Nelson Labs
A Sotera Health company

Sponsor:
Daniel Membreno
Infinita Lab Inc.
Balentine Dr. Suite 200
Newark, CA 94560

Acute Systemic Toxicity Test in Swiss Albino Mice - ISO

Test Article:	Cured coating Panels
Purchase Order:	ZB-PO-6839
Study Number:	1570810-S01
Study Received Date:	05 Dec 2022
Testing Facility:	GV Research Platform c/o Palamur BioSciences
Deviations:	None

Summary: Enclosed is the final report for the testing we coordinated for you. The information is retained by the testing laboratory.

If you have any questions, please feel free to call or email any of our Subcontracting personnel at 801-290-7500 or biocompservice@nelsonlabs.com. Thank you for testing with Nelson Laboratories, LLC.

Tanner Welch electronically approved	08 Feb 2023 20:55 (+00:00)
Reviewed By Tanner Welch	Study Completion Date and Time

STUDY REPORT

STUDY NUMBER

23111

STUDY TITLE

Acute Systemic Toxicity Test with Cured coating Panels in Swiss albino mice

TEST GUIDELINE

ISO 10993-11:2017

ISO 10993-12:2021

SPONSOR

NELSON LABORATORIES

6280 S. Redwood Road,

Salt Lake City, UT 84123, USA.

CRO

GV RESEARCH PLATFORM PVT LTD.,

Sy. No. 403/1 (Old), 120 (New), 4th Floor, Niharika Jubilee One,

Road No.1, Jubilee Hills, Hyderabad – 500033, Telangana State, India.

TEST FACILITY

PALAMUR BIOSCIENCES PRIVATE LIMITED

SH-20, Karvina, Madigattla Village,
Bhoothpur Mandal, Mahabubnagar– 509 382,
Telangana (India).

Study Director: Mr. Adapa Satish Kumar, M.Pharm.

Study Completion Date: 07.02.2023

STUDY DIRECTOR'S STATEMENT

Study Number : 23111

Study Title : Acute Systemic Toxicity Test with Cured coating Panels in Swiss albino mice.

I hereby declare that this study was performed in accordance with mutually agreed and approved study plan that was constructed based on the Standard Operating Procedures of Palamur Biosciences Private Limited (Test Facility). Palamur Biosciences Private Limited complies with various national/international quality systems such as OECD GLP, AAALAC, CDSCO, NABL/ISO-17025.

The report is a complete, true and accurate representation of the study, it reflects the raw data generated during the study period, as mentioned in the approved Study Plan.

As a Study Director, I accept overall responsibility for the technical conduct of the study as well as the documentation, analysis, interpretation and reporting of the results and validity of the data.

All the documents pertaining to the study, including the raw data, original study plan and final report have been retained at the archives of the test facility.

Study Director : **Mr. Adapa Satish Kumar, M.Pharm.**

Signature :

Date : 07-02-2023

Palamur Biosciences Private Limited,
SH-20, Karvina, Madigattla Village,
Bhoothpur Mandal, Mahabubnagar – 509 382,
Telangana (India).

CERTIFICATE OF AFFIRMATION

Study Number : 23111

Study Title : Acute Systemic Toxicity Test with Cured coating Panels in Swiss albino mice.

This is to certify that the test facility management has provided sufficient number of qualified personnel, appropriate facilities, equipment and materials in timely manner and proper conduct of this study in accordance with mutually agreed study plan.

Test Facility Management : **Dr. S. Ramamoorthy, Ph.D., F.A.Sc.**

Signature :

Date : 07.02.2023

Palamur Biosciences Private Limited

CONTENTS

ABBREVIATIONS

^{0}C	:	Degree Celsius
%	:	Percentage
b.w.	:	Body Weight
cm	:	Centimetre
cm^2	:	Centimetres Square
CPCSEA	:	Committee for the Purpose of Control and Supervision of Experiments on Animals
CCSEA	:	Committee for Control and Supervision of Experiments on Animals
g	:	Gram(s)
GLP	:	Good laboratory Practice
hr	:	Hour(s)
IAEC	:	Institutional Animal Ethics Committee
ISO	:	International Organization for Standardization
Kg	:	Kilogram(s)
mg	:	Milligram(s)
min	:	Minute(s)
mL	:	Millilitre(s)
mm	:	Millimetre(s)
No.	:	Number
OECD	:	Organization for Economic Co-operation and Development
PBS	:	Palamur Biosciences Private Limited
QAU	:	Quality Assurance Unit
RO	:	Reverse Osmosis
SOP	:	Standard Operating Procedure
SR	:	Study Report
TFM	:	Test Facility Management
TIDS	:	Test Item Data Sheet

ACUTE SYSTEMIC TOXICITY TEST WITH CURED COATING PANELS IN SWISS ALBINO MICE

SUMMARY AND CONCLUSION

Acute systemic toxicity test with Cured coating Panels in Swiss albino mice sponsored by **Nelson Laboratories**, was tested in 20 mice at Palamur Biosciences Private Limited. The acute systemic toxicity test was performed as per ISO 10993-11:2017- Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity Tests for Irritation, ISO 10993-12:2021 - Biological Evaluation of Medical Devices - Part 12: Sample preparation and reference materials, in compliance with mutually agreed study plan.

The test item was extracted in the ratio of 6 cm^2/mL at 51°C for 71 hrs 55 min. with physiological saline (polar extract) and sesame oil (non-polar extract), separately. Both, polar and non-polar controls (without test item) were also exposed to similar conditions.

The test was performed with 4 groups each group containing 5 animals. The prepared polar and non-polar extracts of test & control item were administered to animals via intravenous (IV) and intraperitoneal (IP) routes, respectively. The animals were observed till day 3 (for 72 hrs) for any systemic effects and clinical signs.

All animals were found normal and no signs of clinical toxicity were observed throughout the experiment. All the animals used in this study gained body weight when compared to its respective day 0 (First day dosing).

All the animals were euthanized after 72 hours observation period and no gross necropsy was performed as there was no mortality and toxic clinical signs during the experimental period.

Conclusion

Based on the results obtained, it is concluded that the given test item, Cured coating Panels meets the Acute systemic toxicity requirement of ISO 10993-11:2017 and is classified as **"Non-toxic"** to the mice under the conditions of present study.

1. STUDY OBJECTIVE

The purpose of this acute systemic toxicity test was to identify the systemic toxicity potential of the extracts of Cured coating Panels when administered to Swiss albino mice.

2. STUDY COMPLAINCE

- This study was conducted as per the mutually agreed study plan and the Standard Operating Procedures of Palamur Biosciences Private Limited.

3. TEST GUIDELINES

- Biological Evaluation of Medical Devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017).
- Biological Evaluation of Medical Devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021).

4. STUDY SCHEDULE

Study Initiation Date	:	10.01.2023
Experiment Start Date	:	28.01.2023
Acclimatization Start Date	:	28.01.2023
Administration of Extracts	:	03.02.2023
Necropsy	:	06.02.2023
Experiment Completion Date	:	06.02.2023
Study Completion Date	:	07.02.2023

5. LIST OF STUDY PERSONNELS (RESPONSIBILITIES)

Personnel	Name
Study Director	Mr. Adapa Satish Kumar
Study Personnel	Mr. A. Sri Rama Charyulu, M.Sc. Ms. P. Priyanka, B.Sc. Mr. A. Levin Astley, M.Sc. Ms. Rajitha, B.Sc., MLT.
Study Pathologist	Dr. P. V. Sai Charitha, M.V. Sc.

6. MATERIALS AND METHODS

6.1 Test item details

Date of receipt at test facility: 10 January 2023

The following information was provided by the Sponsor. A copy of the TIDS was attached as an **APPENDIX-1.**

Name of the test item	:	Cured coating Panels
Physical appearance	:	Black rectangles
Lot No.	:	NA
Intended use	:	NA
Storage condition	:	Ambient (18 to 28°C)
Sterility	:	Non-Sterile
Sponsor's study code	:	1570810
Contact duration	:	Limited (≤ 24 hr)
Surface area	:	231.04 cm^2
Extraction Ratio	:	6 cm^2/mL
Extraction condition	:	50±2°C and 72±2 hrs
Date of Expiry	:	NA
Supplied by	:	Nelson Laboratories 6280 S. Redwood Road, Salt Lake City, UT 84123 USA

Safety of handling: Protective gloves, face mask, aprons/ protective suit and goggles were used to ensure the health and safety of the personnel.

Test item identity and stability: The identity and stability of the test item is the responsibility of the sponsor. No analysis was performed to confirm at Palamur Biosciences Private Limited.

6.2 Solvent details

Polar Solvent

Name of the Solvent	:	Sodium chloride injection IP 0.9% w/v (Normal Saline)
Batch No.	:	2H21087
Appearance	:	Clear colourless solution

Manufacturing date	:	Aug 2022
Expiry date	:	Jul 2025

Non-Polar Solvent

Name of the Solvent	:	Sesame oil
Batch No.	:	372322
Appearance	:	Clear Yellow colour Liquid
Packed date	:	05.2022
Expiry date	:	05.2025

Note: Physical appearance of the solvents before extraction were considered as normal.

7. TEST SYSTEM

7.1 Justification for the selection of test system

Mice were chosen as the test system because this species is commonly used for systemic toxicity testing and it meets the regulatory requirement of most of the regulatory agencies.

7.2 Test system details

Species	:	*Mus musculus* (Mouse)
Strain	:	Swiss albino
Source	:	Palamur Biosciences Private Limited, Mahabubnagar, Telangana, India.
Body weight at the time of dosing	:	17.33-20.98 g
Sex	:	Female (Nulliparous and non-pregnant)
Number of groups	:	4 (G1, G2, G3 & G4)
Number of animals	:	20
		Polar control extract (G1) - 5
		Polar test item extract (G2) - 5
		Non-polar control extract (G3) - 5

Non-polar test item extract (G4) - 5

Acclimatization : Prior to acclimatization, a physical health examination was performed on all animals by the veterinarian. Healthy animals were acclimatized to the experimental room for 6 days.

7.3 Housing

Location : Rodent experiment facility, Block-A, Room No. – 02.

Temperature : 19.24– 22.9°C

Relative Humidity : 45 - 61%

Photo period : 12 hours light and 12 hours dark

Room air exchanges : Minimum 12-15 air exchanges per hour

Caging : Animals were housed in group of 5 animals per cage in polypropylene mice cages (approximately internal dimensions of 225 mm x 160 mm x 130 mm) with corn cob bedding.

Method of identification : All the animal cages were identified by cage cards and followed by corresponding individual animal numbers marked with marker pen on the base of the tail.

Diet and water : Rodent pellet diet manufactured by Krishna Valley Agro LLP. The source of the water was borewell water which was purified with RO water plant present at the premises. Both drinking water and feed were provided *ad libitum*.

Note: The feed and water were routinely analyzed and are considered not to contain any contaminants that could reasonably be expected to affect the purpose or integrity of the study. Feed and water analysis reports were included in the raw data file.

7.4 Randomization

4 Mice were taken extra for randomization. Microsoft Excel program was used for randomization and animals were used within ± 20% of the mean body weight for group. Randomization was performed before the day of dosing.

8. ANIMAL WELFARE

The test facility is certified by the Committee for Control and Supervision of Experiment on Animals (CCSEA) for breeding and experimentation. Certification No.: 1312/PO/RcBiBt-S/RcBiBt-L/09/CPCSEA.

9. IAEC APPROVALS

This study has been approved by the Institutional Animals Ethics Committee (IAEC) of the Palamur Biosciences Private Limited, Proposal No. PAL/IAEC/2023/01/01/20 under the project title "Acute systemic toxicity test with Cured coating Panels in mice" dated on 05.01.2023. All the procedures were followed as per the guidelines of CCSEA, India. An authorized photocopy of IAEC approval was maintained in the study raw data file.

10. EXPERIMENTAL PROCEDURES

10.1 Route of Administration and Justification for Selection

Polar Control and test item extracts were administered intravenously and Non polar Control and test item extracts were administered intraperitoneal as per the ISO 10993 Part 11:2017 standard specifications.

10.2 Dose Selection and Justification for Selection

As suggested in the guideline ISO 10993, Part 11:2017, the undiluted extracts were used for the testing at a dose volume of 50ml/kg in both IV and IP routes.

10.3 Preparation of test and control extracts

As per the TIDS provided by the sponsor, absorption check was not performed.

The test item was extracted in the ratio 6cm^2/mL at 51°C for 71 hrs 55 min. with polar (physiological saline) and non-polar solvents (sesame oil), separately.

Both, polar and non-polar controls were also kept under similar conditions. After extraction, the test item(s) were removed from the respective extracts. No colour change and no particulates were observed in both the polar and non- polar control extracts,

whereas polar test item extracts was changed to Orange- brown coloured particulate suspension and non-polar extract was changed to dark yellow coloured suspension. Both extracts were found normal. Representative images were attached as an **Appendix 2**

The pH of the control & test item extracts was found to be approximately, 6.0 for polar and 5.0 for non-polar test extracts which is between pH 2.0 and pH 11.5. No centrifugation and filtration were performed and the extracts were administered without dilution to the test system.

Name of the Extraction	Surface area of the test item (cm^2)	Volume of solvent added (mL)	Physical appearance		Volume of Extract (mL)	pH of the extract
			Before extraction	After extraction		
Polar control extraction	-	10	Normal	No colour change	10	7
Non-polar control extraction	-	10	Normal	No colour change	10	6
Polar test item extraction	231.04	38.5 = 39 mL	Normal	Orange-brown coloured particulate suspension	38	6
Non-polar test item extraction	231.04	38.5 = 39 mL	Normal	Dark yellow coloured suspension	38	5

Note: g-gram, mL- millilitre.

10.4 Administration of test and control extracts

Animals were restrained and the polar extracts were given for G1 (polar control item extract) and G2 (polar test item extract) intravenously (IV) at 50 mL/kg body weight. Whereas non-polar extracts were given for G3 (non-polar control item extract) and G4 (non-polar test item extract) intraperitoneally (IP) at 50 mL/kg body weight (**refer Table-22.5**).

11. OBSERVATIONS

11.1 Mortality / Viability

All animals were examined individually twice daily for mortality during acclimatization and experimental period.

11.2 Clinical observations

All the animals were examined individually once daily for any clinical signs of toxicity. The clinical signs were observed and recorded at 30 min, 4, 24, 48 and 72 hr after the administration of extracts.

11.3 Body weight

Individual body weight of the animals was recorded at the start of acclimatization, Day 0 (prior to the administration of extracts), Day 1, Day 2, and Day 3.

12. RESULTS

12.1 Mortality

No mortality, no morbidity was observed in any of the animals used in this experiment (**refer Table-22.1**).

12.2 Clinical observations

All animals were normal and no signs of clinical toxicity were observed in any of the animals used in this experiment (**refer Table-22.2**).

12.3 Body weights

All animals showed increase in body weight when compared with day 0 body weights (**refer Table-22.3 & Table-22.4**).

13. PATHOLOGY

13.1 Euthanasia

All animals were humanely sacrificed by carbon dioxide asphyxiation at termination and discarded.

13.2 Necropsy

Macroscopic/ gross pathological examination was not performed after 72 hr observation period as there is no mortality and toxic clinical signs during the experimental period (**refer Table-22.6**).

14. CLASSIFICATION CRITERIA

- As none of the animals treated with the test extract shows a significantly greater biological reactivity than animals treated with the vehicle control during the observation period. So the test item meets the requirements of this test.
- As there was no mortality, toxic clinic signs and decreased body weight of the animals observed - the test item meet the requirements of the test.

15. CONCLUSION

Based on the above results obtained, it is concluded that the polar and non-polar extracts of the test item, Cured coating Panels meets the requirement of ISO 10993-11:2017 and is classified as "**Non-toxic"** when administered to mice as per the experimental conditions.

16. ARCHIVES

Raw data and other documents arising out of this study will be stored in the archives of Palamur Biosciences Private Limited, SH-20, Karvina, Madigattla Village, Bhoothpur Mandal, Mahabubnagar – 509382, Telangana (India), for up to nine years after completion of the study work. No later than nine years after completion of the study, instructions for returning or disposing of the archives will be requested from the sponsor. Implementation of such instructions may be at charge to the sponsor.

The archived materials will include the following documents:

- Study plan (Original 1 of 2)
- All relevant correspondence concerned with the study.
- Raw data
- Study report (Original 1 of 2)

17. STUDY PLAN AMENDMENTS

No study plan amendment was raised during the Study period.

18. DEVIATIONS

No SOP and Study plan deviations were observed during the study.

19. REFERENCES

- Compendium of CCSEA 2018: Guidelines for Laboratory Animal Facility 2015: 7;

pg- 61-96.

- Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process (ISO 10993-1:2018).
- Biological Evaluation of Medical Devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2021).
- Biological Evaluation of Medical Devices - Part 2: Animal welfare requirements (ISO 10993-2:2006).
- Biological Evaluation of Medical Devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017).

20. SPONSOR REPRESENTATIVE (Monitoring Scientist)

Sponsor's Representative: Tanner Welch

Monitoring Scientist: Chad Summers,

Nelson Laboratories,

6280 S. Redwood Road, Salt Lake City, UT 84123 USA.

21. CONFIDENTIAL

Information, data embodied in this study report are strictly confidential and are issued on the understanding that they will be held confidentially and not disclosed to third parties without the prior consent of the Sponsor.

22. TABLES

22.1 Mortality

Animal Number		1 to 24	01 to 20
Sex		**Female**	**Female**
Day of Observations*	Mortality	Incidences	Incidences
Acclimatization Phase (Day 1-6)	Mortality	0/24	-
Treatment / Experiment Phase (Day 0-3)	Mortality	-	0/20

*Mortality was observed twice daily.

22.2 Clinical signs

Animal Number		1 to 24	01 to 20
Sex		**Female**	**Female**
Day of Observations*	Clinical Signs	Incidences	Incidences
Acclimatization Phase (Day 1-6)	Normal	24/24	-
Treatment / Experiment Phase (Day 0-3)	Normal	-	20/20

*Clinical signs were observed once daily.

22.3 Individual body weight (g)

Acclimatization		Treatment					
A.No.	Day 1	A.No.	Group / Sex	Day 0*	Day 1	Day 2	Day 3
1	19.44	01	G1/ Female	19.98	20.02	20.11	20.23
2	18.65	02		19.56	19.65	19.72	19.85
3	19.21	03		17.33	17.41	17.51	17.62
4	19.35	04		19.66	19.78	19.83	19.91
5	20.57	05		17.85	17.92	17.99	18.06
6	18.41	06	G2 / Female	18.62	18.73	18.84	18.95
7	17.60	07		20.53	20.60	20.68	20.76
8	18.72	08		18.90	18.97	19.04	19.18
9	17.54	09		20.93	21.01	21.07	21.18
10	20.27	10		18.67	18.73	18.83	18.95
11	17.39	11	G3 / Female	20.51	20.60	20.67	20.74
12	18.30	12		20.19	20.26	20.35	20.48
13	20.73	13		18.42	18.51	18.59	18.72
14	18.56	14		20.98	21.05	21.12	21.29
15	19.75	15		20.79	20.86	20.91	21.03
16	19.12	16	G4 / Female	19.48	19.55	19.63	19.75
17	18.61	17		18.86	18.92	19.00	19.13
18	17.21	18		17.89	17.94	18.01	18.12
19	18.18	19		18.89	18.96	19.05	19.16
20	20.36	20		19.38	19.45	19.56	19.67
21	18.19						
22	17.17						
23	20.67						
24	20.79						

Note: A. No.- Animal number; g- Grams; *- Prior to dosing.

22.4 Individual %body weight change

% Body weight change				
Treatment				
A.No.	**Group / Sex**	**Day 0 – Day 1**	**Day 0 – Day 2**	**Day 0 - Day 3**
01	G1/ Female	0.20	0.65	1.25
02		0.46	0.82	1.48
03		0.46	1.04	1.67
04		0.61	0.86	1.27
05		0.39	0.78	1.18
06	G2 / Female	0.59	1.18	1.77
07		0.34	0.73	1.12
08		0.37	0.74	1.48
09		0.38	0.67	1.19
10		0.32	0.86	1.50
11	G3 / Female	0.44	0.78	1.12
12		0.35	0.79	1.44
13		0.49	0.92	1.63
14		0.33	0.67	1.48
15		0.34	0.58	1.15
16	G4 / Female	0.36	0.77	1.39
17		0.32	0.74	1.43
18		0.28	0.67	1.29
19		0.37	0.85	1.43
20		0.36	0.93	1.50

Note: A.No.- Animal number; %- Percent.

22.5 Administration details

Group No.	Extract	A.No.	Body weight (g)	Sex	Dose & Route	Volume administered (mL)
G1	Polar control item extract	01	19.98	Female	50 mL/kg b.w. & IV	1.0
		02	19.56			1.0
		03	17.33			0.9
		04	19.66			1.0
		05	17.85			0.9
G2	Polar test item extract	06	18.62	Female	50 mL/kg b.w.& IV	0.9
		07	20.53			1.0
		08	18.90			0.9
		09	20.93			1.0
		10	18.67			0.9
G3	Non-polar control item extract	11	20.51	Female	50 mL/kg b.w. & IP	1.0
		12	20.19			1.0
		13	18.42			0.9
		14	20.98			1.0
		15	20.79			1.0
G4	Non-polar test item extract	16	19.48	Female	50 mL/kg b.w. & IP	1.0
		17	18.86			0.9
		18	17.89			0.9
		19	18.89			0.9
		20	19.38			1.0

Note: A.No.- Animal number; g- Gram; mL- Millilitres; kg- Kilogram; b.w.- body weight; IV- Intravenous; IP- Intraperitoneal.

22.6 Necropsy findings

Animal Number	Sex	Mode of Death	Macroscopic/Gross pathological observation	
			External	Internal
01	F	TS	NA	NA
02	F	TS	NA	NA
03	F	TS	NA	NA
04	F	TS	NA	NA
05	F	TS	NA	NA
06	F	TS	NA	NA
07	F	TS	NA	NA
08	F	TS	NA	NA
09	F	TS	NA	NA
10	F	TS	NA	NA
11	F	TS	NA	NA
12	F	TS	NA	NA
13	F	TS	NA	NA
14	F	TS	NA	NA
15	F	TS	NA	NA
16	F	TS	NA	NA
17	F	TS	NA	NA
18	F	TS	NA	NA
19	F	TS	NA	NA
20	F	TS	NA	NA

Key: M- Male; TS- Terminal Sacrifice; NA- Not applicable.

APPENDIX-1: TEST ITEM DATA SHEET (TIDS)

Test / Reference Item Data Sheet (Medical Device) Palamur bio

Study Sponsor (Company Name and address)	Nelson Laboratories 6280 S. Redwood Road Salt Lake City, UT 84123 USA
Study compliance	☐ GLP ■ NON GLP
Name of Test Item / (Sponsor's ID for Test / Reference Item)	Cured coating Panels
Name of Reference Item	n/a
Intended Use of the Device	n/a
Contact Duration	■ Limited (≤ 24 hr) ☐ Prolonged (> 24 hr to 30 Days) ☐ Permanent (> 30 Days)
Total Surface area / Dimensions (length, Inner Diameter, Outer Diameter, width, radius etc.)	231.04cm2
Extraction Ratio	☐ 3cm²/mL ■ 6cm²/mL ☐ 0.2g/mL ☐ 0.1g/mL
Weight (For irregular shaped devices)	☐ GVRP/Palamur to measure weight during testing
Physical appearance	black rectangles
Batch No / Product Code	n/a
Lot No.	n/a
Extraction Conditions: ☐ 37 ± 1°C and 24 ± 2 hrs ☐ 37 ± 1°C and 72 ± 2 hrs ■ 50 ± 2°C and 72 ± 2 hrs ☐ 70 ± 2°C and 24 ± 2 hrs ☐ 121 ± 2°C and 1 ± 0.1hrs ☐ Others:	
Sterility: ☐ Sterile ■ Non-sterile	
Absorption check	☐ Yes ■ No
If Absorption check not required, provide the details	non-absorbant
Date of Expiry / Valid up to	n/a
Quantity sent	4
Component (s) to be used for extraction / testing	☐ Refer to provided Nelson Aux document for additional details
Predicate device (for Implantation / others) (if supplied by Sponsor kindly fill the Reference Item Data Sheet)	☐ Supplied by Sponsor ☐ Procured by Test facility ■ n/a

Page 1 of 2

10/10/23
VERIFIED BY TIC

APPENDIX-1: TEST ITEM DATA SHEET (TIDS) (Continued)

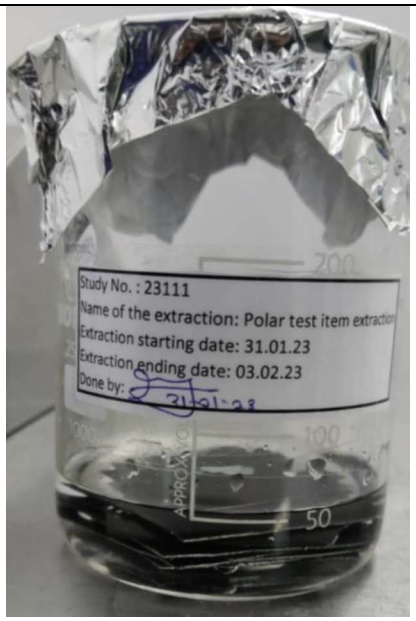
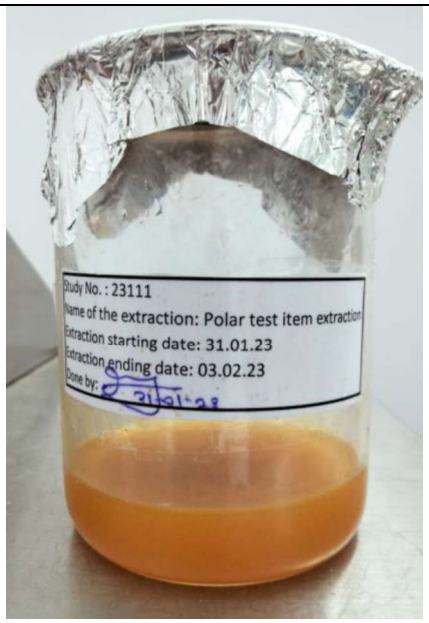
Test / Reference Item Data Sheet (Medical Device) Palamur bio

Storage conditions: ■ Ambient (18 to 28°C) ☐ Cool and dry (2 to 8°C) ☐ Frozen (< -10°C) ☐ Others _____ (specify the temperature / storage condition)	
Safety Precautions, if any	n/a
Material safety data sheet attached	☐ Yes ■ No
Certificate of analysis	☐ Yes ■ No
Others if any,	
Fate of remaining Test/Reference Item after completion of projects	☐ Dispose at test facility ■ Return back ☐ Return unused samples
List of Studies to be performed	☐ Guinea Pig Maximization Sponsor Study Code: ■ Intracutaneous Reactivity Sponsor Study Code: 1570808 ■ Acute Systemic Toxicity Sponsor Study Code: 1570810 ☐ Material Mediate Pyrogenicity Sponsor Study Code:
Any additional information (optional)	
Name of the Sponsor's Representative	Tanner Welch
Name of the Monitoring Scientist	Chad Summers
Signature and date	29 DEC 2022

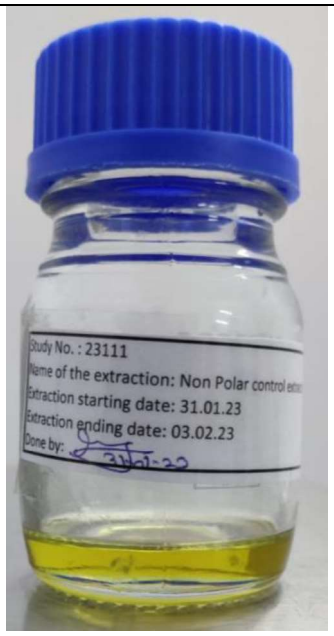
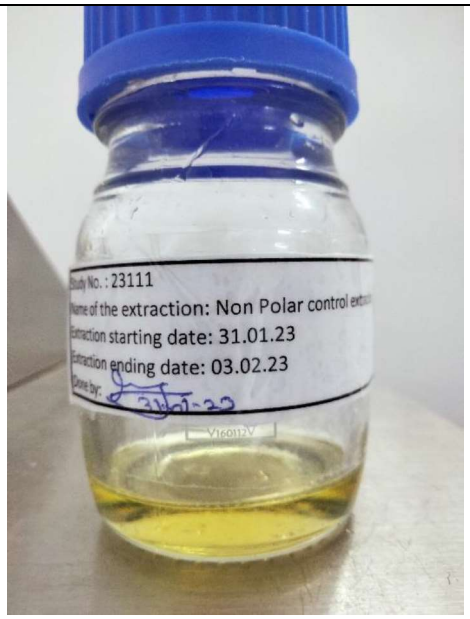
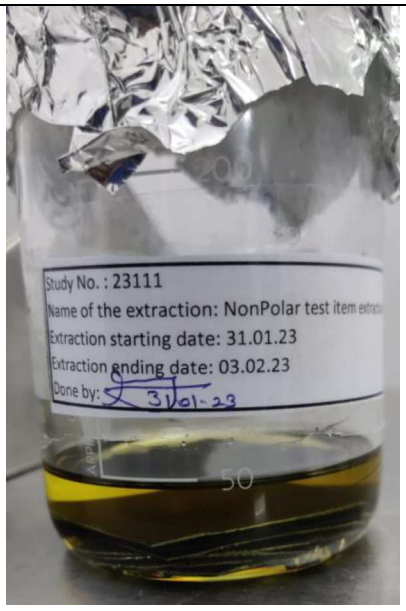
PALAMUR BIOSCIENCES PRIVATE LIMITED
SH-20, Karvina, Madigattla Village, Bhoothpur Mandal, Mahabubnagar District,
Telangana State -509382, India.
Mobile: +91 9000411835, 7382448855 EXT:201

10/01/23
VERIFIED BY TIC

APPENDIX-2: REPRESENTATIVE IMAGES

	
Polar control before extraction	Polar control after extraction
	
Polar test before extraction	Polar test after extraction

APPENDIX-2: REPRESENTATIVE IMAGES (Continued)

	
Non-Polar control before extraction	Non-Polar control after extraction
	
Non-Polar test before extraction	Non-Polar test after extraction