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CNAS L3940

Final Report

Animal irritation test

by intracutaneous (intradermal) administration

B-S2025-090528E-102

Test Article: **Light-curing resin (surgical guides, trays)**

Sponsor:

Name: Shenzhen Zhongchuang Medical Group Co., Ltd

Address: Room 204, Administration Building, Jia Tai Pharmaceutical, No.1 Industrial Zone, Tangwei Community, Fuhai Street, Bao'an District, Shenzhen City

Manufacturer:

Name: Shenzhen Zhongchuang Medical Group Co., Ltd

Address: Room 204, Administration Building, Jia Tai Pharmaceutical, No.1 Industrial Zone, Tangwei Community, Fuhai Street, Bao'an District, Shenzhen City

四川省医疗器械生物材料和制品检验中心有限公司 检验专用章

Sichuan Testing Center for Biomaterials and Medical Devices Co., Ltd.

Supplementary Explanation

1. The report is invalid without the special inspection seal of inspection body and laboratory and the signature of the approving person.
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4. The data and conclusions in this report are the inspection results of the items tested in the sample.
5. The results and name of the institution of the report shall not be used for advertising, evaluation and commercial publicity without the written approval.

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Statement of Quality Assurance Activities

This study has been reviewed in accordance with the provisions of the ISO/IEC 17025:2017. Based on a review of this study, it has been concluded that this report accurately describes the methods and standard operating procedures, and that the report results accurately reflect the raw data of the study.

Phase Inspected	Date inspected	Auditor	Date reported to Management
Test	2025-09-19	Liping Zheng	2025-09-19
Report generation	2025-09-30	Lifang Jia	2025-09-30

Wen Zou

QA Representative: Wen Zou

2025-11-07

Date:

1. Summary

The test article was evaluated for intracutaneous reactivity in accordance with the standard of the ISO 10993-23: 2021 Biological evaluation of medical devices Part 23: Tests for irritation.
The test article and the solvent controls (polar and non-polar) were topically injected into the intradermal of three rabbits. The sites were graded for dermal erythema and oedema at 0h, 24h, 48h, and 72h after injected. Data of the time points at 24h, 48h, and 72h were used for calculation and evaluation.
Under the conditions of this study, the final test article score for polar extract was 0.8 and the final test article score for non-polar extract was 0.0, all less than 1.0. The requirement of the ISO 10993-23 intracutaneous reactivity test was met by the test result.

Study and Supervisory

Personnel: **Liaochuan Wang**
Zhirong Liu
Liping Zheng

Study supervisor: lifang Jia
Lifang Jia

Director: Jie Liang — 2025-11-07
Jie Liang — **Date Completed**

This report is authorized by signatures above.

Sichuan Testing Center for Biomaterials and Medical Devices Co., Ltd.

2. Introduction

2.1 Purpose

The purpose of this study was to determine the potential effect for intracutaneous application of the test article extract to irritate skin of the rabbit.

2.2 Testing Guidelines

Biological evaluation of medical devices Part 23: Tests for irritation. (ISO 10993-23: 2021)
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: 2022)

2.3 Dates

Test Article Received:	2025-09-15
Intracutaneous Injection:	2025-09-22
Observation Ended:	2025-09-25

3. Compliance

Sichuan Testing Center for Biomaterials and Medical Devices Co., Ltd. has been accredited by China National Accreditation Service for Conformity Assessment (CNAS L3940). Our inspection body and laboratory is also a testing institution licensed by the Sichuan Provincial Department of Science and Technology for the use of experimental animals (SYXK (川) 2023-0017).

4. Materials

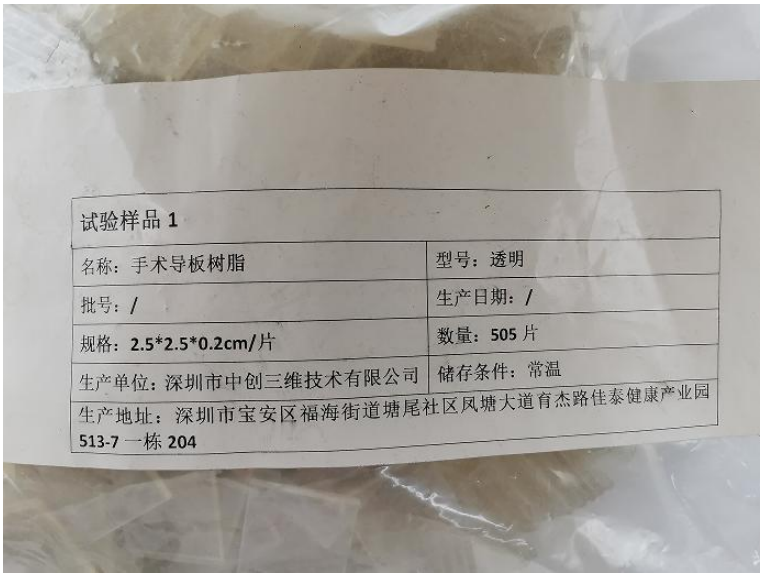
4.1 Test article

Test Article:	Light-curing resin (surgical guides, trays) (Fig.1)
Sample Serial No:	S2025-090528
Specification:	2.5*2.5*0.2cm/unit
Model：	Transparent; blue
Batch:	/
Physical State:	See test article image
Storage Conditions:	Room temperature

The above test article information was provided by the sponsor. The sponsor is responsible for all test article characterization data.


S2025-090528

A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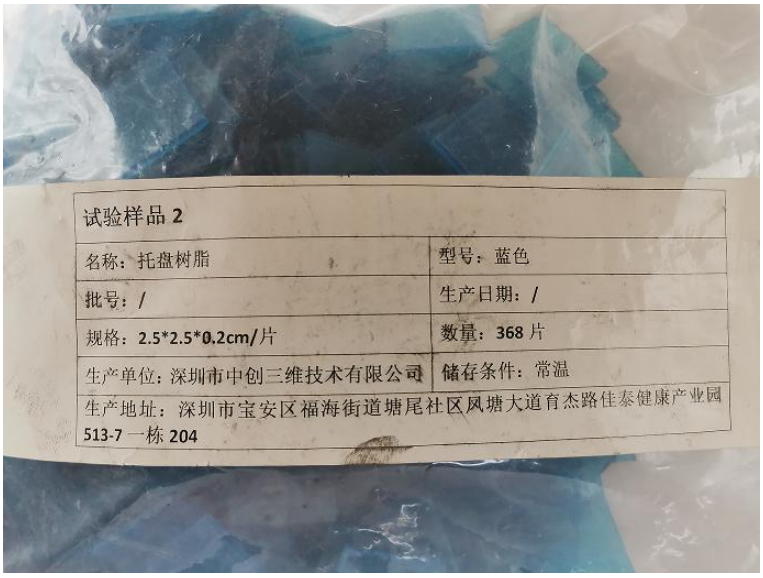
型号：透明
批号：/
生产日期：/
规格：2.5*2.5*0.2cm/片
数量：505 片
生产单位：深圳市中创三维技术有限公司
储存条件：常温
生产地址：深圳市宝安区福海街道塘尾社区凤塘大道育杰路佳泰健康产业园 513-7 一栋 204

B


S2025-090528

C



D

Fig.1. Photograph of the sample. A. The test sample for use 1; B. Sample label 1; C. The test sample for use 2; D. Sample label 2.

4.2 Polar solvent control

Name:	0.9% sodium chloride injection
Manufacturer:	Sichuan Medcalo Pharmaceutical Co., Ltd.
Model:	500mL
Batch:	25052612
Color	Colorless
Physical State:	Liquid
Storage Conditions:	Room temperature

4.3 Non-polar solvent control

Name:	Cottonseed oil
Manufacturer:	Hebei J&K superfine materials Co., Ltd.
Model:	2.5L
Batch:	L5B0Y33
Color	Yellow
Physical State:	Liquid
Storage Conditions:	Room temperature.

5. Identification of test system

Species:	Rabbit.
Breed:	Japanese White.
Number of Animals:	Three.
Sex:	No particular gender was prescribed for this test.
Body Weight Range:	2.2kg, 2.2kg, 2.3kg.
Selection:	Only healthy animals, previously unused and female non-pregnant animals with healthy intact skin were selected.
Source:	Chengdu Xiling Biotechnology Co., Ltd, Permit Code: SCXK（川）

	2024-0048.
Acclimation Period:	3 days- 5 days.
Identification Method:	Label.
IACUC:	This procedure has been approved by the Sichuan Testing Center for Biomaterials and Medical Devices Co., Ltd. Institutional Animal Care and Use Committee, and is reviewed at least annually by the same committee.

6. Justification of test system

The rabbit is specified as an appropriate animal for evaluating potential dermal reaction by the current ISO standards. The rabbit is widely used for this purpose and relative ranking of irritant scores and the average scores difference of test article and control can be determined.

7. Test system management

Husbandry:	Conditions conformed to the standard of ISO 10993-2: 2022 Biological evaluation of medical devices part 2: Animal welfare requirements.
Feed:	Breeding farm for Institute of laboratory animals of sichuan academy of medical sciences and sichuan provincal people's hospial. Permit Code: SCXK（川）2020-003.
Water:	Freely available water was delivered through an automatic water system.
Contamination:	Reasonably expected contaminations in feeding stuffs or water supply did not have the potential to influence the outcome of this test.
Housing:	Animals were housed in groups in stainless steel suspended cages identified by a card, indicating the lab number, animal numbers, test code, sex, animal code, date and dosed.
Environmental:	The room temperature was monitored daily. The room temperature range was 19℃-22℃. The room humidity was monitored daily. The humidity range was 50%-55%. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Personnel:	Associates involved were appropriately qualified and trained.

8. Test design

8.1 Sample Preparation

According to the request of the sponsor, two color samples were extracted at a 1:1 ratio. After calculation, the surface area of each sample of both colors was 14.5 cm².

Vehicle	Extraction Ratio	Amount	Volume of Vehicle	Extraction Condition
Polar	3cm²/mL	58.0cm²	19.3mL	37℃, 72h, 60rpm
Non-polar	3cm²/mL	58.0cm²	19.3mL	37℃, 72h, 60rpm

Solvent Control: The extraction vehicle was prepared in the same way.

The condition of extracts:

Vehicle	Extract	Condition of Extracts		
		Color	Clarity	Particulates
Polar	Test	Colorless	Clear	None
	solvent control	Colorless	Clear	None
Non-polar	Test	Yellow	Clear	None
	solvent control	Yellow	Clear	None

Note: The extracts were tested immediately following extraction. The extracts were not centrifuged, filtered, or otherwise altered prior to using.

8.2 Test Procedure

4h prior to treatment, the fur on each rabbit's back was clipped with an electric clipper. On the time of treatment, 20 sites were designated on each rabbit. 10 on each side of the back were located cranial to caudal. The assignment of the injection points showed as the Fig.2. The sites were free of blemishes that could interfere with the interpretation of results.

0.2mL test article extract liquid was injected into each test site (intradermal inject, Showed in Fig.2) with a 2mL injector (5# needle). The distance between each site was 1cm at least. The solvent control was similarly injected into the control sites by another injector that showed in Fig.2.

The dermal responses for erythema and oedema were observed and recorded at 0h, 24h, 48h, and 72h after injected in accordance with the scoring system for intracutaneous (intradermal) reaction of ISO 10993-23: 2021 (Tab.1). Data of the time points at 24h, 48h, and 72h were used for calculation and evaluation.

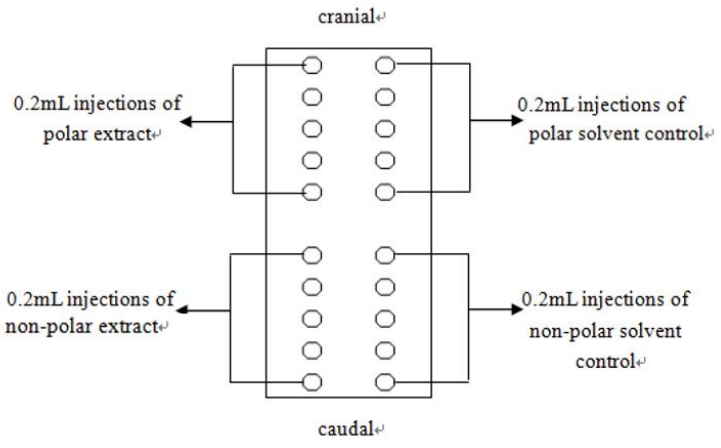


Fig.2. Arrangement of injection sites.

Tab.1. Scoring system for intracutaneous (intradermal) reaction

Reaction	Numerical grading
Erythema and eschar formation	
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-definite 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.	

9. Evaluation of results

After the 72h grading, all erythema grades plus oedema grades 24h, 48h and 72h are totalled separately for each test article or solvent control for each individual animal. To calculate the score of a test article or solvent control on each individual animal, divide each of the totals by 15 (3 scoring time points × 5 test or solvent control sample injection sites). To determine the overall mean score for each test article and each corresponding solvent control, add the scores for the three animals and divide by three. The final test article score can be obtained by subtracting the score of the solvent control from the test article score. The requirements of the test are met if the final test article 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.

10. Results

Under the conditions of this study, individual results of intradermal reactions scoring appear in Tab. 2 and Tab.3.

Tab.2. Intradermal reaction for polar extract at each time interval

Animal Number	Immediately after the injection			
	Test article		Solvent control	
	ER*	ED**	ER	ED
1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
2	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
3	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
Animal Number	24h			
	Test article		Solvent control	
	ER	ED	ER	ED
1	1+1+1+1+1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
2	1+1+1+1+1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
3	1+1+0+1+1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
Animal Number	48h			
	Test article		Solvent control	
	ER	ED	ER	ED
1	1+1+1+1+1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
2	1+1+1+1+1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
3	0+1+0+1+1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
Animal Number	72h			
	Test article		Solvent control	
	ER	ED	ER	ED
1	1+0+1+1+1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
2	1+1+0+1+1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
3	0+1+0+1+1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0

The overall mean score*** for polar extract of the test article = (38+0)/ (15×3) =0.8.

The overall mean score for polar solvent control = (0+0)/ (15×3) =0.0.

The final test article score for polar extract = 0.8-0.0=0.8.

*: ER for erythema.

**: ED for oedema.

***: Overall mean score=Total (ER+ED) divided by 45 (3 grading periods × 5 sites × 3 animals)

Tab.3. Intradermal reaction for non-polar extract at each time interval

Animal Number	Immediately after the injection			
	Test article		Solvent control	
	ER	ED	ER	ED
1	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
2	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
3	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0	0+0+0+0+0
Animal Number	24h			
	Test article		Solvent control	
	ER	ED	ER	ED
1	1+1+1+1+1	1+1+1+1+1	1+1+1+1+1	1+1+1+1+1
2	1+1+1+1+1	1+1+1+1+1	1+1+1+1+1	1+1+1+1+1
3	1+1+1+1+1	1+1+1+1+1	1+1+1+1+1	1+1+1+1+1
Animal Number	48h			
	Test article		Solvent control	
	ER	ED	ER	ED
1	1+1+1+1+1	0+0+0+0+0	1+1+1+1+1	0+0+0+0+0
2	1+1+1+1+1	0+0+0+0+0	1+1+1+1+1	0+0+0+0+0
3	1+1+1+1+1	0+0+0+0+0	1+1+1+1+1	0+0+0+0+0
Animal Number	72h			
	Test article		Solvent control	
	ER	ED	ER	ED
1	1+1+1+1+1	0+0+0+0+0	1+1+1+1+1	0+0+0+0+0
2	1+1+1+1+1	0+0+0+0+0	1+1+1+1+1	0+0+0+0+0
3	1+1+1+1+1	0+0+0+0+0	1+1+1+1+1	0+0+0+0+0

The overall mean score for non-polar extract of the test article = (45+15) / (15×3) =1.3.

The overall mean score for non-polar solvent control = (45+15) / (15×3) =1.3.

The final test article score for non-polar extract =1.3-1.3=0.0.

Results apply only to the test article tested. No further evaluation of these results is made by. Any extrapolation of these data to other samples is the responsibility of the sponsor.

11. Conclusion

Under the conditions of this study, the final test sample scores for polar and non-polar extracts were less than 1.0. The requirement of the ISO 10993-23 intracutaneous reactivity test was met by the test result.

12. Quality assurance

The study has been performed according to standard operating procedures and standard protocols. Inspections were conducted at intervals adequate to assure the integrity of the study in compliance with ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. The final report was reviewed for conformance to the section 7.8 of ISO/IEC 17025: 2017.

13. Deviation

This experiment was conducted according to ISO 10993-23: 2021 Biological evaluation of medical devices Part 23: Tests for irritation without deviation.

14. Record Storage

All raw data pertaining to this study and a copy of the final report are to be retained in designated archive files in our inspection body and laboratory.