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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 Sensitization Test (Guinea Pig Maximization Test) of HEXETATE 3.0

Sample Name

HEXETATE 3.0

Report ID

M2026060405E-02

Contents

Summary

The test sample, HEXETATE 3.0, Lot: 20260524001, was extracted in sodium chloride injection and sesame oil. The extracts were evaluated the sensitization based on the requirements of ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization.

Each extract was intradermally injected and patched to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and patched to five control guinea pig (per vehicle). Following a recovery period, the test and control animals received a challenge patch of the appropriate test sample extract and reagent control. Remove the dressings and patches after (24±2) h. All sites were scored at (24±2) and (48±2) hours after patch removal.

Under the conditions of this study, the guinea pig showed no sensitization reaction after the induction of test extracts and the positive rate is 0%. There was no evidence that the test sample extracts would cause sensitization on guinea pig.

Study and supervisory personnel: Ruyi Xiao Fei Wang Fang Lu Yuanwei Wang Yifan Li

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 sample identified below was extracted and the extracts were evaluated the potential to cause sensitization following guinea pig maximization test. This study was conducted based on the requirement of ISO 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization.

Date

The test sample was received on June 04, 2026. The test sample was prepared on June 15, 2026. Intradermal induction, topical induction and challenge were done on June 18, 2026, June 24, 2026 and July 10, 2026 respectively. The observations were conducted on July 12 and 13, 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:

	Intradermal induction	Topical induction	Challenge
SC Test:	clear	clear	clear
SC Control:	clear	clear	clear

	SO Test:	clear	clear	clear
	SO Control:	clear	clear	clear
pH of Extracts:		Intradermal induction	Topical induction	Challenge
	SC Test:	6	6	6
	SC Control:	6	6	6

Positive Control: 2, 4-dinitrochlorobenzene was selected as positive control.

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 reagents used in this study were identified as following:

Table 1 Table of animal system

Species:	Albino Guinea pig
Breed:	Hartley
Source:	Beijing Jinmuyang Experimental Animal Breeding Co., Ltd.
Sex:	Male
Body Weight Range:	339.4 g-445.4 g at injection (standard requirements: 300g～500g)
Age:	Young adult
Acclimation Period:	5 days
Number of Animals:	Thirty
Identification Method:	Chemical Staining Method 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 balance	YP50001	SW-YS-186	2026/07/16
Carbon Dioxide Euthanasia Chamber	CL-1000L	SW-YS-3068	/
Pipettor	100-1000μL	SW-YS-522	2026/10/28
Electronic balance	YP502	SW-YS-375	2026/10/10
Vertical sterilizer	LMQ.C	SW-YS-3214	2026/10/07
Cleaning bench	SJ-CJ-2FD	SW-YS-3034	2027/03/25
Cleaning bench	SJ-CJ-2FD	SW-YS-201	2027/03/25
Steel ruler	300 mm	SW-YS-657	2026/11/30
Multilayer constant temperature shaker	TH2-B2-3	SW-YS-3075-1	2026/07/27
Multilayer constant temperature shaker	TH2-B2-3	SW-YS-3075-2	2026/07/27
Multilayer constant temperature shaker	TH2-B2-3	SW-YS-3102-2	2026/10/28
Medicine cool cabinet (Refrigerated cabinet)	YP-680YL/LC	SW-YS-3145	2027/03/27
Pipette	(1~10) mL	SW-YS-4162	2027/05/31
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
Freund's Complete Adjuvant	0000546958	F5881-10 mL	SIGMA	4°C

Table 3 Table of Reagents(continue)

Reagent	Lot	Model	Manufacturer	Storage Condition
Sodium dodecyl sulfate	20250618	500g	Xi'an Tianmao Baoding Biotechnology Co., Ltd.	RT

3.2. Justification of Test System

The albino 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 and specified in the ISO 10993-10:2021 testing standards.

Per OECD 406, the sensitivity and reliability of experimental technique are assessed every three months by use of substances which are known to have mild-to moderate skin sensitization properties. In a properly conducted test, a response of at least 30 % in an adjuvant test is expected for mild/moderate sensitizer. The Dermal Reaction of Positive Challenge is 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 in group 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-23°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: Associate 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 became injured, ill, or moribund, care was conducted in accordance with current veterinary medical practice. If warranted for human reason, euthanasia was 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 were approved by the IACUC prior to conduct.

4. Method

On the first day of treatment, fifteen guinea pigs per extract (ten for test, five for control) were

weighted and identified. The fur over the dorsoscapular region was removed with an electric clipper.

4.1. Intradermal Induction Phase

The test animals were injected with the test sample extract and the control animal were injected with the control vehicle. Three rows of the intradermal injections (two per row) were given to each animal with an approximate 2 cm × 4 cm boundary of the fur clipped area as illustrated below:

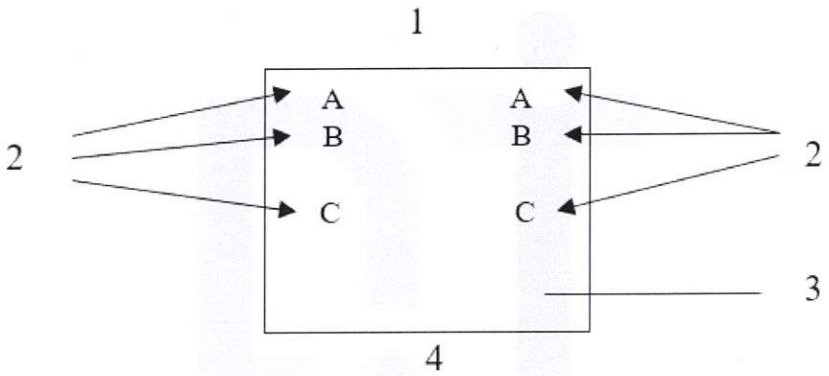

Figure 1 location of intradermal injection sites

1-cranial end; 2-0.1 mL intradermal injections; 3-clipped intrascapular region; 4-caudal end

Control animals:

A. 0.1 mL of 50:50 (v/v) mixture of FCA and the extraction vehicle.

B. 0.1 mL of control vehicle.

C. 0.1 mL emulsifier wich was the control vehicle (concentration selected for site B) emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the extraction vehicle.

Test animal:

A. 0.1 mL of 50:50 (v/v) mixture of FCA and the extraction vehicle.

B. 0.1 mL of test extract.

C. 0.1 mL emulsifier wich was the test extract (concentration selected for site B) emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the extraction vehicle.

4.2. Topical Induction Phase

Prior to conducting the topical induction phase, the fur over the dorsoscapular region was removed with an electric clipper. The area was left uncovered.

At 5 days after completion of the intradermal induction phase, the maximum concentration that can be achieved in 4.1 does not produce irritation, pretreat the area with 10 % sodium dodecyl sulfate massaged into the skin.

At 6 days after completion of the intradermal induction phase, 2 cm × 4 cm section of absorbent gauze patch, saturated with of freshly prepared 1.0 mL test sample extract, was then topically applied to the previously injected sites of the test animals. Each patch was secured with a nonreactive tape and the trunk of each animal was wrapped with bandage. At (48±2) hours, the binders and patches were removed.

4.3. Challenge Phase

At 14 days after unwrapping the topical induction phase wraps, the fur was removed from the upper flank areas with an electric clipper. The 2 cm × 2 cm absorbent gauze patch was saturated with 0.5 mL test sample. Each site was patched for the challenge phase. The control animals were similarly patched. Each patch was secured to the skin. The trunk of each animal was wrapped with bandage to maintain well-occluded sites. At (24±2) hours, the wraps and patches were removed and any residue remaining at the sites was removed.

4.4. Observation

Observations and scores for dermal reactions were conducted at (24±2) h, (48±2) h after challenge patch removal. If necessary, the fur was clipped from each site to facilitate scoring. Scoring was recorded in accordance with the criteria shown below:

Table 4 Grading system for reactions

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

5. Evaluation and Statistics

Grades of 1 or greater in the test group generally indicated sensitization, provided grades of less than 1 are seen in the control animals. If grades of 1 or greater were noted in control animals, then the reactions of test animals which exceeded the most severe reaction in control animals are presumed to be due to sensitization. The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

If the test group has a greater number of animals showing a response than the control, although the intensity of the reaction is not greater than the exhibited by the control. 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.

6. Results

All animals appeared normal throughout the study. All injection sites appeared normal immediately following injection. Results of scores for individual animals appear in Table 5.

Table 5 Dermal Reaction of Challenge

Group	SC					SO				
	Animal Number	* Weight /g	Score (24±2) hours	Score (48±2) hours	Positive Rate%	Animal Number	* Weight /g	Score (24±2) hours	Score (48±2) hours	Positive Rate%
Test	1	384.8	0	0	0	16	390.0	0	0	0
	2	367.6	0	0		17	384.9	0	0	
	3	354.7	0	0		18	339.4	0	0	
	4	377.1	0	0		19	374.6	0	0	
	5	378.9	0	0		20	378.7	0	0	
	6	364.0	0	0		21	359.1	0	0	
	7	385.9	0	0		22	360.0	0	0	
	8	390.1	0	0		23	387.4	0	0	
	9	380.4	0	0		24	406.5	0	0	
	10	373.4	0	0		25	402.1	0	0	
Control	11	357.0	0	0	0	26	390.2	0	0	0
	12	350.4	0	0		27	374.5	0	0	
	13	381.0	0	0		28	349.7	0	0	
	14	415.4	0	0		29	415.2	0	0	
	15	399.2	0	0		30	445.4	0	0	
Note: *is the weight of the animals at intradermal induction phase.										

7. Conclusion

Under the conditions of this study, the guinea pig showed no sensitization reaction after the induction of test extracts and the positive rate is 0%, there was no evidence that the test sample extracts would cause sensitization on guinea pig. Results and conclusions apply only to the test

sample tested. No further evaluation of these results is made by Desheng. Any extrapolation of these data to other samples is 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 10993-10:2021 Biological evaluation of medical devices – Part 10: Tests for skin sensitization
- 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 Dermal Reaction of Positive Challenge

Group	Animal Number	*Weight /g	Score		Positive Rate%
			(24±2) h	(48±2) h	
Test	1	444.8	2	1	100
	2	396.8	1	1	
	3	442.5	2	1	
	4	391.5	2	1	
	5	473.9	2	2	
	6	402.3	2	1	
	7	347.1	1	1	
	8	442.6	1	1	
	9	460.1	2	1	
	10	426.1	1	1	
Control	11	419.8	0	0	0
	12	378.5	0	0	
	13	428.2	0	0	
	14	420.0	0	0	
	15	429.8	0	0	

Note 1: *is the weight of the animals at intradermal induction phase.

Note 2: The data of positive control come from Desheng (No.: M2026031412E)

Date of positive test: March 20, 2026 to April 16, 2026.

Note 3: 2.4-Dinitrochlorobenzene:

Inducing concentration: 0.5%, Challenge concentration: 0.1%

Appendix 2: Photo of Test Sample

*****End of Report******