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检测
TESTING
CNAS L18131

Test Report

Report Number: 26060536-02-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.

Facility 1: Industrial Incubation Park, Dayang Road, Baiyun District, Guiyang, China

Telephone: 0851-84614538 Postal Code: 550014

Facility 2: No. 1, 4/F, Building 16.18, No.7888, Tongcheng Avenue, Baiyun District, Guiyang, Guizhou, China

Telephone: 0851-84614538 Postal Code: 550016

Website: www.epintek.com

EPINTEK Guiyang Ltd.
Test Report

Report Number: 26060536-02-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)	2026-07-06 to 2026-07-12
Test Item(s)	Intradermal Reaction Test		
Test Method(s)	ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation		
Conclusion	Under the conditions of this test, the Intradermal Reaction Test result of the tested articles 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

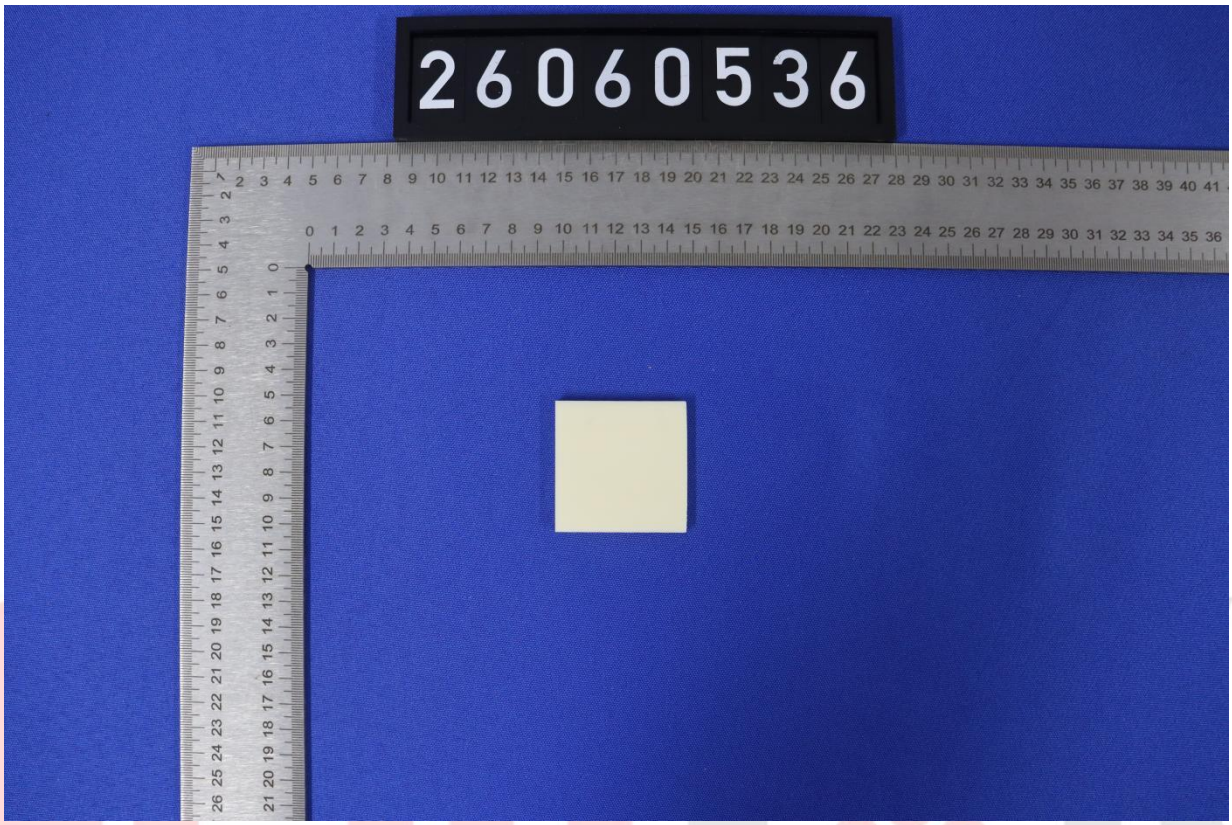
Approved by:_____ Position: Authorized Signatory

Cowboy He

Report Number: 26060536-02-R01EN

No.	Item	Standard Method	Acceptance Criteria	Test Result	Conclusion	Note
1	Intradermal Reaction Test	ISO 10993-23: 2021	The final irritation score is 1.0 or less.	The final scores of the test samples were all 0.0.	Met the Test Standard	Details Shown in Annex.

Report Number: 26060536-02-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

Intradermal Reaction Test

Study No.: 26060536-007240

Model/Specification: PRS-R-01

Lot#: /

EPINTEK Guiyang Ltd.

SUMMARY

1. Purpose

To determine the potential intradermal reaction caused by intradermally injecting the extract to rabbit.

2. Experimental Process

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 3 female rabbits. Used the rabbits with healthy intact skin. Within a 4 h to 18 h period before testing, closely clipped the fur on the back of the animals, allowing a sufficient distance on both sides of the spine for injection of the extracts.

Used the smallest needle appropriate to the viscosity of the test material for the intradermal injection. Injected Intradermally 0.2 mL of the extracts obtained with polar (upper part) and non-polar (lower part) vehicle at five sites on left side of each rabbit. Similarly, injected 0.2 mL of polar and non-polar vehicle control at five sites on the contralateral side of each rabbit.

Described and scored the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each injection site immediately after injection and at (24±2) h, (48±2) h and (72±2) h after injection.

3. Result

The final irritation score (polar) was 0.0. The final irritation score (non-polar) was 0.0.

The final irritation score (polar) of positive control was 7.4. The final irritation score (non-polar) of positive control was 7.3.

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

4. Conclusion

Under the conditions of this study, the final irritation score is 1.0 or less, and the test results of the tested articles met the standard requirements.

1. STUDY SUMMARIES

1.1. Purpose

To determine the potential intradermal reaction caused by the test extract that was intradermally injected into rabbit.

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:	Delara Yang, Coco Ni

1.4. Study Dates

Test Start Date:	2026-07-06
Test Completion Date:	2026-07-12
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. Positive Control

Name:	Sodium Dodecyl Sulfate (SDS)
Lot/ Batch#:	C18682469
Physical State:	White powder
Manufacturer:	Shanghai Macklin Biochemical Co., Ltd.

2.3. Animal

2.3.1. 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

2.3.2. Animal information

Species:	New Zealand White Rabbit
Microbial Levels:	Conventional Grade
Number/Sex:	3/Female (Nulliparous and non-pregnant)
Weight:	2097.2 g to 2426.8 g at the start of the test
Manufacturer:	Shanxi Junxing Biotechnology Co., Ltd.
Production License#:	SCXK (Shan) 2022-01
Quality Certificate#:	NO: 61003200004609

2.3.3. Animal feeding conditions

Rearing Density:	One animal per cage
Cages:	Suspended stainless steel
Animal Identification:	Marked the ID in animal's right ear and identified by a card
Acclimation Period:	7 days
Fodder:	Name: Laboratory Rabbit Pelleted Formulated Feed Manufacturer: Beijing Haweisite Feed Manufacturing Co., Ltd Housing and husbandry method: Continuous supply and free intake
Water:	Pure water Free intake

2.3.4. Animal room environmental conditions

Temperature: 17℃-25℃

Relative Humidity: 30%-70%RH

Ventilation Rate: ≥8 times/h

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

2.4. 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-306	2026-12-21

2.5. Justification of the Test System

The rabbit was whole as an appropriate animal model for evaluating potential intradermal irritants by the testing standards. 20% Sodium Dodecyl Sulfate (SDS) was recommended as the positive substance by guiding principle, the sensitivity of this test system is verified every 6 months using 20% SDS solution. The recent data of positive control came from 26030134-007253 (Completed date: 2026-06-29). **See Attached Table 4 to 6.**

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:

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[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=5.29.

3.2. Grouping

Selected rabbits and grouped according to the following table:

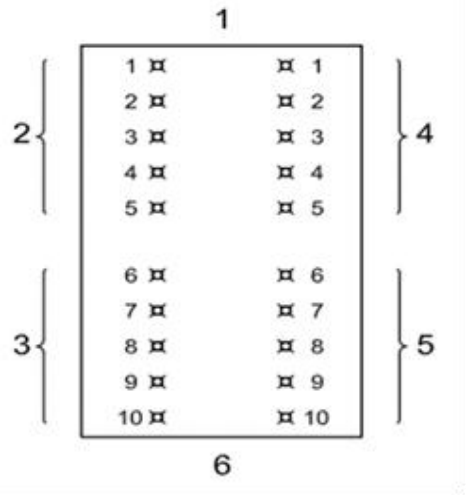
Group No.	Group Name	Amount	Sex	Animal No.	Temporary No.
1	Test/Control group	3	♀	1201 to 1203	F345 to F347

3.3. Experimental Process

3.3.1. Injecting process

Used the rabbits with healthy intact skin. Within a 4 h to 18 h period before testing, closely clipped the fur on the back of the animals, allowing a sufficient distance on both sides of the spine for injection of the extracts.

Used the smallest needle appropriate to the viscosity of the test material for the intradermal injection. Injected intradermally 0.2 mL of the extracts obtained with polar (upper part) and non-polar (lower part) vehicle at five sites on left side of each rabbit. Similarly, injected 0.2 mL of polar and non-polar vehicle control at five sites on the contralateral side of each rabbit. See **Figure 1**.



1-cranial end; 2-0.2 mL injections of polar extract; 3-0.2 mL injections of non-polar extract; 4-0.2 mL injections of polar vehicle control; 5-0.2 mL injections of non-polar vehicle control; 6-caudal end.

Figure 1 Arrangement of the Injection Site

3.3.2. Observation of animals

Described and scored the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each injection site immediately after injection and at (24±2) h, (48±2) h and (72±2) h after injection.

Table 1 Scoring system for intradermal reaction

Erythema and Eschar Formation:	**Irritation score**
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate erythema	3
Severe erythema (beet redness) to eschar formation preventing grading of erythema	4
Oedema Formation:	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema (raised more than 1 mm and extending beyond exposure area)	4
Maximal possible score for irritation	**8**
Other adverse changes at the skin sites shall be recorded and reported.	

3.3.3. 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

- After (72±2) h scoring, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h are totaled separately for each test sample extract or negative control for each individual animal, and then divide each of the totals by 15 (3 scoring time points×5 test or blank sample injection sites) to calculate the scoring of each animal test sample or blank control.
- The scores of the three animals were summed and divided by three to obtain the total mean score for each test sample and the corresponding blank control.
- The total average score of the test samples was subtracted from the total average score of the blank control to obtain the final score of the test samples.
- The requirements of the test are met if the final test sample score is 1.0 or less.
- Should results be inconsistent between animals or controls not perform as anticipated making interpretation of the overall results questionable, the study can be repeated using three additional rabbits.

5. ALTERATION AND DEVIATION

No alteration and deviation happened in this test.

6. RESULTS

The final irritation score (polar) was 0.0. The final irritation score (non-polar) was 0.0.

The final irritation score (polar) of positive control was 7.4. The final irritation score (non-polar) of positive control was 7.3.

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

See Attached Table 1 to 6.

7. CONCLUSION

Under the conditions of this study, the final irritation score is 1.0 or less, and the test results of the tested articles met the standard requirements.

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 Intradermal Observations of Test Group-Polar

Group	Animal No.	Injection Site	Immediately		(24±2) h		(48±2) h		(72±2) h		Average score
			Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	
Polar	1201	T1	0	0	0	0	0	0	0	0	0.0
		T2	0	0	0	0	0	0	0	0	
		T3	0	0	0	0	0	0	0	0	
		T4	0	0	0	0	0	0	0	0	
		T5	0	0	0	0	0	0	0	0	
		C1	0	0	0	0	0	0	0	0	0.0
		C2	0	0	0	0	0	0	0	0	
		C3	0	0	0	0	0	0	0	0	
		C4	0	0	0	0	0	0	0	0	
		C5	0	0	0	0	0	0	0	0	
	1202	T1	0	0	0	0	0	0	0	0	0.0
		T2	0	0	0	0	0	0	0	0	
		T3	0	0	0	0	0	0	0	0	
		T4	0	0	0	0	0	0	0	0	
		T5	0	0	0	0	0	0	0	0	
		C1	0	0	0	0	0	0	0	0	0.0
		C2	0	0	0	0	0	0	0	0	
		C3	0	0	0	0	0	0	0	0	
		C4	0	0	0	0	0	0	0	0	
		C5	0	0	0	0	0	0	0	0	
	1203	T1	0	0	0	0	0	0	0	0	0.0
		T2	0	0	0	0	0	0	0	0	
		T3	0	0	0	0	0	0	0	0	
		T4	0	0	0	0	0	0	0	0	
		T5	0	0	0	0	0	0	0	0	
		C1	0	0	0	0	0	0	0	0	0.0
		C2	0	0	0	0	0	0	0	0	
		C3	0	0	0	0	0	0	0	0	
		C4	0	0	0	0	0	0	0	0	
		C5	0	0	0	0	0	0	0	0	
The total mean score for test sample (T)											0.0
The total mean score for blank control (C)											0.0
The final score=The total mean score for test sample (T) - The total mean score for blank control (C)											0.0

9.2. Attached Table 2 Intradermal Observations of Test Group-Non-polar

Group	Animal No.	Injection Site	Immediately		(24±2) h		(48±2) h		(72±2) h		Average score
			Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	
Non-polar	1201	T6	0	0	0	0	0	0	0	0	0.0
		T7	0	0	0	0	0	0	0	0	
		T8	0	0	0	0	0	0	0	0	
		T9	0	0	0	0	0	0	0	0	
		T10	0	0	0	0	0	0	0	0	
		C6	0	0	0	0	0	0	0	0	0.0
		C7	0	0	0	0	0	0	0	0	
		C8	0	0	0	0	0	0	0	0	
		C9	0	0	0	0	0	0	0	0	
		C10	0	0	0	0	0	0	0	0	
	1202	T6	0	0	0	0	0	0	0	0	0.0
		T7	0	0	0	0	0	0	0	0	
		T8	0	0	0	0	0	0	0	0	
		T9	0	0	0	0	0	0	0	0	
		T10	0	0	0	0	0	0	0	0	
		C6	0	0	0	0	0	0	0	0	0.0
		C7	0	0	0	0	0	0	0	0	
		C8	0	0	0	0	0	0	0	0	
		C9	0	0	0	0	0	0	0	0	
		C10	0	0	0	0	0	0	0	0	
	1203	T6	0	0	0	0	0	0	0	0	0.0
		T7	0	0	0	0	0	0	0	0	
		T8	0	0	0	0	0	0	0	0	
		T9	0	0	0	0	0	0	0	0	
		T10	0	0	0	0	0	0	0	0	
		C6	0	0	0	0	0	0	0	0	0.0
		C7	0	0	0	0	0	0	0	0	
		C8	0	0	0	0	0	0	0	0	
		C9	0	0	0	0	0	0	0	0	
		C10	0	0	0	0	0	0	0	0	
The total mean score for test sample (T)											0.0
The total mean score for blank control (C)											0.0
The final score=The total mean score for test sample (T) - The total mean score for blank control (C)											0.0

9.3. Attached Table 3 Weigh Change and Clinical Observation of Test Group

Animal No.	Weight (g)		Clinical Observation Except Intradermal Reactions
	Test Begin	Test End	
1201	2135.9	2240.7	Normal
1202	2426.8	2483.6	Normal
1203	2097.2	2171.3	Normal

9.4. Attached Table 4 Intradermal Observations of Positive Group - Polar

Group	Animal No.	Injection Site	Immediately		(24±2) h		(48±2) h		(72±2) h		Average score
			Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	
Polar	2204	T1	0	0	4	2	4	3	4	3	6.7
		T2	0	0	4	2	4	3	4	3	
		T3	0	0	4	2	4	3	4	3	
		T4	0	0	4	2	4	3	4	3	
		T5	0	0	4	2	4	3	4	3	
		C1	0	0	0	0	0	0	0	0	0.0
		C2	0	0	0	0	0	0	0	0	
		C3	0	0	0	0	0	0	0	0	
		C4	0	0	0	0	0	0	0	0	
		C5	0	0	0	0	0	0	0	0	
	2205	T1	0	0	4	3	4	4	4	4	7.6
		T2	0	0	4	3	4	4	4	4	
		T3	0	0	4	3	4	4	4	4	
		T4	0	0	4	2	4	4	4	4	
		T5	0	0	4	3	4	4	4	4	
		C1	0	0	0	0	0	0	0	0	0.0
		C2	0	0	0	0	0	0	0	0	
		C3	0	0	0	0	0	0	0	0	
		C4	0	0	0	0	0	0	0	0	
		C5	0	0	0	0	0	0	0	0	
	2206	T1	0	0	4	4	4	4	4	4	8.0
		T2	0	0	4	4	4	4	4	4	
		T3	0	0	4	4	4	4	4	4	
		T4	0	0	4	4	4	4	4	4	
		T5	0	0	4	4	4	4	4	4	
		C1	0	0	0	0	0	0	0	0	0.0
		C2	0	0	0	0	0	0	0	0	
		C3	0	0	0	0	0	0	0	0	
		C4	0	0	0	0	0	0	0	0	
		C5	0	0	0	0	0	0	0	0	
The total mean score for test sample (T)											7.4
The total mean score for blank control (C)											0.0
The final score=The total mean score for test sample (T) - The total mean score for blank control (C)											7.4

Note: The recent data of positive control came from 26030134-007253 (Completed date: 2026-06-29).

9.5. Attached Table 5 Intradermal Observations of Positive Group - Non-polar

Group	Animal No.	Injection Site	Immediately		(24±2) h		(48±2) h		(72±2) h		Average score
			Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	
Non-polar	2204	T6	0	0	4	2	4	4	4	4	7.3
		T7	0	0	4	2	4	4	4	4	
		T8	0	0	4	2	4	4	4	4	
		T9	0	0	4	2	4	4	4	4	
		T10	0	0	4	2	4	4	4	4	
		C6	0	0	0	0	0	0	0	0	0.0
		C7	0	0	0	0	0	0	0	0	
		C8	0	0	0	0	0	0	0	0	
		C9	0	0	0	0	0	0	0	0	
		C10	0	0	0	0	0	0	0	0	
	2205	T6	0	0	4	2	4	4	4	4	7.3
		T7	0	0	4	2	4	4	4	4	
		T8	0	0	4	2	4	4	4	4	
		T9	0	0	4	2	4	4	4	4	
		T10	0	0	4	2	4	4	4	4	
		C6	0	0	0	0	0	0	0	0	0.0
		C7	0	0	0	0	0	0	0	0	
		C8	0	0	0	0	0	0	0	0	
		C9	0	0	0	0	0	0	0	0	
		C10	0	0	0	0	0	0	0	0	
	2206	T6	0	0	4	4	4	4	4	4	7.3
		T7	0	0	4	4	4	4	4	4	
		T8	0	0	4	4	4	4	4	4	
		T9	0	0	3	2	4	3	4	3	
		T10	0	0	4	2	4	2	4	3	
		C6	0	0	0	0	0	0	0	0	0.0
		C7	0	0	0	0	0	0	0	0	
		C8	0	0	0	0	0	0	0	0	
		C9	0	0	0	0	0	0	0	0	
		C10	0	0	0	0	0	0	0	0	
The total mean score for test sample (T)											7.3
The total mean score for blank control (C)											0.0
The final score=The total mean score for test sample (T) - The total mean score for blank control (C)											7.3

Note: The recent data of positive control came from 26030134-007253 (Completed date: 2026-06-29).

9.6. Attached Table 6 Weigh Change and Clinical Observation of Positive Group

Animal No.	Weight (g)		Clinical Observation Except Intradermal Reactions
	Test Begin	Test End	
2204	2290.3	2342.8	Normal
2205	2184.1	2219.2	Normal
2206	2258.6	2327.4	Normal

Note: The recent data of positive control came from 26030134-007253 (Completed date: 2026-06-29).

……End of the Report……