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检测
TESTING
CNAS L 10463

Test Report

Report Number: 25111081-04-R02EN

Sponsor: Changzhou Dreure Medical Material Co., Ltd.

Factory: Changzhou Dreure Medical Material Co., Ltd.

Sample Name: Ultra Clean Autoclave Bag/ Roll Bag

Model/ Specification: /

Test Category: Commission Test

EPINTEK Suzhou Ltd.

苏州爱谱质量技术服务有限公司 检验检测专用章

Declaration

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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 Suzhou Ltd.
Test Report

Report Number: 25111081-04-R02EN

Sample Name	Ultra Clean Autoclave Bag/ Roll Bag	Sample ID	25111081
Model/ Specification	/		
Sponsor	Changzhou Dreure Medical Material Co., Ltd.		
Address	No.7 Jinhua Road, Wujin Economic Development Zone, Changzhou, Jiangsu, China.		
Factory	Changzhou Dreure Medical Material Co., Ltd. / No.7 Jinhua Road, Wujin Economic Development Zone, Changzhou, Jiangsu, China.		
Test Facility	EPINTEK Suzhou Ltd.		
Test Category	Commission Test	Lot/Batch#	S20251114
Produced Date	/	Sample Quantity	8 PCS
Received Date	2025-11-17	Test Date(s)	2025-11-22 to 2025-12-19
Test Item(s)	Skin Sensitization Test		
Test Method(s)	ISO 10993-10: 2021 Biological evaluation of medical devices-Part 10: Tests for skin sensitization.		
Conclusion	The Skin Sensitization Test results of the tested articles met the standard requirements. (Stamp for Test Report) Issued Date: 2025-12-30		
Note	"NA" means "not applicable", "/" means "blank"		

Approved By: Look Lu

Look Lu

Position: Authorized Signatory

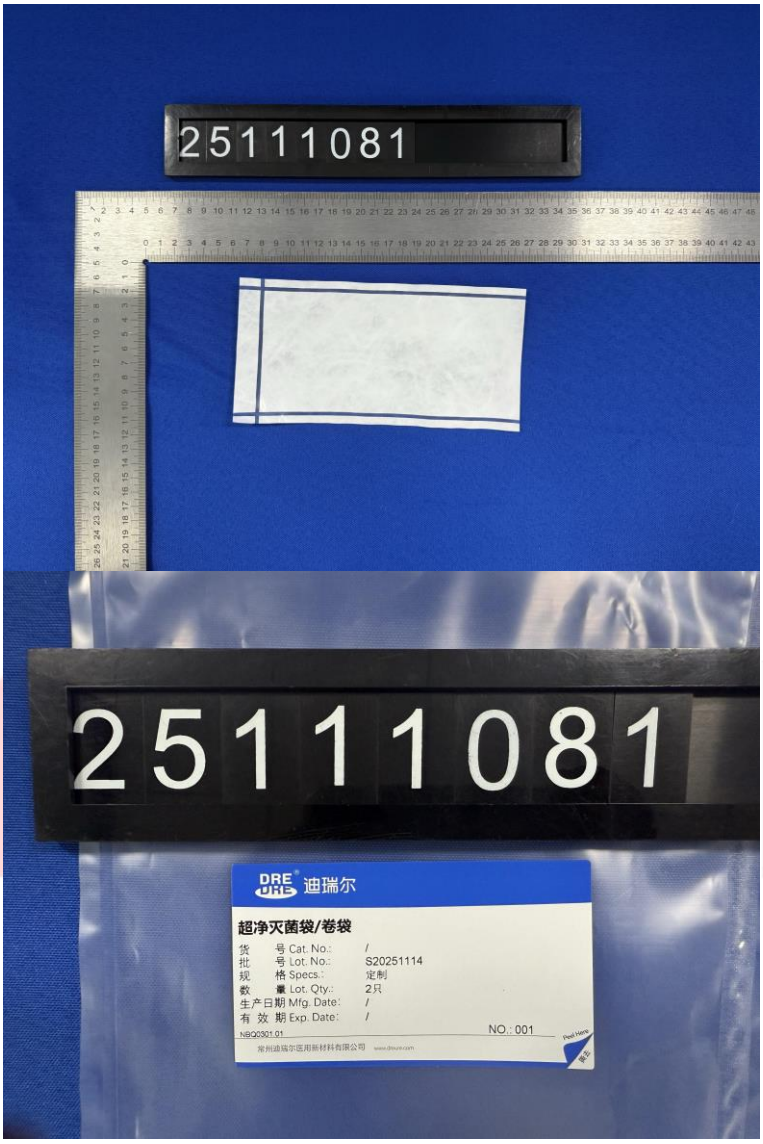
EPINTEK Suzhou Ltd.
Test Report

Report Number: 25111081-04-R02EN

No.	Item	Standard Method	Acceptance Criteria	Test Result	Conclusion	Note
1	Skin Sensitization Test	ISO 10993-10: 2021	The grades of less than 1 are seen in the test group, or 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 were observed in all animals except dermal reactions.	Met the standard	Shown in Annex.
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苏州检验检测专用章

Report Number: 25111081-04-R02EN

Picture & Introduction

Description for Sample, Model/Specification
Initial State: Unsterilized Intended Clinical Usage: / (The information of sample hereby are provided by the sponsor.)
Misc
/

Test Report

Animal Test - Skin Sensitization Test

Sponsor: Changzhou Dreure Medical Material Co., Ltd.

Sample Name: Ultra Clean Autoclave Bag/ Roll Bag

Model/ Specification: /

Sample Amount for this test: 360 cm^2

Lot/Batch#: S20251114

EPINTEK Suzhou Ltd.

SUMMARY

1. Purpose

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

2. Process Description

The test article was sterilized by high pressure steam sterilization (121℃/30min) and random sampled (Two materials sampled in equal proportions) and extracted by 6 cm^2/mL, extraction condition was 50℃ 72h. Extraction solvents were 0.9% Sodium Chloride (SC) and Sesame Oil (SO).

A pair of 0.1 mL intradermal injections was made into each animal in the clipped intrascapular region. At 6 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 negative control animals similarly, used the negative liquid alone. If the test article extracts did not produce irritation, pretreated the area with 10% sodium dodecyl sulfate massaged into the skin (24±2) h before the patch was applied.

At 15 d after completion of the topical induction phase, challenged all animals with the test extract 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 dermal reactions for erythema and oedema according to the Magnusson and Kligman grading.

3. Results

The grades of less than 1 were 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 were observed in all animals except dermal reactions.

4. Conclusion

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

Edited by: Colin Lu

Colin Lu

Checked by: Patryk Chen

Patryk Chen

1. STUDY SUMMARIES

1.1. Study Name (Study No.)

Ultra Clean Autoclave Bag/ Roll Bag - Skin Sensitization Test (25111081-006901)

1.2. Study Purpose

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

1.3. Testing Facility

Name:	EPINTEK Suzhou Ltd.
Address:	Floors 1-3, West side of Building A2; Floors 1-4, Building 4; Floor 5, Building 3. No. 558, Fenhu Avenue, Lili Town, Wujiang District, Suzhou, China

1.4. Sponsor

Name:	Changzhou Dreure Medical Material Co., Ltd.
Address:	No.7 Jinhua Road, Wujin Economic Development Zone, Changzhou, Jiangsu, China.
ATTN:	Wenqing Shi
Contact Information:	+86 152 9518 5667 / wenqing.shi@dreure.com

1.5. Study Alteration Treatment

Before the study start, the study protocol was approved by Study Director and Sponsor. Any study alteration should be approved by Study Director.

1.6. Deviation(s) and Incident(s) Treatment

If any deviation or incident occurred during the test, the related information would be recorded timely and a deviation report should be submitted with the final report to interpretative the specific effect(s) on the final result caused by the deviation or incident.

1.7. Major Laboratory Personnel

Study Director:	Patryk Chen
Main Operation Personnel:	Otto Wang, Betty Liu

1.8. Schedule of the Study

Protocol Effective Date:	/
Test Start Date:	2025-11-22
Test Completion Date:	2025-12-19
Report Completion Date:	2025-12-23

2. CONTROL AND TEST SYSTEM CONFIRMATION

2.1. Negative Control

2.1.1. Polar control information (SC)

Name:	0.9% Sodium Chloride (SC)
Lot/ Batch#:	2508032A
Physical State:	Colorless Liquid
Manufacturer:	Double-Crane Pharmaceutical

2.1.2. Non-polar control information (SO)

Name:	Sesame Oil (SO)
Lot/ Batch#:	20240802M3
Physical State:	Light yellow oily liquid
Manufacturer:	Shanxi Jinyang

2.2. Positive Control

Denomination:	2, 4-Dinitrochlorobenzene (DNCB)
Content:	98%
Lot/ Batch#:	237329
Physical State:	Pale yellow solid
Manufacturer:	Sigma
Induction Concentration:	0.5%
Challenge Concentration:	0.1%

2.3. Animal

2.3.1. Animal use license

Application scope:	Barrier Environment (SPF grade: Mouse, Rat, Hamster, Guinea pig, Rabbit)
Animal Use License#:	SYXK(Su)2024-0063
Application scope:	General Environment (General grade: Hamster, Guinea pig, Rabbit)
Animal Use License#:	SYXK(Su)2021-0084

2.3.2. Animal information

Species:	Hartley Guinea Pig
Microbial Levels:	Conventional
Number/Sex:	30/Male
Weight:	Weighting 300 g to 500 g at the start of the test
Manufacturer:	FMC Laboratory Animals Inc.
Production License#:	SCXK(Zhe)2024-0012
Quality Certificate#:	20251107Cdzz06000000081

2.3.3. Animal feeding conditions

Rearing Density:	5 animals per cage
Cages:	Plastic cage
Animal Identification:	Stain with marker and identified by a cage card
Acclimation Period:	At least 5 days under the same conditions as for the actual test
Fodder:	Name: Guinea pig Growth and Reproduction Formula Feed
	Manufacturer: KEAO XIELI FEED CO., LTD
	Daily 40 g quantitative uptake per animal
Padding:	Name: Corn cob
	Manufacturer: KEAO XIELI FEED CO., LTD
	Periodic replacement
Water:	Barreled 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
Electronic Balance	EPB-690	2026-06-10
Constant temperature vibrator	EPB-311	2026-05-13
Clean Bench	EPB-598	2026-06-10

2.4.2. Main reagents

Name	Lot/ Batch#	Manufacturer
Freund's Complete Adjuvant (FCA)	SLCK7708	Sigma
Sodium Dodecyl Sulfate (SDS)	C17557563	Macklin

2.5. Justification of the 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. 2, 4-Dinitrochlorobenzene (DNCB) is recommended as the positive substance by guiding principle. 2, 4-Dinitrochlorobenzene (DNCB) has been substantiated at EPINTEK Suzhou LTD once every 3 months with this method. The recent data of positive control came from 25081853-010649 (Completed Date: 2025-12-08). **See Attached Table 3~4.**

3. TEST DESIGN

3.1. Extract Preparation

3.1.1. Extraction process[1)]

Samples were sterilized by high pressure steam sterilization (121℃/30min) and taken under sterile conditions and prepared as follows.

Test phase	Sampling Manner	Actual Sampling	Ratio	Solvent	Amount	Conditions
Intradermal induction	Random (Two materials sampled in equal proportions)	60 cm^2	6 cm^2/mL	SC	10.0 mL	50℃ 72h 60 rpm
		60 cm^2	6 cm^2/mL	SO	10.0 mL	50℃ 72h 60 rpm
Topical induction		60 cm^2	6 cm^2/mL	SC	10.0 mL	50℃ 72h 60 rpm
		60 cm^2	6 cm^2/mL	SO	10.0 mL	50℃ 72h 60 rpm
Challenge		60 cm^2	6 cm^2/mL	SC	10.0 mL	50℃ 72h 60 rpm
		60 cm^2	6 cm^2/mL	SO	10.0 mL	50℃ 72h 60 rpm

1) The vehicle (without the test article) was similarly prepared to serve as the negative control, the extraction process was dynamic.

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	Not	Not	Colorless and clear
SO	Not	Not	Light yellow and Clear

1) Used the final extracts immediately.

3.2. Grouping

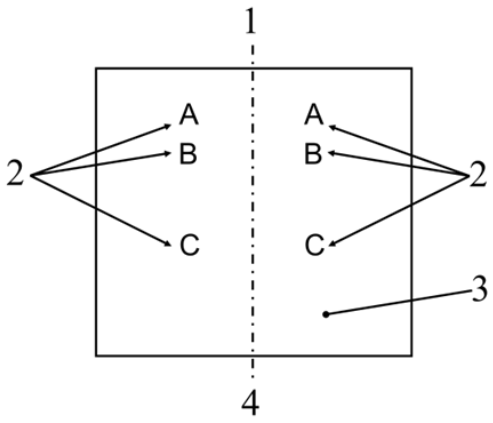
Took 30 guinea pigs and divided them into four groups.

Group No.	Group Name	Amount	Sex	Numbered list	Animal Temporary Number
1	Negative control (SC)	5	♂	1101-1105	♂: K 761~K 790
2	Test group (SC)	10	♂	2106-2115	
3	Negative control (SO)	5	♂	3116-3120	
4	Test group (SO)	10	♂	4121- 4130	

3.3. Experimental Process

3.3.1. Intradermal induction phase I

A pair of 0.1 mL intradermal injections was made for each of the following, into each animal, at the injection sites (A, B and C) 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 solvent.

Site B: The test article extract, the negative control animals were injected with the solvent alone.

Site C: The test article extract, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent (50%), the negative control animals were injected with an emulsion of the negative liquid with adjuvant.

Figure 1 Location of intradermal injection sites

3.3.2. Topical induction phase Ⅱ

At 6 d after completion of the intradermal induction phase, administered the test article extract 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 negative control animals similarly, used the negative liquid alone. If the test article extract did not produce irritation, pretreated the area with 10% sodium dodecyl sulfate massaged into the skin (24±2) h before the patch was applied.

3.3.3. Challenge phase

At 15 d after completion of the topical induction phase, challenged all animals with test article extract 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

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. Full-spectrum lighting was used to visualize the dermal reactions. Described and graded the dermal reactions for erythema and oedema according to the Magnusson and Kligman grading given in **Table 1** for each challenge site and at each time interval.

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 dermal reactions were observed every day. Weighting all the test animals at the beginning and end of the test.

4. EVALUATION CRITERION

1) 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.
2) 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.
3) If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge.
4) 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.
5) The outcome of the test is presented as the frequency of positive challenge results in test and control animals.

5. ALTERATION AND DEVIATION

There were no changes and deviations of technical parameters that affect the experimental results.

6. RESULTS

The grades of less than 1 were 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 were observed in all animals except dermal reactions.
See Attached Table 1~2.

7. CONCLUSION

Under the conditions of this study, test article 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 Suzhou Ltd.

9. ATTACHED TABLE

9.1. Attached Table 1 Sensitization Dermal Reactions

Group	Animal Number	(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	Test	Control	Test	Control	
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)	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 (SO)	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 (SO)	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 Number	Weight (g)		Clinical Observation except Dermal Reactions
		Test Begin	Test End	
Negative control (SC)	1101	308.60	372.18	Normal
	1102	324.79	434.78	Normal
	1103	340.86	394.23	Normal
	1104	336.11	378.55	Normal
	1105	317.16	376.22	Normal
Test group (SC)	2106	335.84	429.12	Normal
	2107	334.08	418.77	Normal
	2108	327.17	382.41	Normal
	2109	331.65	414.00	Normal
	2110	345.06	421.42	Normal
	2111	321.04	477.84	Normal
	2112	328.15	376.51	Normal
	2113	339.31	399.69	Normal
	2114	326.05	432.76	Normal
	2115	319.84	428.75	Normal
Negative control (SO)	3116	319.51	392.90	Normal
	3117	353.89	374.93	Normal
	3118	337.81	371.06	Normal
	3119	312.48	395.93	Normal
	3120	326.34	385.63	Normal
Test group (SO)	4121	328.26	441.84	Normal
	4122	341.19	405.19	Normal
	4123	343.27	441.75	Normal
	4124	315.82	427.96	Normal
	4125	334.18	374.55	Normal
	4126	342.55	421.10	Normal
	4127	323.12	395.26	Normal
	4128	345.04	403.06	Normal
	4129	325.20	406.57	Normal
	4130	337.55	327.06	Normal

9.3. Attached Table 3 Sensitization Dermal Reactions of Positive Group

Group	Animal Number	(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	Test	Control	Test	Control	
Negative control	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	0	0	2	0	1	0	100%
	6137	0	0	2	0	2	0	
	6138	0	0	1	0	1	0	
	6139	0	0	2	0	2	0	
	6140	0	0	1	0	2	0	

Note: The data of positive control came from 25081853-010649 (Completed Date: 2025-12-08).

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

Group	Animal Number	Weight (g)		Clinical observation except dermal reactions
		Test began	Test end	
Negative control	5131	372.90	459.35	Normal
	5132	458.99	528.54	Normal
	5133	418.61	528.30	Normal
	5134	411.78	494.81	Normal
	5135	354.63	440.15	Normal
Positive control (DNCB)	6136	435.02	531.88	Normal
	6137	344.86	419.98	Normal
	6138	327.72	415.02	Normal
	6139	369.34	473.73	Normal
	6140	389.50	477.29	Normal

Note: The data of positive control came from 25081853-010649 (Completed Date: 2025-12-08).

End of Report