中国认可
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检测
TESTING
CNAS L18131

Test Report

Report Number: 26060536-01-R01EN

Sponsor:	Shenzhen Zhongchuang 3D Technology Co., Ltd
Factory:	Dongguan Daji 3D Technology Co., Ltd.
Sample Name:	Permanent crown resin
Model/Specification:	PRS-R-01
Test Category:	Commission Test

EPINTEK Guiyang Ltd.

Declaration

1. The report is invalid without the special stamp for test report of the test facility.
2. Partial copy is invalid without written approval of the test facility.
3. Any copy is invalid without the special stamp of the test facility for test report.
4. The report is invalid without the signature of the authorized signatory.
5. The report is invalid once altered.
6. Any comment to the report should be submitted in writing to the test facility, otherwise it may not be accepted.
7. The results in this report are relevant only to the articles tested.
8. The sponsor is responsible for the authenticity of the sample and its information.

Test Facility: EPINTEK Guiyang Ltd.

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EPINTEK Guiyang Ltd.
Test Report

Report Number: 26060536-01-R01EN

Sample Name	Permanent crown resin	Sample ID	26060536
Model/Specification	PRS-R-01		
Sponsor	Shenzhen Zhongchuang 3D Technology Co., Ltd		
Address	Room 204, Administration Building, Jia Tai Pharmaceutical, No.1 Industrial Zone, Tangwei Community, Fuhai Street, Bao'an District, Shenzhen City		
Factory	Dongguan Daji 3D Technology Co., Ltd./Room 401, Building 2, No. 6 Xiyi Street, Xingfa South Road, Wusha, Chang'an Town, Dongguan City		
Test Facility	EPINTEK Guiyang Ltd., Facility 1		
Test Category	Commission Test	Lot#	/
Produced Date	2026.06.06	Sample Quantity	2 PCS
Received Date	2026-06-17	Test Date(s)	2026-07-03 to 2026-07-09
Test Item(s)	Acute Systemic Toxicity Test		
Test Method(s)	ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity		
Conclusion	The test result of acute systemic toxicity test of the test sample met the standard requirements. (Stamp for Test Report) Issued Date:		
Notes	"NA" means "not applicable", "/" means "blank".		

Drafted by:_____ Reviewed by:_____

Lucy Luo Iris Yang

Approved by:_____ Position: Authorized Signatory

Cowboy He

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No.	Item	Standard Method	Acceptance Criteria	Test Result	Conclusion	Note
1	Acute Systemic Toxicity Test	ISO 10993-11: 2017	➢ If during the observation period of an acute systemic toxicity test none of the animals treated with the test sample shows a significantly greater biological reactivity than animals treated with the vehicle control, the sample meets the requirements of this test. ➢ If two or more animals die, or if behaviour such as convulsions or prostration occurs in two or more animals, or if body weight loss greater than 10 % occurs in three or more animals, the sample does not meet the requirements of the test; otherwise, the sample meets the standard requirements.	All animals gained weight normally; no abnormal clinical signs were found in all animals.	Met the Standard	Details Shown in Annex

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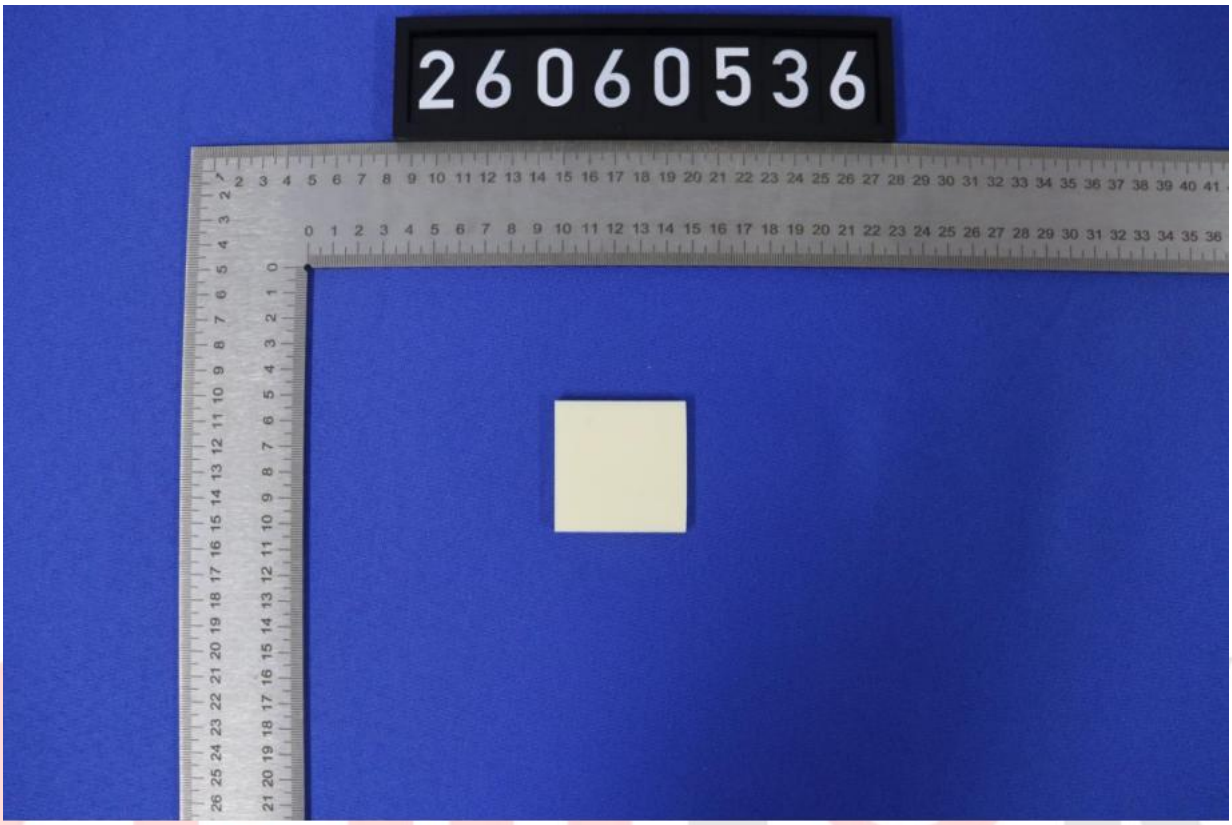
Picture of Sample

Description for Sample, Model/Specification
Initial State: Unsterilized Physical State: Solid (The information of sample hereby is provided by the sponsor.)
Misc
None

Annex of Test Report

Acute Systemic Toxicity Test

Study No.: 26060536-007072

Model/Specification: PRS-R-01

Lot#: /

EPINTEK Guiyang Ltd.

SUMMARY

1. Purpose

To evaluate the potential of a test article extraction to cause acute systemic toxicity in mouse.

2. Process Description

The test article was overall sampled by 3 cm^2/mL. Extraction condition was 50℃, 72 h. Extraction vehicles were 0.9% sodium chloride (SC) and corn oil (CO).

Took 20 male mice and divided them into four groups. The mice of group 1 and group 2 were given the polar extract and control solution by tail vein injection, and the mice of group 3 and group 4 were given the non-polar extract and control solution by intraperitoneal injection, and the dose volume was 50 mL/kg.

After administration, observed the instant response of the mouse. Furthermore, monitored and recorded the status of test groups and control groups (e.g. toxicosis symptom, mortality) in 4 h, 24 h, 48 h and 72 h. Body weight measurements were made immediately before dosing, daily for the first three days after dosing.

3. Result

All animals gained weight normally; no abnormal clinical signs were found in all animals.

4. Conclusion

Under the conditions of this study, the result of acute systemic toxicity test of test article extracts met the standard.

1. STUDY SUMMARIES

1.1. Purpose

To evaluate the potential of a test article extraction to cause acute systemic toxicity in mouse.

1.2. Deviation(s) and Incident(s) Treatment

If any deviation or incident has occurred in the test, the information will be recorded in a deviation report timely, and incorporated in this test report to evaluate the impact to final result(s).

1.3. Major Laboratory Personnel

Study Director:	Iris Yang
Main Operation Personnel:	Nicole Ran, Joshua Su

1.4. Study Dates

Test Start Date:	2026-07-03
Test Completion Date:	2026-07-09
Report Completion Date:	2026-08-05

2. TEST INFORMATION

2.1. Negative Control and Extraction Vehicle

2.1.1. Polar

Name:	0.9% Sodium Chloride (SC)
Lot/ Batch#:	D26040108
Physical State:	Colorless Transparent Liquid
Manufacturer:	Guizhou Kelun Pharmaceutical Co., Ltd.

2.1.2. Non-polar

Name:	Corn oil (CO)
Lot/ Batch#:	C18849298
Physical State:	Light yellow oily liquid
Manufacturer:	Shanghai Macklin Biochemical Co., Ltd.

2.2. Animal

2.2.1. Animal use license

Application scope:	Open Environment: (General grade: Rabbit, Guinea pig, Hamster, Sheep, Miniature pig, Dog, Monkey) Barrier Environment: (SPF grade: Mice, Rat, Guinea pig, Rabbit, Hamster)
Animal License No.:	SYXK (Gui) 2023-0005

2.2.2. Animal information

Species:	ICR mouse
Microbial Levels:	SPF Grade
Number/Sex:	20/Male
Weight:	17.68 g to 21.94 g before the start of the test
Manufacturer:	Changsha Tianqin Biotechnology Co., Ltd.
Production License#:	SCXK (Xiang) 2024-0023
Quality Certificate#:	No. 430726261100262562

2.2.3. Animal feeding conditions

Rearing Density:	Five animals per cage
Cages:	Plastic cage
Animal Identification:	Marked by pen and identified by a cage card
Acclimation Period:	5 days
Fodder:	Name: Laboratory Mouse & Rat Pelleted Formulated Feed Sterilization method: ^{60}Co irradiation sterilization Manufacturer: Beijing Haweisite Feed Manufacturing Co., Ltd Housing and husbandry method: Continuous supply and free intake
Padding:	Name: Corn cob Autoclaved sterilization and periodic replacement Manufacturer: Pizhou Xiaohe Technology Development Co., Ltd.
Water:	Pure water Autoclaving and free intake

2.2.4. Animal room environmental conditions

Temperature: 20℃-25℃

Relative Humidity: 30%-70%RH

Differential Pressure: ≥10 Pa

Ventilation Rate: ≥15 times/h

Lights: 12 hours light/dark cycle, full spectrum fluorescent lights

2.3. Main Instruments

Name	No.	Calibration Due Date
Constant Temperature Culture Oscillator	EPME-258	2027-02-27
Biosafety Cabinet	EPME-072	2027-02-27
pH Meter	EPME-338	2027-03-15
Electronic Balance	EPME-159	2027-06-02

2.4. Justification of the Test System

The species and number of animals used were recommended by standard guidelines.

3. TEST DESIGN

3.1. Sample Preparation

3.1.1. Extraction process[1)]

Samples are aseptically sampled after disinfection by immersion in alcohol and prepared as follows:

Sampling Manner	Actual Sampling[2)]	Ratio	Vehicle	Amount	Conditions
Overall sampling	50 cm^2	3 cm^2/mL	SC	16.6 mL	50℃, 72 h, 60 rpm
	50 cm^2	3 cm^2/mL	CO	16.6 mL	50℃, 72 h, 60 rpm

1) The vehicle (without the test article) was similarly prepared to serve as the negative control. Extraction was carried out under dynamic conditions.

2) The surface area of a single sample is 50 cm^2 (provided by the sponsor).

3.1.2. Final extract treatment[1)]

Final extract	Additional processing prior to the testing or Not	Presence of particles or Not	Color and Clear or Not
SC[2)]	Not	Not	Colorless and Clear
CO	Not	Not	Light yellow and Clear

1) Used the final extracts immediately.
2) pH=5.22.

3.2. Grouping

Selected ICR mice and grouped according to the following table:

Group No.	Group Name	Amount	Sex	Animal No.	Temporary No.	Routes of Administration
1	Negative control (SC)	5	♂	1101 to 1105	G51 to G55	Tail vein injection
2	Test group (SC final extracts)	5	♂	2106 to 2110	G56 to G60	
3	Negative control (CO)	5	♂	3111 to 3115	G61 to G65	Intraperitoneal injection
4	Test group (CO final extracts)	5	♂	4116 to 4120	G66 to G70	

3.3. Experimental Process

The mice of group 1 and group 2 were given the polar extract and control solution. The dose volume was 50 mL/kg.

The mice of group 3 and group 4 were given the non-polar extract and control solution. The dose volume was 50 mL/kg.

After injection, observed the instant response of the mouse. Furthermore, monitored and recorded the status of test groups and control groups (e.g. toxicosis symptom, mortality) in 4 h, 24 h, 48 h and 72 h.

Body weight measurements were made immediately before dosing, daily for the first three days after dosing.

4. EVALUATION CRITERION

- If during the observation period (72 h) of an acute systemic toxicity test none of the animals treated with the test article shows a significantly greater biological reactivity than animals treated with the vehicle control, the test article meets the requirements of this test.
- If two or more animals die, or if behavior such as convulsions or prostration occurs in two or more animals, or if a body weight loss greater than 10 % occurs in three or more animals, the test article does not meet the requirements of the test.
- If any animals treated with the test article show only slight signs of biological reactivity, and not more than one animal shows gross symptoms of biological reactivity or dies, repeat the testing using groups of ten animals.
- On the repeat test, if all ten animals treated with the test article show no scientifically meaningful biological reactivity above the vehicle control animals during the observation period, the test article meets the requirements of this test.

5. ALTERATION AND DEVIATION

No alteration and deviation happened in this test.

6. RESULTS

All animals gained weight normally; no abnormal clinical signs were found in all animals.

See **Attached Table 1 to 2.**

7. CONCLUSION

Under the conditions of this study, the result of acute systemic toxicity test of test article extracts met the standard.

8. ARCHIVING

All correspondence, including original copy of the protocol, original copy of the test report, and all raw data generated during the study (i.e., documentation forms as well as any other notes of raw data, printouts of instruments and computers) are stored in the archives room of the EPINTEK Guiyang Ltd.

9. ATTACHED TABLE

9.1. Attached Table 1 Results of Animals Body Weight and Dosage

Group	Animal No.	Dosage （mL）	Weight（g）				Body Weight Change *
			Before Dosing	24 h	48 h	72 h	
Negative control (SC)	1101	0.92	18.30	20.49	21.74	24.03	31%
	1102	0.94	18.41	20.04	22.52	23.96	30%
	1103	0.94	18.46	19.97	21.40	23.47	27%
	1104	1.1	21.94	23.95	25.72	27.09	23%
	1105	0.90	17.68	19.76	21.83	23.67	34%
Test group (SC final extracts)	2106	0.98	19.56	21.68	21.98	22.23	14%
	2107	1.0	19.83	21.63	23.01	24.90	26%
	2108	0.92	18.30	19.39	19.89	20.16	10%
	2109	1.1	20.85	21.72	24.39	25.57	23%
	2110	0.98	19.60	21.98	23.03	23.46	20%
Negative control (CO)	3111	0.92	18.01	20.41	21.22	21.81	21%
	3112	0.90	18.00	19.28	20.83	22.74	26%
	3113	0.90	17.96	19.05	21.26	23.77	32%
	3114	1.0	19.70	21.01	22.05	22.59	15%
	3115	1.0	19.68	20.75	22.43	24.91	27%
Test group (CO final extracts)	4116	0.98	19.54	20.28	21.82	24.43	25%
	4117	0.92	18.31	19.13	21.23	21.32	16%
	4118	0.98	19.53	20.99	22.65	25.47	30%
	4119	1.1	21.24	22.25	23.62	24.44	15%
	4120	1.1	20.01	21.47	23.16	24.87	24%

* Body weight changes were calculated based on the pre-injection body weight.

9.2. Attached Table 2 Results of the Observed Signs

Group	Animal No.	Symptom				
		0 h	4 h	24 h	48 h	72 h
Negative control (SC)	1101	—	—	—	—	—
	1102	—	—	—	—	—
	1103	—	—	—	—	—
	1104	—	—	—	—	—
	1105	—	—	—	—	—
Test group (SC final extracts)	2106	—	—	—	—	—
	2107	—	—	—	—	—
	2108	—	—	—	—	—
	2109	—	—	—	—	—
	2110	—	—	—	—	—
Negative control (CO)	3111	—	—	—	—	—
	3112	—	—	—	—	—
	3113	—	—	—	—	—
	3114	—	—	—	—	—
	3115	—	—	—	—	—
Test group (CO final extracts)	4116	—	—	—	—	—
	4117	—	—	—	—	—
	4118	—	—	—	—	—
	4119	—	—	—	—	—
	4120	—	—	—	—	—

Note: "—"shows there were no signs of toxicity.

……End of the Report……