/08029 Date : 04/12/2020 Date of Analysis : 04/12/2020 to 10/12/2020
Sample Particulars: One Sample of **Rat & Mice Feed**	**Sample Qty** : 500 g

Sl. No.	Tests	Results	Acceptable Limits	Test Method
Description: Brown colored pellets				
1	Energy, Kcal/kg	3649.0	3000 - 4000	F/WP/029
2	Carbohydrates, %	60.5	60 – 70	F/WP/030
3	Crude Fat, %	5.3	5 - 6	AOAC 21st Edition
4	Crude protein, %	18.8	18 - 21	AOAC 21st Edition
5	Crude Fibre, %	4.3	3.8 - 5	IS:10226 (Part 1)-1982,Reaff 2005
6	Total Ash, %	6.3	5 - 8	AOAC 21st Edition
7	Moisture, %	9.1	NMT 10	AOAC 21st Edition
8	Calcium, %	1.05	1.0 – 1.6	AOAC 21st Edition
9	Iron as Fe, ppm	250.0	250.0	AOAC 21st Edition
10	Potassium, %	0.69	0.68 – 1.0	AOAC 21st Edition
11	Sodium, %	0.24	0.23 – 0.25	AOAC 21st Edition
12	Magnesium, %	0.20	0.20	AOAC 21st Edition
13	Zinc as Zn, ppm	79.0	77 - 80	AOAC 21st Edition
14	Manganese as Mn, ppm	100.0	100.0	AOAC 21st Edition

Note: NMT- Not More Than.

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Annexure 10. Contaminant Analysis for Feed (Contd.,)

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Email : info@robustmaterials.com **Website :** www.robustmaterials.com

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TEST REPORT

M/s. Liveon Biolabs Pvt Ltd. Plot No. 46 & 47, 2nd Phase, Water Tank Road, KIADB Industrial Area, Antharasanahalli, Tumakuru-572 106.	Report No. : RCA/2020/08029 Report date : 11/12/2020 Ref. : Test Request Form Ref. Date : 04/12/2020 Job Order No : RCA/2020/08029 Date : 04/12/2020 Date of Analysis : 04/12/2020 to 10/12/2020
Sample Particulars: One Sample of **Rat & Mice Feed**	**Sample Qty** : 500 g

Sl. No.	Tests	Results	Acceptable Limits	Test Method
15	Phosphorous as P, %	0.7	0.65 – 0.8	AOAC 21st Edition
16	Nitrogen Free Extract, %	56.2	-	F/WP/031A
17	Lead as Pb, mg/Kg	<0.1	<1.5	By AAS
18	Cadmium as Cd, mg/Kg	<0.1	<0.4	By AAS
19	Mercury as Hg, mg/Kg	<0.01	<0.1	By AAS
20	Arsenic as As, mg/Kg	<0.01	<1.0	By AAS
21	Aflatoxin B1,µg/Kg	Not Detected	10	WP/02/SOP/43
22	Aflatoxin B2, µg/Kg	Not Detected	5.0	WP/02/SOP/43
23	Aflatoxin G1, µg/Kg	Not Detected	5.0	WP/02/SOP/43
24	Aflatoxin G2, µg/Kg	Not Detected	5.0	WP/02/SOP/43

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Annexure 10. Contaminant Analysis for Feed (Contd.,)

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Sample Particulars: One Sample of **Rat & Mice Feed**	**Sample Qty** : 500 g

Sl. No.	Tests	Results	Acceptable Limits	Test Method
15	Phosphorous as P, %	0.7	0.65 – 0.8	AOAC 21st Edition
16	Nitrogen Free Extract, %	56.2	-	F/WP/031A
17	Lead as Pb, mg/Kg	<0.1	<1.5	By AAS
18	Cadmium as Cd, mg/Kg	<0.1	<0.4	By AAS
19	Mercury as Hg, mg/Kg	<0.01	<0.1	By AAS
20	Arsenic as As, mg/Kg	<0.01	<1.0	By AAS
21	Aflatoxin B1,µg/Kg	Not Detected	10	WP/02/SOP/43
22	Aflatoxin B2, µg/Kg	Not Detected	5.0	WP/02/SOP/43
23	Aflatoxin G1, µg/Kg	Not Detected	5.0	WP/02/SOP/43
24	Aflatoxin G2, µg/Kg	Not Detected	5.0	WP/02/SOP/43

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Sample Particulars: One Sample of **Rat & Mice Feed**	**Sample Qty** : 500 g

Sl. No.	Test	Result	Acceptable Limits	Protocol
ORGANOCHLORINE GROUP				
25	Aldrin (expressed as Dieldrin), mg/Kg	<0.01	<0.05	AOAC 21st Edition
26	Alpha HCH, mg/Kg	<0.01	<0.05	AOAC 21st Edition
27	Beta HCH, mg/kg	<0.01	<0.05	AOAC 21st Edition
28	Chlordane (cis & trans) , mg/Kg	<0.01	<0.05	AOAC 21st Edition
29	Chlorothalonil, mg/Kg	<0.01	<0.05	AOAC 21st Edition
30	Chlorpyriphos, mg/Kg	<0.01	<0.05	AOAC 21st Edition
31	Chlorpyriphos methyl, mg/Kg	<0.01	<0.05	AOAC 21st Edition
32	Delta HCH, mg/Kg	<0.01	<0.05	AOAC 21st Edition
33	Dicofol, mg/Kg	<0.01	<0.05	AOAC 21st Edition
34	Dieldrin (see Aldrin) , mg/Kg	<0.01	<0.05	AOAC 21st Edition
35	Endosulphan (All isomers), mg/Kg	<0.01	<0.05	AOAC 21st Edition
36	Endrin, mg/Kg	<0.01	<0.05	AOAC 21st Edition
37	Heptachlor, mg/Kg	<0.01	<0.05	AOAC 21st Edition
38	Lindane, mg/Kg	<0.01	<0.05	AOAC 21st Edition
39	Delta Hexa chloro Hexane, mg/Kg	<0.01	<0.05	AOAC 21st Edition

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Annexure 10. Contaminant Analysis for Feed (Contd.,)

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Sample Particulars: One Sample of **Rat & Mice Feed**	**Sample Qty** : 500 g

Sl. No.	Test	Result	Acceptable Limits	Protocol
40	op DDD, mg/Kg	<0.01	<0.05	AOAC 21st Edition
41	op DDE, mg/Kg	<0.01	<0.05	AOAC 21st Edition
42	op DDT, mg/Kg	<0.01	<0.05	AOAC 21st Edition
43	pp DDD, mg/Kg	<0.01	<0.05	AOAC 21st Edition
44	pp DDE, mg/Kg	<0.01	<0.05	AOAC 21st Edition
45	pp DDT, mg/Kg	<0.01	<0.05	AOAC 21st Edition
ORGANOPHOSPHOROUS GROUP				
46	4-bromo-2-chlorophenol, mg/Kg	<0.01	<1.0	AOAC 21st Edition
47	Profenophos, mg/Kg	<0.01	<1.0	AOAC 21st Edition
48	Chlorfenvinphos, mg/Kg	<0.01	<1.0	AOAC 21st Edition
49	Chlorpyrifos, mg/Kg	<0.01	<1.0	AOAC 21st Edition
50	Diazinon, mg/Kg	<0.01	<1.0	AOAC 21st Edition
51	Dichlorvos, mg/Kg	<0.01	<1.0	AOAC 21st Edition
52	Ethion, mg/Kg	<0.01	<1.0	AOAC 21st Edition
53	Fenitrothion, mg/Kg	<0.01	<1.0	AOAC 21st Edition
54	Dimethoate (Including Omethoate), mg/Kg	<0.01	<1.0	AOAC 21st Edition
55	Malathion, mg/Kg	<0.01	<1.0	AOAC 21st Edition
56	Monocrotophos, mg/Kg	<0.01	<1.0	AOAC 21st Edition
57	Oxyfluorfen, mg/Kg	<0.01	<1.0	AOAC 21st Edition
58	Parathion, mg/Kg	<0.01	<1.0	AOAC 21st Edition
59	Parathion ethyl, mg/Kg	<0.01	<1.0	AOAC 21st Edition
60	Parathion-methyl, mg/Kg	<0.01	<1.0	AOAC 21st Edition
61	Paraoxon methyl, mg/Kg	<0.01	<1.0	AOAC 21st Edition
62	Phorate, mg/Kg	<0.01	<1.0	AOAC 21st Edition
63	Phosalone, mg/Kg	<0.01	<1.0	AOAC 21st Edition
64	Profenophos, mg/Kg	<0.01	<1.0	AOAC 21st Edition

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Annexure 10. Contaminant Analysis for Feed (Contd.,)

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TEST REPORT

M/s. Liveon Biolabs Pvt Ltd. Plot No. 46 & 47, 2nd Phase, Water Tank Road, KIADB Industrial Area, Antharasanahalli, Tumakuru-572 106.	Report No. : RCA/2020/08029 Report date : 11/12/2020 Ref. : Test Request Form Ref. Date : 04/12/2020 Job Order No : RCA/2020/08029 Date : 04/12/2020 Date of Analysis : 04/12/2020 to 10/12/2020
Sample Particulars: One Sample of **Rat & Mice Feed**	**Sample Qty** : 500 g

Sl. No	TESTS	RESULTS	Permissible Limit	PROTOCOL
Description: Light Brown Coloured Corn Cob.				
65	Staphylococcus aureus/25g	Absent	Nil	IS:5887(P-2) 1976 Reaff 2018
66	Salmonella/25g	Absent	Nil	IS:5887(P-3) 1999 Reaff 2018
67	Aspergillus niger, cfu/g	Absent	-	IS:5403 - 1999 Reaff 2018
68	Escherichia coli/g	Absent	Nil	IS:5887 (P-1) 1976 Reaff 2018
69	Pseudomonas sp,/25g	Absent	Nil	Annex D of IS:13428-2002
70	Total microbial count, cfu/g	<10	$<1x10^3$	IS:5402-2012 Reaff 2018

----------END OF THE REPORT----------

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Annexure 11. Contaminant Analysis for Bedding Materials

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TEST REPORT

M/s. Liveon Biolabs Pvt Ltd. Plot No. 46 & 47, 2nd Phase, Water Tank Road, KIADB Industrial Area, Antharasanahalli, Tumakuru-572 106.	Report No. : RCA/2020/08031 Report date : 11/12/2020 Ref. : Test Request Form Ref. Date : 04/12/2020 Job Order No : RCA/2020/08031 Date : 04/12/2020 Date of Analysis : 04/12/2020 to 10/12/2020
Sample particulars: One Sample of **Corn Cob.**	Sample Qty : 500 g
Batch No: LBPL-CC-0020	

Sl. No.	Test	Result	Acceptable Limits	Protocol
1	Lead as Pb, mg/Kg	<0.01	0.1	By AAS
2	Cadmium as Cd , mg/Kg	<0.01	0.1	By AAS
3	Mercury as Hg, mg/Kg	<0.01	0.025	By AAS
4	Arsenic as As, mg/Kg	<0.01	0.1	By AAS
5	Aflatoxin B1,µg/Kg	Not Detected	0.5	WP/02/SOP/43
6	Aflatoxin B2, µg/Kg	Not Detected	0.5	WP/02/SOP/43
7	Aflatoxin G1, µg/Kg	Not Detected	0.5	WP/02/SOP/43
8	Aflatoxin G2, µg/Kg	Not Detected	0.5	WP/02/SOP/43
ORGANOCHLORINE GROUP				
9	Aldrin (expressed as Dieldrin), mg/Kg	<0.01	0.01	AOAC 21st Edition
10	HCH (alpha & beta), mg/Kg	<0.01	0.01	AOAC 21st Edition
11	Chlordane (cis & trans) , mg/Kg	<0.01	0.01	AOAC 21st Edition
12	Chlorothalonil, mg/Kg	<0.01	0.01	AOAC 21st Edition
13	Delta HCH, mg/Kg	<0.01	0.01	AOAC 21st Edition
14	Dicofol, mg/Kg	<0.01	0.01	AOAC 21st Edition
15	Dieldrin (see Aldrin) , mg/Kg	<0.01	0.01	AOAC 21st Edition
16	Endosulphan (All isomers), mg/Kg	<0.01	0.01	AOAC 21st Edition
17	Endrin, mg/Kg	<0.01	0.01	AOAC 21st Edition
18	Heptachlor, mg/Kg	<0.01	0.01	AOAC 21st Edition
19	Lindane, mg/Kg	<0.01	0.01	AOAC 21st Edition

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Annexure 11. Contaminant Analysis for Bedding Materials (Contd.,)

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Sample particulars: One Sample of **Corn Cob.**	Sample Qty : 500 g
Batch No: LBPL-CC-0020	

Sl. No.	Test	Result	Acceptable Limits	Protocol
PESTICIDE RESIDUES				
20	op DDD, mg/Kg	<0.01	0.01	AOAC 21st Edition
21	op DDE, mg/Kg	<0.01	0.01	AOAC 21st Edition
22	op DDT, mg/Kg	<0.01	0.01	AOAC 21st Edition
23	pp DDD, mg/Kg	<0.01	0.01	AOAC 21st Edition
24	pp DDE, mg/Kg	<0.01	0.01	AOAC 21st Edition
25	pp DDT, mg/Kg	<0.01	0.01	AOAC 21st Edition
ORGANOPHOSPHOROUS GROUP				
26	4-bromo-2-chlorophenol, mg/Kg	<0.01	0.01	AOAC 21st Edition
27	Profenophos, mg/Kg	<0.01	0.01	AOAC 21st Edition
28	Chlorfenvinphos, mg/Kg	<0.01	0.01	AOAC 21st Edition
29	Chlorpyrifos, mg/Kg	<0.01	0.01	AOAC 21st Edition
30	Diazinon, mg/Kg	<0.01	0.01	AOAC 21st Edition
31	Dichlorvos, mg/Kg	<0.01	0.01	AOAC 21st Edition
32	Ethion, mg/Kg	<0.01	0.01	AOAC 21st Edition
33	Fenitrothion, mg/Kg	<0.01	0.01	AOAC 21st Edition
34	Dimethoate (Including Omethoate), mg/Kg	<0.01	0.01	AOAC 21st Edition
35	Malathion, mg/Kg	<0.01	0.01	AOAC 21st Edition
36	Monocrotophos, mg/Kg	<0.01	0.01	AOAC 21st Edition
37	Oxyfluorfen, mg/Kg	<0.01	0.01	AOAC 21st Edition
38	Chlorpyriphos methyl, mg/Kg	<0.01	0.01	AOAC 21st Edition

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Sample particulars: One Sample of **Corn Cob.**	Sample Qty : 500 g
Batch No: LBPL-CC-0020	

Sl. No.	Test	Result	Acceptable Limits	Protocol
39	Parathion ethyl, mg/Kg	<0.01	0.01	AOAC 21st Edition
40	Parathion-methyl, mg/Kg	<0.01	0.01	AOAC 21st Edition
41	Paraoxon methyl, mg/Kg	<0.01	0.01	AOAC 21st Edition
42	Phorate, mg/Kg	<0.01	0.01	AOAC 21st Edition
43	Phosalone, mg/Kg	<0.01	0.01	AOAC 21st Edition
44	Profenophos, mg/Kg	<0.01	0.01	AOAC 21st Edition
45	Acephate mg/Kg	<0.01	0.01	AOAC 21st Edition
46	Etrimfos mg/kg	<0.01	0.01	AOAC 21st Edition
47	Iprobenphos mg/kg	<0.01	0.01	AOAC 21st Edition
48	Methamidophos mg/kg	<0.01	0.01	AOAC 21st Edition
49	Oxydemeton-methyl mg/kg	<0.01	0.01	AOAC 21st Edition
50	Phosphamidon mg/kg	<0.01	0.01	AOAC 21st Edition
51	Quinalphos mg/kg	<0.01	0.01	AOAC 21st Edition
52	T riazophos mg/kg	<0.01	0.01	AOAC 21st Edition
53	4-bromo-2-chlorophenol(metabolite of Profenophos)	<0.01	0.01	AOAC 21st Edition

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Sample particulars: One Sample of **Corn Cob.**	Sample Qty : 500 g
Batch No: LBPL-CC-0020	

Sl. No	TESTS	RESULTS	Permissible Limit	PROTOCOL
Description: Light Brown Coloured Corn Cob.				
54	Staphylococcus aureus/25g	Absent	Nil	IS:5887(P-2) 1976 Reaff 2018
55	Salmonella/25g	Absent	Nil	IS:5887(P-3) 1999 Reaff 2018
56	Aspergillus niger, cfu/g	Absent	-	IS:5403 - 1999 Reaff 2018
57	Escherichia coli/g	Absent	Nil	IS:5887 (P-1) 1976 Reaff 2018
58	Pseudomonas sp,/25g	Absent	Nil	Annex D of IS:13428-2002
59	Total microbial count, cfu/g	<10	$<1x10^3$	IS:5402-2012 Reaff 2018

----------END OF THE REPORT----------

Verified by 11/12/2020

Authorized by 11/12/2020

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Note :1. The results listed refer only to the tested samples and applicable parameters. **2.** Test certificate should not be reproduced except in full, without written approval of the laboratory. **3.** The submitted samples are drawn by the laboratory unless otherwise specified. **4.** Endorsement of product is neither inferred nor implied. **5.** Samples will be destroyed after 15days from the date of issue of test report unless otherwise specified. **6.** This report cannot be used as evidence in the court of law & should not be used in any advertising media without our permission in writing. **7.** Total liability of our lab is limited to the invoice amount and any disputes arising out of this report are subject to Bangalore jurisdiction only. **8.** Laboratory is not responsible for the authenticity of photocopied test reports.

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