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ISO/IEC 17025
TESTING LABORATORY
AT-1894

Test Facility

Weihai Desheng Technology Testing Co., Ltd.

Building 6, No. 369 Shuangdao Road, Torch Hi-Tech Industrial Development Zone, Weihai, Shandong, China

264200

Client

HEXETATE TECHNOLOGY CO., LTD.

Room 6101-E3, CITIC Plaza, No.233 Tianhe North Road Tianhe District, Guangzhou, China

Test Report

Skin Irritation Test of HEXETATE 3.0

Sample Name

HEXETATE 3.0

Report ID

M2026060405E-03

Contents

Summary

The test article, HEXETATE 3.0, Lot: 20260524001, was extracted in sodium chloride injection and sesame oil. The test articles were evaluated for irritation based on the requirement of ISO 10993-23:2021 Biological evaluation of medical device – Part 23: Tests for irritation.

Dropped 0.5 mL of the extract onto a 2.5 cm × 2.5 cm absorbent gauze pad and applied it on both sides of the animal's back. At the same time, applied the gauze pad soaked in the extraction vehicles to the remaining positions on both sides of the animal's back. The application sites were covered with a bandage (semi-closed or closed) for a minimum of 4 h. Removed the patch and marked the contact site. Removed the residual test material by washing with warm water, and then wiped it dry. The contact sites were observed and scored at (1 ± 0.1) h, (24 ± 2) h, (48 ± 2) h and (72 ± 2) h after removal of the applications.

Under the conditions of the test, the test article caused no skin irritation to rabbits. The test article met the test requirements.

Study and supervisory personnel: Ruyi Xiao Fei Wang Zhuangzhuang Ma Yaran Ji

Editor Peixiang Liu — Date: 2026.07.28

Reviewer Peng Jiang — Date: 2026.07.28

Approver Luyu Wang — Date: 2026.07.28

1. Introduction

Purpose

The test article identified below was extracted and the extracts were evaluated for the potential to cause skin irritation to rabbits. This study was conducted based on the requirement of ISO 10993-23:2021 Biological evaluation of medical device – Part 23: Tests for irritation.

Date

The test article was received on June 04, 2026. The test article was prepared on June 18, 2026. The animals were applied on June 24, 2026, and the observations were conducted on June 24, 25, 26 and 27, 2026.

Compliance

The laboratory meets the requirement of international standard ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. The China National Accreditation Service for Conformity Assessment accreditation No. is CNAS L8240. The ANSI National Accreditation Board (ANAB) Accreditation Certification No. is AT-1894.

2. Material

2.1 Sample Identification

The test sample and its source information are provided by the client. The laboratory is responsible for the conformity status of the tested items on the sample. The representativeness and authenticity of the submitted sample are the responsibility of the entrusting party.

Test Sample Name:	HEXETATE 3.0
Test Sample Identification:	M2026060405
Manufacturer:	HEXETATE TECHNOLOGY CO., LTD.
Manufacturer Address:	Room 6101-E3, CITIC Plaza, No.233 Tianhe North Road

	Tianhe District, Guangzhou, China
Model:	7cm×17cm
Lot:	20260524001
Manufacturing Date:	2025/05/23
Expiration Date:	2030/05/23
Stability Testing:	Not supplied by the sponsor
Strength, Purity and Composition:	Sponsor selects not to provide this information to Desheng and takes full responsibility for this data and can supply this information if requested to do so.
Status:	Bagged, Intact
Sterilization State:	Non-sterilized
Physical Description:	Solid
Storage Condition:	Room temperature
Test Sample Handing:	Disposed by laboratory

2.2 Testing Preparation

Test Part:	HEXETATE 3.0-PMMA RESIN SHEET
Vehicles:	Polar: Sodium chloride injection (SC); Non-polar: Sesame oil (SO).
Preparation:	Took the test article under aseptic conditions and placed in a closed inert container. Added vehicles in a ratio of 3 cm^2/mL. The test articles were agitated for extraction at 50°C for 72 hours. The extraction vehicles without test article were similarly prepared to serve as solvent control.

Condition of Extracts:	Test	Control
SC:	clear	clear
SO:	clear	clear

pH of Extracts:	Test	Control

SC: 6 6

Positive Control: Sodium dodecyl sulfate was selected as positive control. The concentration was 15%.

The state of the extracts did not change before and after the extraction. They shall be used for testing within 24h after extraction. The extracts were not processed by filtration, centrifugation, dilution or other methods, and their pH values were not changed.

3 Test System

3.1. Test System Management

The test animal system, equipment and reagent used in this study were identified as following:

Table 1 Table of animal system

Species:	Albino Rabbit
Breed:	New Zealand
Source:	Beijing Jinmuyang Experimental Animal Breeding Co., Ltd.
Sex:	Male
Body Weight Range:	2.7 kg-2.9 kg (standard requirements: not less than 2kg)
Age:	Young adult
Acclimation Period:	Minimum 5 days
Number of Animals:	Six
Identification Method:	Ear tag The animal was identified according to SOP-MD-6.6-DW-006 Standard Operating Procedure for Test Animal Number and Identification.

Table 2 Table of Equipment

Equipment	Model Number	Identification Number	Calibration Validity
Electronic platform scale	TCS-30	SW-YS-3204	2026/09/24
Pipettor	100-1000μL	SW-YS-522	2026/10/28
Vertical sterilizer	LMQ.C	SW-YS-3214	2026/10/07
Cleaning bench	SJ-CJ-2FD	SW-YS-3034	2027/03/25
Steel ruler	300 mm	SW-YS-657	2026/11/30
Multilayer constant temperature shaker	TH2-B2-3	SW-YS-3075-2	2026/07/27
Medicine cool cabinet (Refrigerated cabinet)	YP-680YL/LC	SW-YS-3145	2027/03/27
Pipette	(2~20) mL	SW-YS-4163	2027/05/31

Table 3 Table of Reagents

Reagent	Lot	Model	Manufacturer	Storage Condition
Sodium chloride injection	B25121702B	500 mL:4.5 g	Shandong Kelun Pharmaceutical Co., Ltd.	RT
Sesame oil	20251205M1	1L	Zhejiang Tianyushan Medicinal Oil Co., Ltd.	RT
Magenta	/	25 g	Xi'an Tianmao Baoding Biotechnology Co., Ltd.	RT

3.2. Justification of Test System

The irritation test in albino rabbits is specified in the ISO 10993-23:2021 testing standards and has been used historically to evaluate biomaterial.

The positive challenge is conducted every three months to ensure the sensitivity and reliability of experimental technique. The experimental results are summarized in Appendix 1.

3.3. Animal Management

Husbandry:	Conditions conformed to Standard Operating Procedures that are based on Guide for the Care and Use of Laboratory Animals.
Food:	A commercially available feed from SPF (Beijing) Biotechnology Co., Ltd. was provided daily.
Water:	Potable water was provided *ad libitum* through species appropriate water container.
Contaminants:	Reasonably expected contaminants in feed or water supplies did not have the potential to influence the outcome of this test, complying with the requirements of the internal procedure SOP-MD-6.6-DW-008 "Standard Operating Procedures for Monitoring Laboratory Animal Feed, Bedding and Drinking Water".
Housing:	Animals were housed alone in stainless steel cages identified by a card indicating the testing ID, animal number, sex and treatment date.
Environment:	The room temperature was monitored daily. The temperature for the room was within a range of 20°C-22°C. The room humidity was monitored daily. The relative humidity range for the room was 30%-65%. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, previously unused animals were selected, females should be nulliparous and non-pregnant.
Sedation Analgesia or Anesthesia:	Sedation, analgesia or anesthesia was not necessary during the routine course of this procedure.

Veterinary Care: In the unlikely event that an animal becomes injured, ill, or moribund, care shall be conducted in accordance with current veterinary medical practice. If warranted for human reason, euthanasia shall be conducted in accordance with Standard Operating Procedure. The objective of the study will be given due consideration in any decision and the study sponsor will be advised.

IACUC: This procedure has been approved by Desheng Institutional Animal Care and Use Committees (IACUC), and is reviewed at least annually by the same committees. Any significant changes to this procedure shall be approved by the IACUC prior to conduct.

4. Method

4.1. Preparation of animals

Removed the back fur on both sides of animals' spines (an area approximately 10 cm×15 cm) within 4 h to 24 h prior to test for application and observation of all test sites.

4.2. Application of extracts and extract vehicle

Dropped 0.5 mL of the extract onto a 2.5 cm × 2.5 cm absorbent gauze pad and applied it on both sides of the animal's back as shown in Figure 1. At the same time, applied the gauze pad soaked in the extraction vehicles to the remaining positions on both sides of the animal's back as shown in Figure 1. The application sites were covered with a bandage (semi-closed or closed) for a minimum of 4 h. Removed the patch and marked the contact site with 0.5% magenta. Removed the residual test material by washing with warm water, and then wiped it dry.

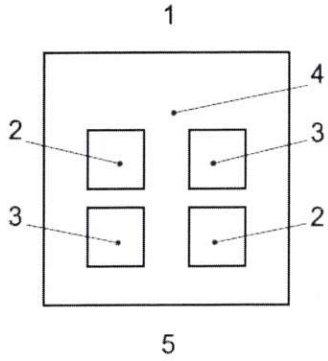


Figure 1 Location of skin application sites

1- cranial end; 2- test site; 3- control site; 4- clipped dorsal region; 5- caudal end.

4.3. Observation of animals

The skin reactions for erythema and oedema were described and scored according to the scoring system given in Table 4, for each contact site at each time interval. The appearance of each contact site was observed and recorded at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h after removal of the applications.

Table 4 Scoring system for skin reaction

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

5. Evaluation and Statistics

Only (24±2) h, (48±2) h and (72±2) h observations were used for calculations and evaluation. The score of each animal was calculated by adding the primary irritation score of erythema and edema caused by the test material at each specified time and dividing by the sum 6 (2 test sites, 3 observation time) of all the scores. To obtain the primary irritation index for the test sample, all the primary irritation scores of the individual animals were added and divided by the number of animals. The primary irritation score of the control site was calculated by the same method. The primary irritation score of the test material was subtracted from the score of the control group to obtain the primary irritation score. This value was the primary irritation index. The cumulative irritation index was compared with the categories of irritation response given in Table 5.

Table 5 Primary or cumulative irritation index categories in a rabbit

Mean score	Response category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

6. Results

Clinical Observations: None of the animals in study showed abnormal clinical signs during the 72 hours test period after removal of the applications.

Dermal Observations: At all observation time points, no abnormal reactions were observed in the skin at the application site. The final scores of (24±2) h, (48±2) h and (72±2) h are presented in Table 6. The detail information is included in Appendix 2.

Table 6 Calculation of the primary irritation index and final result

Time interval	SC						SO					
	Test			Control			Test			Control		
	2671	2672	2673	2671	2672	2673	2674	2675	2676	2674	2675	2676
(24±2) h	0	0	0	0	0	0	0	0	0	0	0	0
(48±2) h	0	0	0	0	0	0	0	0	0	0	0	0
(72±2) h	0	0	0	0	0	0	0	0	0	0	0	0
A1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
A2	0.0			0.0			0.0			0.0		
PII	0.0						0.0					
Response category	Negligible						Negligible					

Note: A1 is the primary irritation score for an animal that calculated by dividing the sum of all the scores by 6.
A2 is obtained by adding all the primary irritation scores of the individual animals and divided by the number of animals.

7. Conclusion

Under the conditions of this study, the test article caused no skin irritation to rabbits. The test article met the test requirements.

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

8. Records

All raw data pertaining to this study and a copy of the final report were retained in designated Desheng archive files.

9. References

- ISO 10993-23:2021 Biological evaluation of medical device – Part 23: Tests for irritation
- ISO 10993-12:2021 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

10. Protocol Changes

The study followed standard procedures without any methodological modifications during the test.

11. Abnormal Conditions

No abnormalities were observed during the test.

Appendix 1 Positive Challenge Result

Schedule 1 Calculation of the primary irritation index and final result of positive control

Time interval	Group					
	Test			Control		
	2482	2483	2484	2482	2483	2484
(24±2) h	8	8	8	0	0	0
(48±2) h	8	8	8	0	0	0
(72±2) h	7	6	6	0	0	0
Total	23	22	22	0	0	0
A1	3.8	3.7	3.7	0.0	0.0	0.0
A2	3.7			0.0		
PII	3.7					
Response category	Moderate					

Note: A1 is the primary irritation score for an animal that calculated by dividing the sum of all the scores by 6.

A2 is the primary irritation score of the test item or control item, which shall be obtained by summing all individual primary irritation scores of each animal and dividing the aggregate sum by the total number of test animals.

The data of positive control comes from Desheng (No.: M2026061609E-01).

Date of positive test: June 17, 2026 to June 21, 2026

Appendix 2 Testing Results

Schedule 1 Results of scores for sodium chloride

Group	No.	Sites	SC							
			(1±0.1) h		(24±2) h		(48±2) h		(72±2) h	
			ER	OE	ER	OE	ER	OE	ER	OE
Test	2671	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0
	2672	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0
	2673	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0
Control	2671	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0
	2672	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0
	2673	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0

Note1: ER: Erythema, OE: Oedema

Note 2: L-left, R-right

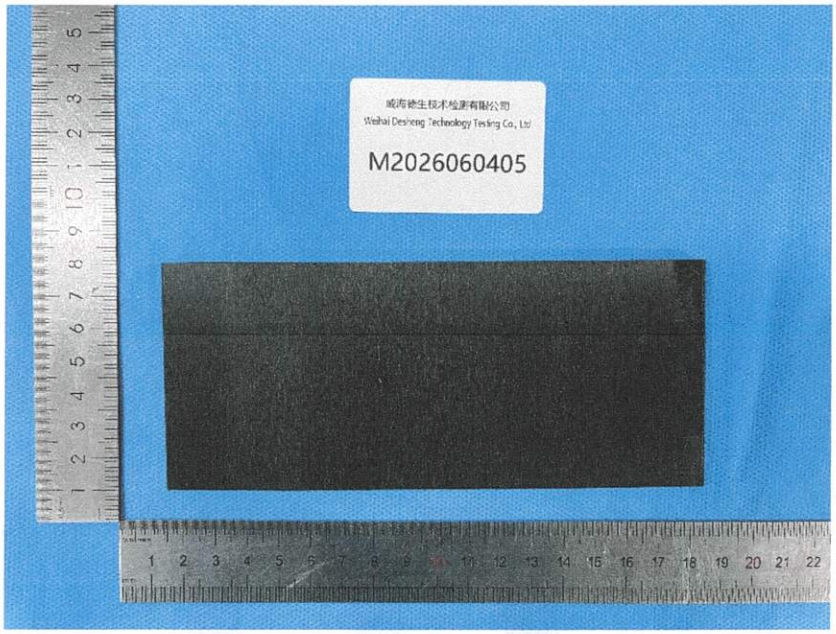
Schedule 2 Results of scores for sesame oil

Group	No.	Site	SO							
			(1±0.1) h		(24±2) h		(48±2) h		(72±2) h	
			ER	OE	ER	OE	ER	OE	ER	OE
Test	2674	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0
	2675	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0
	2676	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0
Control	2674	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0
	2675	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0
	2676	L	0	0	0	0	0	0	0	0
		R	0	0	0	0	0	0	0	0

Note1: ER: Erythema, OE: Oedema

Note 2: L-left, R-right

Appendix 3 Photo of Test Article



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