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TESTING
CNAS L18131

Test Report

Report Number: 26060536-03-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.

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EPINTEK Guiyang Ltd.
Test Report

Report Number: 26060536-03-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	6 PCS
Received Date	2026-06-17	Test Date(s)	2026-07-05 to 2026-08-01
Test Item(s)	Skin Sensitization Test (GPMT method)		
Test Method(s)	ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization		
Conclusion	The Skin Sensitization Test (GPMT method) results of the tested articles show no skin sensitization reactivity. （Stamp for Test Report） Issued Date：		
Notes	“NA” means “not applicable”, “/” means “blank”.		

Drafted by:_____ Reviewed by:_____

Lucy Luo Iris Yang

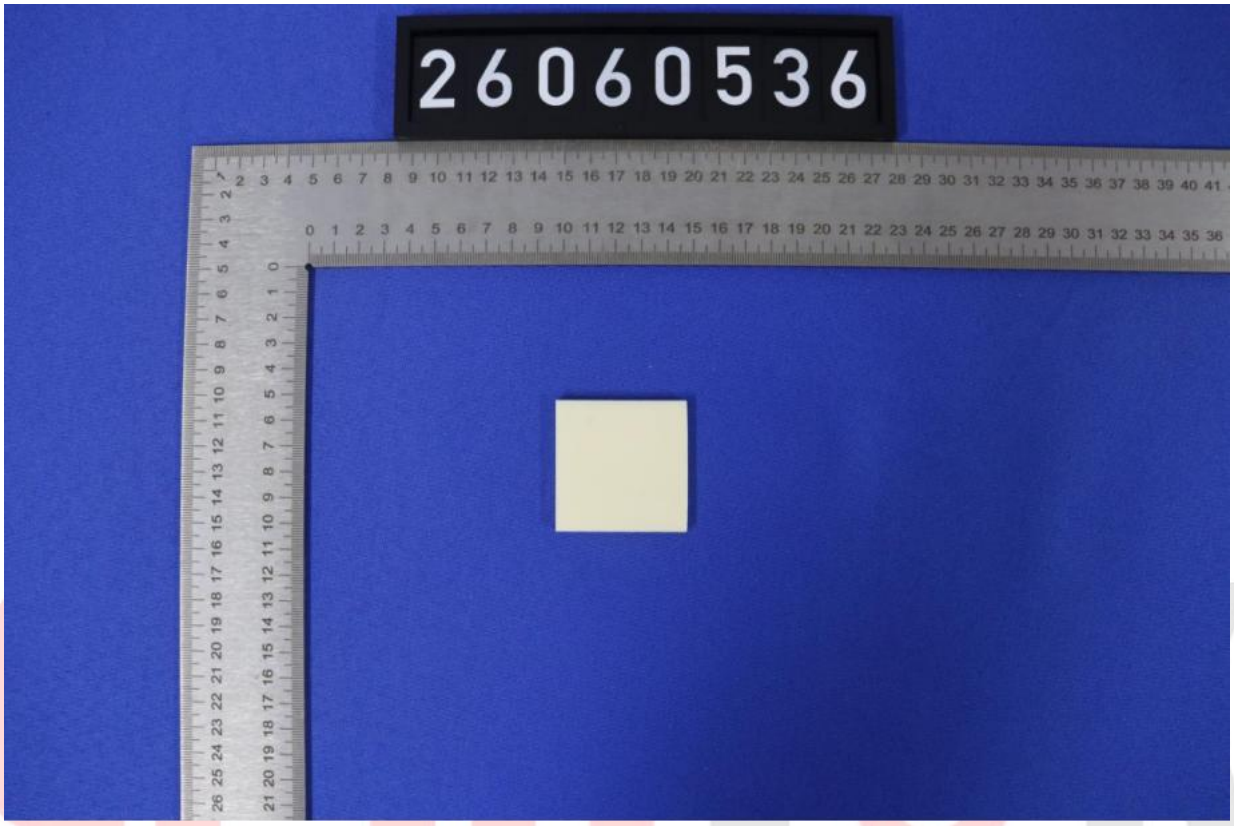
Approved by:_____ Position: Authorized Signatory

Cowboy He

Report Number: 26060536-03-R01EN

No.	Item	Standard Method	Acceptance Criteria	Test Result	Conclusion	Note
1	Skin Sensitization Test (GPMT method)	ISO 10993-10: 2021	There is no skin sensitization reactivity if the grades of less than 1 are seen in the test group, or if the reactions of test animals which not exceed the most severe reaction in control animals.	The grades of less than 1 were seen in the test group, the positive rate of all test groups was 0%. No abnormal clinical symptoms other than skin reactions were observed in all animals	No skin sensitization reactivity	Details Shown in Annex

Report Number: 26060536-03-R01EN

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

Skin Sensitization Test (GPMT method)

Study No.: 26060536-006901

Model/Specification: PRS-R-01

Lot#: /

EPINTEK Guiyang Ltd.

SUMMARY

1. Purpose

To evaluate the potential of the test article extracts to cause skin sensitization in the guinea pig according to GPMT method.

2. Process Description

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

For intradermal induction, made a pair of 0.1 mL intradermal injections of each of the following, into each animal, at the injection sites, as shown in Figure 1, in the clipped intrascapular region. At 7 d after completion of the intradermal induction phase, administered the test article extracts by topical application to the intrascapular region of each animal, used a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secured with an occlusive dressing. Removed the dressings and patches after (48±2) h. Treated the control animals similarly, used the control liquid alone. If the test article extracts did not produce irritation, pretreated the area with 0.5 mL of 10% sodium dodecyl sulfate massaged into the skin (24±2) h before the patch was applied.

At 14 d after completion of the topical induction phase, challenged all animals with the test article extracts and negative control. Administered all animals by topical application to sites that were not treated during the induction stage, used absorbent gauze (2.5 cm×2.5 cm) soaked. Secure with an occlusive dressing. Removed the dressings and patches after (24±2) h.

Observed the appearance of the challenge skin sites of the test and control animals (24±2) h and (48±2) h after removal of the dressings. Described and scored the skin reactions for erythema and oedema according to the Magnusson and Kligman grading.

3. Result

The grades of less than 1 are seen in the test group. The positive rate of all test groups was 0%.

The positive rate of all negative control groups was 0%.

The positive rate of all Positive control groups was 100%

No abnormal clinical symptoms other than skin reactions were observed in all animals.

4. Conclusion

Under the conditions of this study, the sample extract showed no significant evidence of causing skin sensitization in the guinea pig.

1. STUDY SUMMARIES

1.1. Purpose

To evaluate the potential of the test article extracts to cause skin sensitization in the guinea pig according to GPMT method.

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

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, Xunwan Zhu

1.4. Study Dates

Test Start Date:	2026-07-05
Test Completion Date:	2026-08-01
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/D26051902
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. Positive Control

Denomination:	2, 4-Dinitrochlorobenzene (DNCB)
Content:	≥99%
Lot/ Batch#:	D2527134
Physical State:	Yellow solid
Manufacturer:	Shanghai Aladdin Bio-Chem Technology Co., Ltd.
Induction Concentration:	0.5%
Challenge Concentration:	0.25%

2.3. Animal

2.3.1. Animal use license

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

2.3.2. Animal information

Species:	Hartley Guinea Pig
Microbial Levels:	Conventional Grade
Number/Sex:	30/Male
Weight:	307.4 g to 469.1 g before the start of the test
Manufacturer:	Guanghui Biotechnology (Sihui) Co., Ltd.
Production License#:	SCXK (Yue) 2025-0083
Quality Certificate#:	No. SCXK (Yue) 2025-00832026622148

2.3.3. Animal feeding conditions

Rearing Density:	5 animals per cage
Cages:	Plastic cage
Animal Identification:	Marked on body surface and identified by a cage card
Acclimation Period:	5 days
Fodder:	Name: Laboratory Guinea Pig Pelleted Formulated Feed Manufacturer: Beijing Haweisite Feed Manufacturing Co., Ltd

	Housing and husbandry method: Continuous supply and free intake
Padding:	Name: Corncob Bedding
	Manufacturer: Pizhou Xiaohe Technology Development Co., Ltd.
	Periodic replacement
Water:	Pure water
	Free intake

2.3.4. Animal room environmental conditions

Temperature:	18℃-29℃
Relative Humidity:	30%-70%RH
Ventilation Rate:	≥8 times/h
Lights:	12 hours light/dark cycle, full spectrum fluorescent lights

2.4. Main Instruments and Reagents

2.4.1. 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-044	2027-02-27
Electronic Balance	EPME-307	2026-12-21

2.4.2. Main reagents

Name	LOT#	Manufacturer
Freund's Complete Adjuvant (FCA)	1003590210	SIGMA
Sodium Dodecyl Sulfate (SDS)	C18682469	Shanghai Macklin Biochemical Co., Ltd.

2.5. Justification of the Test System

The guinea pig has been used historically for sensitization studies. The guinea pig is believed to be the most sensitive animal model for this type of study. 2, 4-Dinitrochlorobenzene (DNCB) is recommended as the positive substance by guiding principle. 2, 4-Dinitrochlorobenzene (DNCB) has been substantiated at EPINTEK Guiyang Ltd. once every 3 months with this method. The recent data of positive control came from 26050059-006897 (Completed date: 2026-07-12). See **Attached Table 3 to 4.**

3. TEST DESIGN

3.1. Samples Preparation

3.1.1. Extraction process[1)]

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

Test phase	Sampling Manner	Actual Sampling [2)]	Ratio	Vehicle	Amount	Conditions
Intradermal induction	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
Topical induction		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
Challenge		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)]

Test phase	Final extract	Additional processing prior to the testing or Not	Presence of particles or Not	Color and Clear or Not
Intradermal induction	SC[2)]	Not	Not	Colorless and Clear
	CO	Not	Not	Light yellow and Clear
Topical induction	SC[3)]	Not	Not	Colorless and Clear
	CO	Not	Not	Light yellow and Clear
Challenge	SC[4)]	Not	Not	Colorless and Clear
	CO	Not	Not	Light yellow and Clear

1) Used the final extracts immediately.

2) pH=5.26.

3) pH=5.38.

4) pH=5.35.

3.2. Grouping

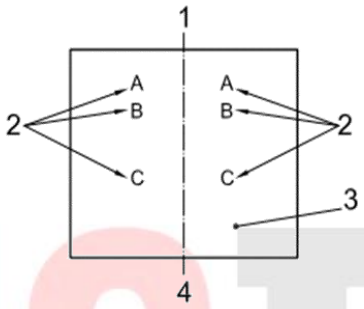
Selected guinea pigs and grouped according to the following table:

Group No.	Group Name	Amount	Sex	Numbered list	Temporary No.
1	Negative control (SC)	5	♂	1101 to 1105	G74 to G78
2	Test group (SC final extract)	10	♂	2106 to 2115	G79 to G88
3	Negative control (CO)	5	♂	3116 to 3120	G89 to G93
4	Test group (CO final extract)	10	♂	4121 to 4130	G94 to G103

3.3. Experimental Process

3.3.1. Intradermal induction phase I

Made a pair of 0.1 mL intradermal injections of each of the following, into each animal, at the injection sites, as shown in Figure 1, in the clipped intrascapular region.



1. Cranial end 2. 0.1 mL intradermal injections 3. Clipped intrascapular region 4. Caudal end

Site A: 50:50 (volume ratio) stable emulsion of Freund's complete adjuvant mixed with the chosen vehicle.

Site B: The test article extract; inject the negative control animals with the vehicle/vehicle alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the vehicle/extraction vehicle (the solution used at site A); inject the control animals with an emulsion of the blank liquid with adjuvant.

Figure 1 Location of intradermal injection sites

3.3.2. Topical induction phase II

At 7 d after completion of the intradermal induction phase, administered the test article extracts by topical application to the intrascapular region of each animal, used a patch of area approximately 8 cm^2 (absorbent gauze), so as to cover the intradermal injection sites. Secured with an occlusive dressing. Removed the dressings and patches after (48±2) h. Treated the control animals similarly, used the control liquid alone. If the test article extracts did not produce irritation, pretreated the area with 0.5 mL of 10% sodium dodecyl sulfate massaged into the skin (24±2) h before the patch was applied.

3.3.3. Challenge phase

At 14 d after completion of the topical induction phase, challenged all animals with the test article extracts and negative control. Administered all animals by topical application to sites that were not treated during the induction stage, used absorbent gauze (2.5 cm×2.5 cm) soaked. Secured with an occlusive dressing. Removed the dressings and patches after (24±2) h.

3.3.4. Observation of animal

The skin reactions of the animals were observed at (24±2) h and (48±2) h after removal of the dressings to stimulate contact areas and scored according to Table 1.

Table 1 Magnusson and Kligman Scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and/or swelling	3

3.3.5. Other observed endpoints

Clinical symptoms except skin reactions were observed every day. Weighed all the test animals at the beginning and end of the test.

4. EVALUATION CRITERION

- Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in control animals.
- If grades of 1 or greater are noted in control animals, then the reactions of test animals which exceed the most severe reaction in control animals are presumed to be due to sensitization.
- If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.
- Occasionally, the test group has a greater number of animals showing a response than the controls, although the intensity of the reaction is not greater than that exhibited by the controls. In these instances, a rechallenge might be necessary to define the response clearly. A rechallenge shall be carried out 1 week to 2 weeks after the first challenge. The method used shall be as described for the first challenge, using a naive side on the animal.
- The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

5. ALTERATION AND DEVIATION

No alteration and deviation happened in this test.

6. RESULTS

The grades of less than 1 are seen in the test group. The positive rate of all test groups was 0%.

The positive rate of all negative control groups was 0%.

The positive rate of all Positive control groups was 100%.

No abnormal clinical symptoms other than skin reactions were observed in all animals.

See **Attached Table 1 to 4.**

7. CONCLUSION

Under the conditions of this study, the sample extract showed no significant evidence of causing skin sensitization in the guinea pig.

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 Sensitization Dermal Reactions

Group	Animal No.	(24±2) h before Phase II Patch Application		Hours Following Challenge Phase				Positive Rate after Challenge Phase
				(24±2) h		(48±2) h		
		Left	Right	Control	Test	Control	Test	
Negative control (SC)	1101	0	0	0	0	0	0	0%
	1102	0	0	0	0	0	0	
	1103	0	0	0	0	0	0	
	1104	0	0	0	0	0	0	
	1105	0	0	0	0	0	0	
Test group (SC final extract)	2106	0	0	0	0	0	0	0%
	2107	0	0	0	0	0	0	
	2108	0	0	0	0	0	0	
	2109	0	0	0	0	0	0	
	2110	0	0	0	0	0	0	
	2111	0	0	0	0	0	0	
	2112	0	0	0	0	0	0	
	2113	0	0	0	0	0	0	
	2114	0	0	0	0	0	0	
	2115	0	0	0	0	0	0	
Negative control (CO)	3116	0	0	0	0	0	0	0%
	3117	0	0	0	0	0	0	
	3118	0	0	0	0	0	0	
	3119	0	0	0	0	0	0	
	3120	0	0	0	0	0	0	
Test group (CO final extract)	4121	0	0	0	0	0	0	0%
	4122	0	0	0	0	0	0	
	4123	0	0	0	0	0	0	
	4124	0	0	0	0	0	0	
	4125	0	0	0	0	0	0	
	4126	0	0	0	0	0	0	
	4127	0	0	0	0	0	0	
	4128	0	0	0	0	0	0	
	4129	0	0	0	0	0	0	
	4130	0	0	0	0	0	0	

9.2. Attached Table 2 Weight Change and Clinical Observation

Group	Animal No.	Weight (g)		Clinical Observation except Dermal Reactions
		Test Begin	Test End	
Negative control (SC)	1101	368.4	426.3	Normal
	1102	432.1	539.4	Normal
	1103	409.2	548.1	Normal
	1104	360.5	500.9	Normal
	1105	385.7	523.7	Normal
Test group (SC final extract)	2106	382.4	466.9	Normal
	2107	382.3	516.3	Normal
	2108	367.2	485.4	Normal
	2109	338.1	463.1	Normal
	2110	351.7	490.8	Normal
	2111	337.6	447.5	Normal
	2112	349.3	475.3	Normal
	2113	385.4	452.6	Normal
	2114	358.4	460.1	Normal
	2115	320.3	477.0	Normal
Negative control (CO)	3116	329.1	493.8	Normal
	3117	307.4	415.2	Normal
	3118	369.8	486.9	Normal
	3119	402.9	537.1	Normal
	3120	419.7	589.4	Normal
Test group (CO final extract)	4121	423.3	597.6	Normal
	4122	359.7	454.2	Normal
	4123	363.5	487.5	Normal
	4124	370.8	526.3	Normal
	4125	469.1	607.0	Normal
	4126	384.2	581.6	Normal
	4127	343.5	430.7	Normal
	4128	378.1	511.4	Normal
	4129	364.6	463.8	Normal
	4130	347.9	502.6	Normal

9.3. Attached Table 3 Sensitization Dermal Reactions of Positive Group

Group	Animal No.	(24±2) h before Phase II Patch Application		Hours Following Challenge Phase				Positive Rate after Challenge Phase
				(24±2) h		(48±2) h		
		Left	Right	Control	Test	Control	Test	
Negative control (AL+SC)	5131	0	0	0	0	0	0	0%
	5132	0	0	0	0	0	0	
	5133	0	0	0	0	0	0	
	5134	0	0	0	0	0	0	
	5135	0	0	0	0	0	0	
Positive control (DNCB)	6136	2	1	0	1	0	2	100%
	6137	2	2	0	2	0	1	
	6138	1	2	0	1	0	1	
	6139	2	1	0	1	0	2	
	6140	1	2	0	2	0	1	

Note: The recent data of positive control came from 26050059-006897 (Completed date: 2026-07-12).

9.4. Attached Table 4 Weight Change and Clinical Observation of Positive Group

Group	Animal No.	Weight (g)		Clinical observation except dermal reactions
		Test began	Test end	
Negative control (AL+SC)	5131	354.3	463.4	Normal
	5132	474.8	581.7	Normal
	5133	362.9	452.5	Normal
	5134	454.8	587.6	Normal
	5135	393.3	492.3	Normal
Positive control (DNCB)	6136	351.7	471.6	Normal
	6137	447.4	524.5	Normal
	6138	436.8	547.8	Normal
	6139	482.2	492.1	Normal
	6140	400.9	499.2	Normal

Note: The recent data of positive control came from 26050059-006897 (Completed date: 2026-07-12).

……End of the Report……