STUDY REPORT
Original: 1/2

STUDY TITLE

ACUTE EYE IRRITATION/CORROSION STUDY OF BIO-X KLEANZE EC IN NEW ZEALAND WHITE RABBITS

(As per OECD Guideline No. 405: Acute Eye Irritation/Corrosion)

STUDY No.: BIO-ATX 2830

Study Completion Date: 18 January 2021

SPONSOR

OKADA ECOTECH PTE LTD
24 PIONEER CRESCENT #04-08
628557 SINGAPORE

TEST FACILITY

BIONEEDS INDIA PRIVATE LIMITED
DEVARAHOSAHALLY,
SOMPURA HOBLI, NELAMANGALA TALUK,
BANGALORE RURAL DISTRICT, PIN - 562 111,
KARNATAKA, INDIA
E-mail: bioneeds@bioneeds.in
Website: www.bioneeds.in
Tel No.: +91 816 - 2214400
Fax: +91 816 - 2214444

CONFIDENTIAL

TABLE OF CONTENTS

QUALITY ASSURANCE STATEMENT 4

STATEMENT OF GLP COMPLIANCE 5

DECLARATION 5

STATEMENT OF CONFIDENTIALITY 6

ABBREVIATIONS OF COMMONLY USED UNITS AND SYMBOLS 7

1. STUDY DETAILS 8

2. SUMMARY 10

3. STUDY COMPLIANCE 11

3.1 GLP Compliance 11
3.2 Regulatory Guideline 11
3.3 Animal Welfare 11

4. SAFETY PRECAUTIONS 11

5. OBJECTIVE 11

6. MATERIALS AND METHODS 11

6.1 Test Item Information 11
6.2 Test System 12
6.3 Husbandry 12
6.4 Acclimatization 13
6.5 Study Design 13
6.6 Preparation of Animals 13
6.7 Preparation of Test item 13
6.8 Dose Selection and Justification for Selection 14
6.9 Route of Administration and Justification for Selection 14
6.10 Test Procedure 14
6.10.1 Pre-Instillation Procedure 14
6.10.2 Instillation of Test Item 14
6.10.3 Post-Instillation Procedure 15
6.11 Observations 15
6.11.1 Clinical Signs of Toxicity and Mortality 15
6.11.2 Scoring of Ocular Lesions 15
6.11.3 Humane Sacrifice 16
6.11.4 Body Weight 16

6.11.5 Pathology 16

7. INTERPRETATION OF RESULTS 16

8. STUDY REPORT PREPARATION AND RESULTS 16

9. AMENDMENTS AND DEVIATIONS 17

10. STUDY REPORT DISTRIBUTION 17

11. ARCHIVING 17

12. REFERENCE 17

13. RESULTS AND DISCUSSION 18

13.1 Clinical Signs of Toxicity and Mortality 18

13.2 Scoring of Ocular Lesions 18

13.3 Slit Lamp Examination 18

13.4 Body Weight 18

13.5 Evaluation of Scoring 18

14. CONCLUSION 18

15. TABLES 19

TABLE 1. INDIVIDUAL ANIMAL CLINICAL SIGNS OF TOXICITY AND MORTALITY RECORD 20

TABLE 2. INDIVIDUAL ANIMAL EYE IRRITATION/CORROSION SCORING RECORD 21

TABLE 3. INDIVIDUAL ANIMAL SLIT LAMP EXAMINATION RECORD 22

TABLE 4. INDIVIDUAL ANIMAL BODY WEIGHT (kg) AND PERCENT CHANGE IN BODY WEIGHT WITH RESPECT TO DAY 1 23

16. ANNEXURES 24

ANNEXURE 1. CERTIFICATE OF ANALYSIS OF BIO-X KLEANZE EC 25

ANNEXURE 2. CONTAMINANT ANALYSIS TEST REPORT OF FEED 26

ANNEXURE 3. CONTAMINANT ANALYSIS TEST REPORT OF WATER 28

ANNEXURE 4. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS) 31

ANNEXURE 5. GLP CERTIFICATE 32

QUALITY ASSURANCE STATEMENT

The Study No.: BIO-ATX 2830, entitled "Acute Eye Irritation/Corrosion Study of Bio-X Kleanze EC in New Zealand White Rabbits" has been inspected as per OECD Principles of Good Laboratory Practice [C(97)186/Final].

The dates of inspections and dates of reporting to the Study Director and the Management have been listed below:

Inspection Dates	Inspection Phases	Reporting Dates	
		Study Director	Management
Initiation Phase			
14 December 2020	Study plan verification	14 December 2020	14 December 2020
08 January 2021	Study plan Amendment No.1 verification	08 January 2021	08 January 2021
In-life Phase			
22 December 2020	Test item administration - Initial test	22 December 2020	22 December 2020
Reporting Phase			
11 January 2021	Draft report inspection	11 January 2021	11 January 2021
13 January 2021	Final report inspection	13 January 2021	13 January 2021

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

.....

(Signature)
Mr. PRAVEEN B.
Quality Assurance Unit

18 January 2021

(Date)

STATEMENT OF GLP COMPLIANCE

The Study No.: BIO-ATX 2830, entitled "Acute Eye Irritation/Corrosion Study of Bio-X Kleanze EC in New Zealand White Rabbits" was performed in compliance with the OECD Principles of Good Laboratory Practice [C(97)186/Final].

DECLARATION

I hereby declare that the work was performed under my 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.

I accept overall responsibility for the technical conduct of the study as well as the interpretation, analysis, documentation and reporting of the results.

D Jhansi
.....
(Signature)
Ms. D. JHANSI
Study Director

18 January 2021
.....
(Date)

STATEMENT OF CONFIDENTIALITY

This report contains **CONFIDENTIAL** and **PROPRIETARY** information of **OKADA ECOTECH PTE LTD., SINGAPORE** will not be disclosed to anyone without the expressed or written approval of sponsor, except to the employees of test facility wherever necessary and to persons authorized by law or judicial judgment.

D. Jhansi
.....
(Signature)
Ms. D. JHANSI
Study Director

18 January 2021
.....
(Date)

.....
(Signature)
Dr. NITIN M. SHETTY
Deputy Test Facility Management

18 January 2021
.....
(Date)

ABBREVIATIONS OF COMMONLY USED UNITS AND SYMBOLS

AAALAC	-	Association for Assessment and Accreditation of Laboratory Animal Care
B	-	Breadth
CPCSEA	-	Committee for the Purpose of Control and Supervision of Experiments on Animals
GHS	-	Globally Harmonized System of Classification and Labelling of Chemicals
GLP	-	Good Laboratory Practice
kg	-	Kilogram
H	-	Height
h/hr(s)	-	Hour(s)
IAEC	-	Institutional Animal Ethics Committee
L	-	Length
min	-	Minute
mL	-	Milliliter
mg	-	Milligram
n	-	Number of animals
N	-	Normal/ No Abnormality Detected
NAD	-	No Abnormality Detected
No.	-	Number
OECD	-	Organization for Economic Co-operation and Development
SD	-	Standard Deviation
TS	-	Terminal Sacrifice
w/v	-	Weight by volume
°C	-	Degree Celsius
%	-	Percentage

1. STUDY DETAILS

1.1	**Study Title**	**:**	Acute Eye Irritation/Corrosion Study of Bio-X Kleanze EC in New Zealand White Rabbits
1.2	**Study Number**	**:**	BIO-ATX 2830
1.3	**Study Code**	**:**	AEIN
1.4	**Sponsor Details**		
	Sponsor	:	Okada Ecotech Pte Ltd 24 Pioneer Crescent #04-08 628557 Singapore
	Sponsor's Representative	:	K. E. Tan Okada Ecotech Pte Ltd 24 Pioneer Crescent #04-08 628557 Singapore
	Monitoring Scientist	:	A. Z. Tan Okada Ecotech Pte Ltd 24 Pioneer Crescent #04-08 628557 Singapore
1.5	**Test Facility**	**:**	Bioneeds India Private Limited Devarahosahally, Sompura Hobli, Nelamangala Taluk, Bangalore Rural District, PIN - 562 111, Karnataka, India
1.6	**Study Responsibilities**		
	Study Director	:	Ms. D. Jhansi., M.Sc Bioneeds India Private Limited, Devarahosahally, Sompura Hobli, Nelamangala Taluk, Bangalore Rural District, PIN - 562 111, Karnataka, India E-mail: bioneeds@bioneeds.in
	Study Co-ordinator	:	Ms. Amulya T. S., B. E. (Biotech)
	Study Personnel	:	Ms. Kowstubha G.D., M.Sc.
	Study Veterinarian	:	Dr. K. R Sneha., M.V.Sc.

1.7 Study Schedule

Study Initiation Date	:	16 December 2020
Experimental Starting Date	:	17 December 2020
Acclimatization Date	:	Start: 17 December 2020 End: 28 December 2020
Initial Test Date	:	22 December 2020
Confirmatory Test Date	:	29 December 2020
Experimental Completion Date	:	01 January 2021
Draft Report Submission Date	:	11 January 2021
Study Completion Date	:	18 January 2021

2. SUMMARY

The test item, Bio-X Kleanze EC was evaluated for Acute Eye Irritation/Corrosion in New Zealand White Rabbits.

The study was performed in two phases i.e., initial and confirmatory tests. Both the eyes of each experimental animal was examined within 24 hours before the treatment. The animals with absence of signs of eye irritation, ocular defects or pre-existing corneal injury were used for the treatment. The pH of 80 dilutions Bio-X Kleanze EC and 160 dilutions Bio-X Kleanze EC were 5.17 and 5.76 receptively as per in-house pH determination.

The initial test was conducted using single Male rabbit as there was no irritant or corrosive effect, confirmatory test was conducted using four male rabbits. The systemic analgesic (tramadol hydrochloride injection 2.5 mg/kg) and two drops of topical ocular anaesthetic (0.5% w/v tetracaine hydrochloride) were given to each animal sixty minutes and five minutes prior to test item instillation respectively. The 0.1 mL of diluted test item was instilled into the conjunctival sac of the left eye and right eye served as control. The eyes were scored approximately at 1, 24, 48 and 72 hours for both initial and confirmatory test. Slit lamp examination was carried out using fluorescein strips (fluorescein sodium ophthalmic strip USP) and were scored approximately at 24 hours for both initial and confirmatory test.

All the animals (initial test and confirmatory test) were observed twice daily for clinical signs of toxicity and mortality. No clinical signs of toxicity and mortality were observed in all the animals (initial and confirmatory tests) after the test item instillation.

In both initial and confirmatory test, no eye irritation record was observed at 24, 48, 72 hour and day 4 observation.

In both initial and confirmatory test, no ocular lesions was observed at 24 hours observation during slit lamp examination.

The body weights were recorded on the day of receipt, on the day of treatment (prior to instillation of test item) and on the day of termination of the experiment. No changes were noted in body weight and percent change in body weights with respect to day 1 in both initial and confirmatory test. All the animals revealed physiologically normal increase in body weight in both initial and confirmatory tests.

All the animals were sacrificed by intravenous administration of sodium thiopentone and carcass was disposed.

For initial and confirmatory test, the mean score calculated across 3 scoring times (approximately 24, 48 and 72 hours after test item instillation) for cornea, iris and conjunctival redness and conjunctival chemosis were 0, 0, 0 and 0.

Conclusion

Based on the results of the experiment and experimental conditions employed, it is concluded that the mean score of test item Bio-X Kleanze EC does not meet the classification criteria hence not classified or categorized according to Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

3. STUDY COMPLIANCE

3.1 GLP Compliance

The study was performed:

a. In compliance with the OECD Principles of Good Laboratory Practice [C(97)186/Final].

b. In accordance with the Standard Operating Procedures at Bioneeds India Private Limited and as per the mutually agreed study plan with the sponsor.

3.2 Regulatory Guideline

The study was performed in accordance with the OECD Guideline for Testing of Chemicals No. OECD 405 (Section 4: Health Effects), "Acute Eye Irritation/Corrosion" adopted on 09 October 2017 (corrected on 26 June 2020).

3.3 Animal Welfare

The study was performed in an AAALAC accredited facility:

a. In accordance with the recommendation of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guideline for laboratory animal facility published in the Gazette of India, 2018.

b. In accordance with the protocol approved by Institutional Animal Ethics Committee (IAEC) (Protocol No.: BIO-IAEC-4047 and Approval Date: 08/09/2020).

4. SAFETY PRECAUTIONS

Gloves, head cap, face mask and goggles were used in addition to protective body garments and slippers to ensure adequate personnel health and safety and to avoid ingestion, inhalation, eye and skin contact with the test item.

5. OBJECTIVE

The objective of this study was to assess the possible ocular irritation and/or corrosive potential of the test item Bio-X Kleanze EC following single ocular instillation to New Zealand White rabbits.

This also gives details on classification and labelling of chemical for safety and risk assessment.

6. MATERIALS AND METHODS

6.1 Test Item Information

The test item information provided by the sponsor as per Test Item Data Sheet and Certificate of Analysis is presented below:

Name of Test Item	:	Bio-X Kleanze EC
CAS No.	:	Not Applicable
Physical appearance (with color)	:	Clear Brown liquid
Batch No.	:	2020061201
Date of Manufacture	:	12 June 2020

Date of Expiry	:	12 June 2023
Storage Conditions	:	Ambient (21 to 29°C)
Batch Produced by (Name and address)	:	Okada Ecotech Pte Ltd, Singapore
Test Item Code by Test Facility	:	D1155-001

The responsibility for the correct identity and stability of the test item rests with the sponsor. The Certificate of Analysis of test item Bio-X Kleanze EC provided by sponsor is presented as Annexures 1.

6.2 Test System

Animal Species	:	Rabbit (*Oryctolagus cuniculus*)
Strain	:	New Zealand White
Justification for Selection of Species	:	Rabbit is the recommended test system by national and international guidelines for eye irritation studies.
Source of Supply	:	Procured from approved breeder: Adita Biosys Private Limited Plot No.: SPL-26, 2nd Phase, KSSIDC Industrial Estate, Madhugiri Road, Antharasanahalli, Tumakuru-572106, Karnataka, India CPCSEA Registration No.: 1868/PO/RcBt/16/CPCSEA
Group,No. of Animals / Test and Sex		G1A : 1 Male (80 dilutions of test item) G1 : 2 Males (80 dilutions of test item) G2 : 2 Males (160 dilutions of test item)
	:	Initial Test : 1 Male Confirmatory Test : 4 Males Total of 5 Males were received
Age at Receipt	:	4 months
Body Weight at Receipt	:	2.01547 kg to 2.20533 kg
Animal Identification	:	During acclimatization: Cage cards During treatment Period: Cage cards and last 4 digits of the animal number was written on the ear of each rabbit using black marker pen. Animal no's.: Nb5973 to Nb5977

6.3 Husbandry

a. Environmental Conditions	:	Animals were housed under standard laboratory conditions, in an environmentally monitored air-conditioned room with adequate fresh air supply (12 to 15 Air changes per hour), room temperature 19.3°C to 22.8°C and relative humidity 47% to 67% with 12 hours fluorescent light and 12 hours dark cycle. The temperature and relative humidity was recorded once daily.

b. Housing : The animals were housed individually in stainless steel wire mesh cage (Size: L 24 x B 18 x H 18 inches) having facilities for holding pelleted feed and drinking water.

c. Feed : Altromin Maintenance diet for rabbits – Rich in crude fibre 2123 manufactured by Altromin Spezialfutter GmbH & Co. KG was provided *ad libitum* to the rabbits throughout the experimental period. The contaminant analysis test report is presented as Annexure 2.

d. Water : Water was provided *ad libitum* throughout the acclimatization and experimental period. Deep bore-well water passed through reverse osmosis unit was provided in plastic water bottles with stainless steel sipper tubes.

The contaminant analysis test report for water nearest to the experimental period has been attached as Annexure 3.

6.4 Acclimatization

Healthy young adult animals were acclimatized for a period of five days and twelve days for initial and confirmatory test respectively to the experimental room conditions and were observed for clinical signs once daily. Veterinary examination of all the animals was performed on the day of receipt.

6.5 Study Design

Initial consideration for exclusion of the test item was pH of ≤2.0 and ≥11.5.

The pH of 80 dilutions Bio-X Kleanze EC and 160 dilutions Bio-X Kleanze EC were 5.17 and 5.76 receptively as per in-house pH determination.

The study was performed in two phases, i.e. initial and confirmatory tests. Initial test was conducted using one animal with highest concentration of Bio-X Kleanze EC (80 dilutions). Observations were done for determination of severity and reversibility of the eye reactions before proceeding to a confirmatory test in two more animals per group with G1 (80 dilutions) and G2 (160 dilutions) as per sponsor communication

6.6 Preparation of Animals

Both the eyes of each experimental animal selected for testing were examined within 24 hours before initiating the treatment using ophthalmoscope. Only those animals with absence of signs of eye irritation, ocular defects or pre-existing corneal injury were used.

6.7 Preparation of Test item

For initial test:

80 dilutions: 0.13 mL of test item was taken and 10 mL of distilled water was added to get 80 dilutions of test item.

For Confirmatory test:

80 dilutions: 0.25 mL of test item was taken and 20 mL of distilled water was added to get 80 dilutions of test item.

160 dilutions: 0.13 mL of test item was taken and 20 mL of distilled water was added to get 160 dilutions of test item.

6.8 Dose Selection and Justification for Selection

The dose of 0.1 mL of diluted test item was instilled as per OECD 405, "Acute Eye Irritation/Corrosion" adopted on 09 October 2017 (corrected on 26 June 2020).

6.9 Route of Administration and Justification for Selection

The test item was instilled into the conjunctival sac of the left eye. The ocular route was selected as it is one of the probable routes of exposure to humans.

6.10 Test Procedure

6.10.1 Pre-Instillation Procedure

Sixty minutes prior to test item instillation, tramadol hydrochloride injection (2.5 mg/kg) was administered by subcutaneous injection (SC) to provide a therapeutic level of systemic analgesia.

Five minutes prior to test item instillation, two drops/eye of a topical ocular anaesthetic (0.5% w/v tetracaine hydrochloride) was applied to both the eyes.

The details of tramadol hydrochloride, tetracaine hydrochloride and sterile water for injection are as below:

1. Tramadol Hydrochloride Injection
   Batch No. : HLI174E
   Manufacture Date : 05/2019
   Expiry Date : 04/2021
   Manufactured by : Himalaya Meditek Pvt Ltd.

2. Tetracaine Hydrochloride
   Lot No. : SLBN2960V
   Expiry Date : 29/11/2022
   Manufacture by : Sigma Aldrich

3. Sterile Water for Injection
   Batch No. : 1906063
   Manufacture Date : Dec 2019
   Expiry Date : Nov 2023
   Manufactured by : Legency Remedies Pvt Ltd.

6.10.2 Instillation of Test Item

After pre-instillation procedure, 0.1 mL of diluted test item was instilled into the conjunctival sac of the left eye by gently pulling the lower lid away from the eye ball. Then the eye lids were gently held together for about a second to prevent loss of test item. The right eye remained untreated and served as the control.

The eyes were rinsed using 0.9% w/v normal saline after 24 hours of treatment (post treatment).

6.10.3 Post-Instillation Procedure

As there was no ocular lesions post instillation procedure was not carried out.

6.11 Observations

The following observations were made during the experimental period.

6.11.1 Clinical Signs of Toxicity and Mortality

The test animals were routinely evaluated for entire duration of the experiment for clinical signs of pain and/or distress twice daily, with a minimum of 6 hours interval between observations up to the end of the experiment. The animals were observed twice daily for mortality.

6.11.2 Scoring of Ocular Lesions

The treated and untreated eye of each animal was scored approximately at 1, 24, 48 and 72 hours after test item instillation for both initial and confirmatory test. The examination of reactions (cornea, iris and aqueous humor) was facilitated by use of slit lamp for both untreated and treated eyes (using fluorescein sodium ophthalmic strip; Batch No.: MIPL/A4/157; Mfg. Date: 12/2019; Exp. Date: 11/2024; Mfg. By: Madhu Instruments Pvt. Ltd.) of the animals approximately at 24 hours after test item instillation for initial test and confirmatory test. The experiment was terminated on 72 hour observation.

At each interval, the cornea, iris and conjunctivae (redness and chemosis) were examined and scored according to the following table:

Grading of Ocular Lesions

Cornea	**Score**
Opacity: degree of density (readings should be taken from most dense area)*	
No ulceration or opacity	0
Scattered or diffuse areas of opacity (other than slight dulling of normal lustre); details of iris clearly visible	1
Easily discernible translucent area; details of iris slightly obscured	2
Nacrous area; no details of iris visible; size of pupil barely discernible	3
Opaque cornea; iris not discernible through the opacity	4
Maximum possible: 4	
* The area of corneal opacity should be noted	
Area of cornea involved	
One-quarter (or less), not zero	1
Greater than one-quarter, but less than half	2
Greater than half, but less than three-quarters	3
Greater than three-quarters, up to whole area	4
Maximum possible: 4	

Iris	**Score**
Normal	0
Markedly deepened rugae, congestion, swelling, moderate circumcorneal hyperaemia; or injection; iris reactive to light (a sluggish reaction is considered to be an effect.	1
Hemorrhage, gross destruction, or no reaction to light	2
Maximum possible: 2	

Conjunctivae	Score
Redness (refers to palpebral and bulbar conjunctivae; excluding cornea and iris)	
Normal	0
Some blood vessels hyperaemic (injected)	1
Diffuse, crimson colour; individual vessels not easily discernible	2
Diffuse beefy red	3
Maximum possible: 3	
Chemosis	**Score**
Swelling (refers to lids and/or nictitating membranes)	
Normal	0
Some swelling above normal	1
Obvious swelling, with partial eversion of lids	2
Swelling, with lids about half closed	3
Swelling, with lids more than half closed	4
Maximum possible: 4	

6.11.3 Humane Sacrifice

The animals did not reveal any severe irritation/corrosion effects. Hence, the animals were not humanely sacrificed.

6.11.4 Body Weight

Body weights were recorded on the day of receipt, prior to instillation of test item (day 1) and at termination (day 4).

6.11.5 Pathology

a) Necropsy

At the end of observation period, both initial and confirmatory test animals were humanely sacrificed by intravenous administration of sodium thiopentone and the carcass was disposed.

Details of sodium thiopentone used is as follows
Batch No. : TP0002
Manufacture Date: 03/2020
Expiry Date : 02/2022
Manufactured by : Shree Anand Life Science Ltd.

7. INTERPRETATION OF RESULTS

The test item was classified according to the globally harmonized system of classification and labelling of chemicals (Refer Annexure 4).

The mean score was calculated across 3 scoring times (approximately 24, 48 and 72 hours after test item instillation) for each animal for cornea, iris and conjunctivae (redness and chemosis) separately.

8. STUDY REPORT PREPARATION AND RESULTS

Individual animal data is summarized and presented as tables. All findings are presented in the study report as per the standard reporting procedure of the test facility.

9. AMENDMENTS AND DEVIATIONS

One amendment was raised to correct the name of monitoring scientist as per revised test item data sheet and no deviations occurred during conduct of the study.

10. STUDY REPORT DISTRIBUTION

Original: 1/2 - Sponsor

Original: 2/2 - Archives, Bioneeds India Private Limited

11. ARCHIVING

All materials and data generated in the study will be stored at archives of the test facility. The study plan, raw data and study report will be maintained in the archives of Bioneeds India Private Limited for 9 years from the date of completion of the study. At the end of archiving period, the sponsor's instructions will be sought either to extend the archiving period or to return the archived material to the sponsor or for the disposal.

12. REFERENCE

The Globally Harmonized System of Classification and Labelling of Chemicals (GHS), 8th edition, 2019 (ST/SG/AC.10/30/REV.8).

13. RESULTS AND DISCUSSION

13.1 Clinical Signs of Toxicity and Mortality

No clinical signs of toxicity and mortality were observed in both initial and confirmatory test animals.

Refer Table 1

13.2 Scoring of Ocular Lesions

In both initial and confirmatory test, no eye irritation record was observed at 24, 48, 72 hour and day 4 observation.

Refer Table 2

13.3 Slit Lamp Examination

In both initial and confirmatory test, no occular lesions was observed at 24 hours observation during slit lamp examination.

Refer Table 3

13.4 Body Weight

No changes were noted in body weights and percent change in body weights with respect to day 1 in both initial and confirmatory test. All the animals revealed physiologically normal increase in body weight.

Refer Table 4

13.5 Evaluation of Scoring

For both initial and confirmatory test, the mean score calculated across 3 scoring times (approximately 24, 48 and 72 hours after test item instillation) for cornea, iris and conjunctival redness and conjunctival chemosis were 0, 0, 0 and 0.

14. CONCLUSION

Based on the results of the experiment and experimental conditions employed, it is concluded that the mean score of test item Bio-X Kleanze EC does not meet the classification criteria hence not classified or categorized according to Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

15. TABLES

TABLE 1. INDIVIDUAL ANIMAL CLINICAL SIGNS OF TOXICITY AND MORTALITY RECORD

Phase of the Experiment	Dose (mL/animal)	Animal No.	Sex	Clinical Signs of Toxicity and Mortality on Day						
				1		2		3		4
				#	*	#	*	#	*	#
Initial Test 80 dilutions	**0.1**	**Nb5973**	**M**	N	N	N	N	N	N	N
Confirmatory Test 80 dilutions	**0.1**	**Nb5974**	**M**	N	N	N	N	N	N	N
	0.1	**Nb5975**	**M**	N	N	N	N	N	N	N
Confirmatory Test 160 dilutions	**0.1**	**Nb5976**	**M**	N	N	N	N	N	N	N
	0.1	**Nb5977**	**M**	N	N	N	N	N	N	N

M: Male; N: Normal; #: First observation; *: Second observation

TABLE 2. INDIVIDUAL ANIMAL EYE IRRITATION/CORROSION SCORING RECORD

Sex: Male

Initial Test										**Dose: 0.1 mL/animal (80dilutions)**	
Animal No.	**Observation Period**	**Ocular Lesions**									
		Conjunctiva				**Iris**		**Cornea**			
		Redness		**Chemosis**				**Opacity**		**Area**	
	Eyes	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**
Nb5973	**1 hr**	0	0	0	0	0	0	0	0	-	-
	24 hrs	0	0	0	0	0	0	0	0	-	-
	48 hrs	0	0	0	0	0	0	0	0	-	-
	72 hrs	0	0	0	0	0	0	0	0	-	-
	Mean Tissue Score	0	0	0	0	0	0	0	0	-	-

Sex: Male

Confirmatory Test										**Dose: 0.1 mL/animal (80dilutions)**	
Animal No.	**Observation Period**	**Ocular Lesions**									
		Conjunctiva				**Iris**		**Cornea**			
		Redness		**Chemosis**				**Opacity**		**Area**	
	Eyes	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**
Nb5974	**1 hr**	0	0	0	0	0	0	0	0	-	-
	24 hrs	0	0	0	0	0	0	0	0	-	-
	48 hrs	0	0	0	0	0	0	0	0	-	-
	72 hrs	0	0	0	0	0	0	0	0	-	-
	Mean Tissue Score	0	0	0	0	0	0	0	0	-	-
Nb5975	**1 hr**	0	0	0	0	0	0	0	0	-	-
	24 hrs	0	0	0	0	0	0	0	0	-	-
	48 hrs	0	0	0	0	0	0	0	0	-	-
	72 hrs	0	0	0	0	0	0	0	0	-	-
	Mean Tissue Score	0	0	0	0	0	0	0	0	-	-

Sex: Male

Confirmatory Test										**Dose: 0.1 mL/animal (160dilutions)**	
		Ocular Lesions									
Animal No.	**Observation Period**	**Conjunctiva**				**Iris**		**Cornea**			
		Redness		**Chemosis**				**Opacity**		**Area**	
	Eyes	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**
Nb5976	**1 hr**	0	0	0	0	0	0	0	0	-	-
	24 hrs	0	0	0	0	0	0	0	0	-	-
	48 hrs	0	0	0	0	0	0	0	0	-	-
	72 hrs	0	0	0	0	0	0	0	0	-	-
	Mean Tissue Score	0	0	0	0	0	0	0	0	-	-
Nb5977	**1 hr**	0	0	0	0	0	0	0	0	-	-
	24 hrs	0	0	0	0	0	0	0	0	-	-
	48 hrs	0	0	0	0	0	0	0	0	-	-
	72 hrs	0	0	0	0	0	0	0	0	-	-
	Mean Tissue Score	0	0	0	0	0	0	0	0	-	-

hr: hour; hrs: hours; LE: Left Eye (Treated Eye); RE: Right Eye (Untreated control Eye)
Mean Tissue Score = (24 hr+48 hr+72 hr)/3

Redness: 0: Normal,

Chemosis: 0: Normal

Iris: 0: Normal

Opacity: 0: No ulceration or opacity

TABLE 3. INDIVIDUAL ANIMAL SLIT LAMP EXAMINATION RECORD

Sex: Male

Group & Dose	Initial Test Dose: 0.1 mL/animal (80 dilutions)		Confimatory Test Dose: 0.1 mL/animal (80 dilutions)				Confimatory Test Dose: 0.1 mL/animal (160 dilutions)			
Animal No.	**Nb5973**		**Nb5974**		**Nb5975**		**Nb5976**		**Nb5977**	
Day	**Day 2 (24 hours)**		**Day 2 (24 hours)**		**Day 2 (24 hours)**		**Day 2 (24 hours)**		**Day 2 (24 hours)**	
Eye	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**	**LE**	**RE**
Lids	N	N	N	N	N	N	N	N	N	N
Ducts	N	N	N	N	N	N	N	N	N	N
Cornea	N	N	N	N	N	N	N	N	N	N
Pupil	N	N	N	N	N	N	N	N	N	N
Sclera	N	N	N	N	N	N	N	N	N	N
Ciliary Bodies	N	N	N	N	N	N	N	N	N	N
Iris	N	N	N	N	N	N	N	N	N	N
Aqueous Humour	N	N	N	N	N	N	N	N	N	N
Lens	N	N	N	N	N	N	N	N	N	N
Vitreous Humour	N	N	N	N	N	N	N	N	N	N

LE: Left Eye; RE: Right Eye; N: Normal/No Abnormality Detected

TABLE 4. INDIVIDUAL ANIMAL BODY WEIGHT (kg) AND PERCENT CHANGE IN BODY WEIGHT WITH RESPECT TO DAY 1

Phase of the experiment	Dose (mL/animal)	Animal No.	Sex	Body weight (kg)		Percentage change in Body with respect to day
				1	4	1 to 4
Initial test (80 dilutions)	**0.1**	**Nb5973**	**Male**	2.05471	2.09482	1.95210
Confirmatory test (80 dilutions)	**0.1**	**Nb5974**	**Male**	2.22136	2.25571	1.54635
		Nb5975		2.30149	2.33802	1.58723
			Mean	**2.26143**	**2.29687**	**1.56679**
			±SD	**0.05666**	**0.05820**	**0.02891**
			n	**2**	**2**	**2**
Confirmatory test (160 dilutions)	**0.1**	**Nb5976**	**Male**	2.30144	2.34273	1.79409
		Nb5977		2.27197	2.30952	1.65275
			Mean	**2.28671**	**2.32613**	**1.72342**
			±SD	**0.02084**	**0.02348**	**0.09994**
			n	**2**	**2**	**2**

SD: Standard deviation; n: Number of animals

16. ANNEXURES

ANNEXURE 1. CERTIFICATE OF ANALYSIS OF BIO-X KLEANZE EC

OKADA ECOTECH PTE LTD (REG NO 199805584M)
24 Pioneer Crescent, #04-08, West Park Bizcentral, Singapore 628557
Tel: (65) 6872 3515 Fax: (65) 6872 6558
Website: www.okada-ecotech.com

CERTIFICATE OF ANALYSIS

Attention : **To whom it may concern**

Product Name : **Bio-X® Kleanze EC**

Batch Number : 2020061201

Date of Test : 1 December 2020

TEST	SPECIFICATIONS	RESULT
Appearance	Clear brown	OK
Odor	Pleasant	OK
Viscosity (cP) (BF DVII #1/100RPM/30Deg C)	20 ± 5 cps	20.0
Specific Gravity	0.95 ± 0.10	0.96
Dispersibility in Water	All proportion dispersible	OK

Tan Aik Zen
(Chemical Engineer)

ANNEXURE 2. CONTAMINANT ANALYSIS TEST REPORT OF FEED

Nr.: QA - 72
Aufbewahrungsdauer:
15 Jahre nach Erstellen

Altromin Spezialfutter GmbH & Co. KG
Im Seelenkamp 20
D-32791 Lage
Tel.: +49 (0)5232 / 6088-0
Fax: +49 (0)5232 / 6088-20
E-Mail: analysen@altromin.de

altromin

Producer Certificate

Description	Maintenance diet for rabbits - Rich in crude fibre
Type	2123
	4mm-pellets, 12.5 kg double plastic bags
Customer	ATNT Laboratories, India
Batch no. / Lot no.	202008241845
Order no.	Altromin Doc. No. 48867
Production date	24.08.2020
Expiry date	24.08.2021

Guaranteed nutritional values

% in air-dry substance	Value*	Tolerance**
Crude protein	13,7	12,0 – 15,4
Crude fat	3,0	2,0 – 5,0
Crude fibre	20,0	16,5 – 23,5
Crude ash	8,4	6,3 – 9,5
Moisture	11,4	< 12,5
NfE - Nitrogen free extracts	43,5	
Calcium	1,0	0,7 – 1,6
Phosphorus	0,5	0,2 – 0,8

* The producer guarantees that nutritional values of this batch are within the declared tolerance values.
** Tolerances according to Annex IV of Regulation (EU) Nr.767/2009.

Physical analysis

Pellet hardness kg/cm² - Kahl	12

Sensory evaluation

Olfactory	ok
Visual	ok

This product is compliant with the specifications and quality requirements of Altromin and therefore has been approved for delivery.

Accepted and released for use on 05/11/2020
05/11/2020

Date: September 21st 2020

Hans-Leopold Altrogge
QA-Manager

This is a computer printout and has therefore not been signed and dated by hand.

ANNEXURE 2 (Contd...). CONTAMINANT ANALYSIS TEST REPORT OF FEED

Nr.: QA - 72-1
Aufbewahrungsdauer:
15 Jahre nach Erstellen

Altromin Spezialfutter GmbH & Co. KG
Im Seelenkamp 20
D-32791 Lage
Tel.: +49 (0)5232 / 6088-0
Fax: +49 (0)5232 / 6088-20

altromin

Producer Certificate

Description	2123 Maintenance diet for rabbits
Customer	ATNT Laboratories, India
Batch no. / Lot no.	202008241845
Production date	24.08.2020
Expiry date	24.08.2021

Guaranteed diet status:

Aflatoxins	
Aflatoxin B1	< 2.5 µg/kg
Aflatoxin B2	< 0.6 µg/kg
Aflatoxin G1	< 2.5 µg/kg
Aflatoxin G2	< 0.6 µg/kg
Sum B1, B2, G1, G2	below detection limit
Heavy metals	
Lead (Pb)	< 1.00 mg/kg
Cadmium (Cd)	< 0.20 mg/kg
Mercury (Hg)	< 0.05 mg/kg
Arsenic (As)	< 1.00 mg/kg
Polychlorinated Biphenyls	
PCB	below detection limit
Pesticides and residuals	
Chlorpyriphos-methyl	< 0.100 mg/kg
2-Phenylphenol	< 0.100 mg/kg
Diphenylamin	< 0.050 mg/kg
Ethoxyquin	< 5.000 mg/kg
Folpet	< 1.000 mg/kg
Piperonylbutoxid	< 0.500 mg/kg
Pirimiphos-methyl	< 0.500 mg/kg
all screened substances not mentioned are usually below detection limit (see attached list)	
Microbiological status	
Total aerobic count	< 10^5 cfu/g
Yeasts	< 10^2 cfu/g
Moulds	< 10^2 cfu/g
E. coli	< 10^1 cfu/g
Salmonella in 25 g	not detectable

Accepted and released for use on 05/11/2020
05/11/2020
Hans-Leopold Altrogge
(Quality Manager)

Date: September 21st 2020

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ANNEXURE 3. CONTAMINANT ANALYSIS TEST REPORT OF WATER

IADFAC Laboratories Pvt. Ltd.

INSTITUTE FOR ANALYSIS OF DAIRY,FOOD & CULTURES.
#8, Siddhi Vinayaka Complex, Nagarabhavi 2nd Stage,2nd Block
Near BDA Complex, 80 Feet Ring Road, Bangalore-560 072
Ph:+91-80-2318 6906 to 10, Cell : +91 8152881444/8152881222
Mail: accounts@iadfac.com/bd@iadfac.com/qa@iadfac.com

CERTIFICATE OF ANALYSIS

BOOKING NO. : 0010
CERTIFICATE NO. : 0010/2020-2021

NAME OF MANUFACTURER/PARTY : BIONEEDS INDIA PRIVATE LIMITED
Devarahosahalli ,Sompura Hobali, Nelamangla Taluk,
Bangalore Rural Dist,
BANGALORE - 562111 KARNATAKA

1. MFG. LIC. NO.	: NM		
2. REFERENCE NO.	: NM	3. DATE	: 06/05/2020
4. DATE OF RECEIPT	: 06/05/2020	5. NAME OF SAMPLE	: Drinking Water (R O Water)

6. DETAILS OF RAW MATERIAL / FINAL PRODUCTS (In Bulk/Finished Pack)

(A) MANUFACTURER NAME	: NM	(B) BATCH NO.	: NM
(C) BATCH SIZE	: NM	(D) DATE OF MFG.	: NM
(E) SAMPLE QUANTITY	: 5Lx1 Can	(F) DATE OF EXPIRY	: NM
(G) PACKING	: Plastic Bottle	(H) STARTING DATE	: 08/05/2020
(I) SEALED	: Sealed	(J) ENDING DATE :	: 19/05/2020
(K) BRAND NAME	: NM	(L) SAMPLING PROTOCOL	: NA
(M) DATE OF SAMPLING /SAMPLE COLLECTION	: 06/05/2020	(N) REPORT GEN. DATE	: 19/05/2020

Specification as per IS 10500:2012

SR	TEST NAME	UNIT	RESULT	ACCEPTABLE LIMIT	PERMISSIBLE LIMIT	METHOD OF TEST
1	CHEMICAL TESTING Water, Residues in Water					
1	Colour	CU	<1	5 Max	15 Max	IS 3025 (Part-4) : 1983
2	Odour	-	Agreeable	Agreeable	Agreeable	IS 3025 (Part-5) : 2018
3	pH Value	-	6.6	6.5-8.5	No Relaxation	IS 3025 (Part-11) : 1983
4	Taste	-	Agreeable	Agreeable	Agreeable	IS 3025 (Part-7&Part-8) : 2017
5	Turbidity (as NTU)	-	<1	1 Max	5 Max	IS 3025 (Part-10) : 1984
6	Total Dissolved Solids	mg/l	23	500 Max	2000 Max	IS 3025 (Part-16) : 1984
7	Aluminium (as Al)	mg/l	<0.02	0.03 Max	0.2 Max	IS 3025 (Part-55) : 2003
8	Boron (as B)	mg/l	<0.1	0.5 Max	2.4 Max	IS 3025 (Part-57) : 2005
9	Calcium (as Ca)	mg/l	1	75 Max	200 Max	IS 3025 (Part-40) : 1991
10	Chloride (as Cl)	mg/l	2	250 Max	1000 Max	IS 3025 (Part-32) : 1988
11	Copper (as Cu)	mg/l	<0.05	0.05 Max	1.5 Max	IS 3025 (Part-42) : 1992
12	Fluoride (as F)	mg/l	<0.1	1.0 Max	1.5 Max	IS 3025 (Part-60) : 2013
13	Free residual Chlorine	mg/l	<0.1	0.2 Min	1.0 Max	IS 3025 (Part-26) : 1986
14	Iron (as Fe)	mg/l	<0.05	1.0 Max	No Relaxation	IS 3025 (Part-53) : 2003
15	Magnesium (as Mg)	mg/l	<1	30 Max	100 Max	IS 3025 (Part-46) : 1994
16	Manganese (as Mn)	mg/l	<0.1	0.1 Max	0.3 Max	IS 3025 (Part-59) : 2006

Remarks : Accepted and released for use 21/05/2020

For IADFAC Laboratories Pvt. Ltd.
Karun
Authorised Signatory
Karunakara A.C. (ID No-132)
Senior Manager-Chemical

CONTD. ON NEXT PAGE.....

AUTHORISED SIGNATORY

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4. Sample drawn and submitted by the party for Analysis unless otherwise stated.
5. Analysed Food samples are destroyed within one month. Analysed Packaged Drinking Water samples destroyed after 3 months.

ANNEXURE 3 (Contd...). CONTAMINANT ANALYSIS TEST REPORT OF WATER

IADFAC Laboratories Pvt. Ltd.

INSTITUTE FOR ANALYSIS OF DAIRY,FOOD & CULTURES.
#8, Siddhi Vinayaka Complex, Nagarabhavi 2nd Stage,2nd Block
Near BDA Complex, 80 Feet Ring Road, Bangalore-560 072
Ph:+91-80-2318 6906 to 10, Cell : +91 8152881444/8152881222
Mail: accounts@iadfac.com/bd@iadfac.com/qa@iadfac.com

CERTIFICATE OF ANALYSIS

BOOKING NO. : 0010
CERTIFICATE NO. : 0010/2020-2021

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Bangalore Rural Dist,
BANGALORE - 562111 KARNATAKA

1. MFG. LIC. NO.	: NM		
2. REFERENCE NO.	: NM	3. DATE	: 06/05/2020
4. DATE OF RECEIPT	: 06/05/2020	5. NAME OF SAMPLE	: Drinking Water (R O Water)

6. DETAILS OF RAW MATERIAL / FINAL PRODUCTS (In Bulk/Finished Pack)

(A) MANUFACTURER NAME	: NM	(B) BATCH NO.	: NM
(C) BATCH SIZE	: NM	(D) DATE OF MFG.	: NM
(E) SAMPLE QUANTITY	: 5Lx1 Can	(F) DATE OF EXPIRY	: NM
(G) PACKING	: Plastic Bottle	(H) STARTING DATE	: 08/05/2020
(I) SEALED	: Sealed	(J) ENDING DATE :	: 19/05/2020
(K) BRAND NAME	: NM	(L) SAMPLING PROTOCOL	: NA
(M) DATE OF SAMPLING /SAMPLE COLLECTION	: 06/05/2020	(N) REPORT GEN. DATE	: 19/05/2020

Specification as per IS 10500:2012

SR	TEST NAME	UNIT	RESULT	ACCEPTABLE LIMIT	PERMISSIBLE LIMIT	METHOD OF TEST
17	Nitrate (as NO3)	mg/l	1.16	45 Max	No Relaxation	IS 3025 (Part-34) : 1988
18	Selenium (as Se)	mg/l	<0.01	0.01 Max	No Relaxation	IS 3025 (Part-56) : 2003
19	Sulphate (as SO4)	mg/l	<1	200 Max	400 Max	IS 3025 (Part-24) : 1986
20	Total Alkalinity as calcium carbonate	mg/l	8.0	200 Max	600 Max	IS 3025 (Part-23) : 1986
21	Total Hardness (as CaCO3)	mg/l	4	200 Max	600 Max	IS 3025 (Part-21) : 2009
22	Cadmium (as Cd)	mg/l	<0.003	0.003 Max	No Relaxation	IS 3025 (Part-41) : 1992
23	Lead (as Pb)	mg/l	<0.01	0.01 Max	No Relaxation	IS 3025 (Part-47) : 1994
24	Mercury (as Hg)	mg/l	<0.001	0.001 Max	No Relaxation	IS 3025 (Part-48) : 1994
25	Total Arsenic (as As)	mg/l	<0.01	0.01 Max	No Relaxation	IS 3025 (Part-37) : 1988
26	Total Chromium (as Cr)	mg/l	<0.05	0.05 Max	No Relaxation	Annexure- J of IS 13428 : 2005
	Pesticide residues					
1	Endosulfan					
a	Alpha Endosulfan	µg/l	<0.01	0.4 Max	No Relaxation	FSSAI Manual of water 2016
b	Beta Endosulfan	µg/l	<0.01	0.4 Max	No Relaxation	FSSAI Manual of water 2016
c	Endosulfan sulphate	µg/l	<0.01	0.4 Max	No Relaxation	FSSAI Manual of water 2016
2	Ethion	µg/l	<0.01	3 Max	No Relaxation	FSSAI Manual of water 2016

Remarks : Accepted and released for use 21/05/2020

For IADFAC Laboratories Pvt. Ltd.
Authorised Signatory
Karunakara A.C. (ID No-132)
Senior Manager-Chemical

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ANNEXURE 3 (Contd...). CONTAMINANT ANALYSIS TEST REPORT OF WATER

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IADFAC Laboratories Pvt. Ltd.

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1. MFG. LIC. NO.	: NM		
2. REFERENCE NO.	: NM	3. DATE	: 06/05/2020
4. DATE OF RECEIPT	: 06/05/2020	5. NAME OF SAMPLE	: Drinking Water (R O Water)

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(C) BATCH SIZE	: NM	(D) DATE OF MFG.	: NM
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(K) BRAND NAME	: NM	(L) SAMPLING PROTOCOL	: NA
(M) DATE OF SAMPLING /SAMPLE COLLECTION	: 06/05/2020	(N) REPORT GEN. DATE	: 19/05/2020

Specification as per IS 10500:2012

SR	TEST NAME	UNIT	RESULT	ACCEPTABLE LIMIT	PERMISSIBLE LIMIT	METHOD OF TEST
3	Monocrotophos	µg/l	<0.01	1 Max	No Relaxation	FSSAI Manual of water 2016
--	--	--	-- End of Report --	--	--	--

Remarks :
Accepted & released for use. 21/05/2020

For IADFAC Laboratories Pvt. Ltd.
Authorised Signatory
Karunakara A.C. (ID No-132)
Senior Manager-Chemical

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Page 3 of 3

ANNEXURE 4. GLOBALLY HARMONIZED SYSTEM OF CLASSIFICATION AND LABELLING OF CHEMICALS (GHS)

Eye Irritation/Corrosion Category

Categories	Criteria
Category 1: (Irreversible effects on eye/serious damage to eyes)	a. At least in one animal effects on the cornea, iris or conjunctiva that are not expected to reverse or have not fully reversed within an observation period of normally 21 Days and/or b. At least in 2 of 3 tested animals a positive response i. Corneal opacity ≥ 3 and/or ii. Iritis > 1.5 Calculation shall be the mean scores of following grading at 24, 48 and 72 hours after installation of the test item.
Category2/2A	Test item that have the potential to induce reversible eye irritation
	a. At least in 2 of 3 tested animals a positive response: i. Corneal opacity ≥ 1 and/or ii. Iritis ≥ 1, and/or iii. Conjunctival redness≥ 2; and/or iv. Conjunctival oedema (chemosis) ≥ 2 Calculated as the mean scores following grading at 24, 48 and 72 hours after installation of the test item and which fully reverses within an observation period of normally 21 Days.
Category 2B	Within Category 2A an eye irritating is considered mildly irritating to eyes (Category 2B) when the effects listed above are fully reversible within 7 days of observation.

ANNEXURE 5. GLP CERTIFICATE

सत्यमेव जयते

National Good Laboratory Practice (GLP) Compliance Monitoring Authority (NGCMA)
Department of Science and Technology
GOVERNMENT OF INDIA

Certificate of GLP Compliance

This is to certify that

Bioneeds India Private Limited
Devarahosahally, Sompura Hobli, Nelamangala Taluk
Bengaluru Rural District - 562111, Karnataka (India)

is a GLP certified test facility in compliance with the NGCMA's Document No. GLP-101 "Terms & Conditions of NGCMA for obtaining and maintaining GLP certification by a test facility" and OECD Principles of GLP.

The test facility conducts the below-mentioned tests/ studies:

- **Physical-chemical Testing (Including Five Batch Analysis)**
- **Toxicity Studies**
- **Mutagenicity Studies**
- **Environmental Toxicity Studies on Aquatic and Terrestrial Organisms**
- **Studies on Behaviour in Water, Soil and Air; Bioaccumulation**
- **Residue Studies**
- **Analytical and Clinical Chemistry Testing**
- **Others**

The specific areas of expertise, test items and test systems are listed in the annexure overleaf.

Validity: September 23, 2020 – September 22, 2023

Certificate No. : GLP/C-153/2020
Issue Date : 13-10-2020

[redacted]

भारत सरकार ★ Govt. of India
राष्ट्रीय जी एल पी अनुपालन निगरानी प्राधिकरण
National GLP Compliance Monitoring Authority
विज्ञान और प्रौद्योगिकी विभाग ★ Dept. of Science and Technology

(Dr. Neeraj Sharma)
Head, NGCMA

ANNEXURE 5 (Contd...). GLP CERTIFICATE

National GLP Compliance Monitoring Authority (NGCMA)

Annexure to Certificate of GLP Compliance No. GLP/C-153/2020

Areas of Expertise:

- **Physical-chemical Testing (Including Five Batch Analysis)**
- **Toxicity Studies**
  - Acute Toxicity
  - Developmental and Reproductive Toxicity
  - Eye Irritation/ Corrosion (*in vitro* and *in vivo*)
  - Guinea Pig Maximization
  - Immunogenicity
  - Inhalation Toxicity
  - Local Lymph Node Assay (LLNA)
  - Local Tolerance
  - Neurotoxicity
  - Phototoxicity
  - Pyrogen Test
  - Repeated Dose Toxicity
  - Skin Irritation/ Corrosion (*in vitro* and *in vivo*)
  - Skin Sensitization (*in vitro* and *in vivo*)
- **Mutagenicity Studies**
  - 3T3 NRU Assay (*in vitro*)
  - Bacterial Reverse Mutation (AMES) Test
  - Cell Gene Mutation Test (*in vitro and in vivo*)
  - Chromosomal Aberration Test (*in vitro* and *in vivo*)
  - Comet Assay
  - Cytotoxicity (*in vitro*)
  - Micronucleus Test (*in vitro* and *in vivo*)
  - Mouse Lymphoma Assay (MLA)
  - MTT Assay
- **Environmental Toxicity Studies on Aquatic and Terrestrial Organisms**
- **Studies on Behaviour in Water, Soil and Air; bioaccumulation**
- **Residue Studies**
- **Analytical and Clinical Chemistry Testing**
- **Others**
  - ADME Studies
  - Bioanalysis
  - Biocompatibility Studies
  - Drug Metabolism & Pharmacokinetic (DMPK)
  - Hemocompatibility Studies
  - Implantation Studies
  - In chemico Skin Sensitization: Direct Peptide Reactivity Assay
  - Maximum Tolerated Dose (MTD) Studies
  - Method Development
  - Method Validation
  - Skin Absorption (*in vitro*)

Test Item(s): Agrochemicals, Cosmetics Products, Feed Additives, Food Additives, Industrial chemicals, Medical Devices (*Applicable only for Bio-compatibility, not applicable for Batch Release parameters required as per MDR, 2017*) and Pharmaceuticals (Human and Veterinary)

Test System(s): Algae, Bovine, Cell lines, Chicken, Collembolan, Crop plant seeds, Cyanobacteria, Daphnia, Diatoms, Earthworm, *E-Coli*, Fish, Guinea Pigs, Hamsters, Honeybees, Human Cavader Skin, Human Lymphocytes, Japanese quail, Lemna, Mallard duck, Mice, Pigeon, Predatory Mites, Rabbit, Rat, *Salmonella typhimurium*, Silkworm and Tissue Culture.

भारत सरकार ★ Govt. of India
राष्ट्रीय जी एल पी अनुपालन निगरानी प्राधिकरण
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(Dr. Neeraj Sharma)
Head, NGCMA