

Report No.: REP-26-005234EN-01

Test Report

Sample Name: Medical-grade Poly(L-lacticacid)

Client Name: eSUNMed Biotechnology (Shenzhen)Co.,
Ltd

Client Address: 3F, No.9, Yifeng Hua Innovation Industrial
Park, Xinshi Community Dalang Street,
Longhua District, Shenzhen

Test Items: Skin sensitization test

Date of Issue: 2026.02.28

Shanghai WEIPU Testing Technology Group Co., LTD.

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DECLARE

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Task No.	/	Detection category	Commission test
Sample No.	BP-S-26000622	Sample source	Sent by client
Sample name	Medical-grade Poly(L-lactic acid)	Batch number	PLLA25111102
Specification	PLLA10	Sample quantity	1
Model	PLLA10		
Manufacturer	eSUNMed Biotechnology (Shenzhen)Co., Ltd. Wuhan branch office		
Manufacturer address	Room 401. Building 13 Block B, Donghu Hi-tech International Health City, No. 24,Gold-Industrial-Park Road, Zhengdian Street Jiangxia District, Wuhan		
Client	eSUNMed Biotechnology (Shenzhen)Co., Ltd		
Client address	3F, No.9, Yifeng Hua Innovation Industrial Park, Xinshi Community Dalang Street, Longhua District, Shenzhen		
Receiving date	2026.01.05		
Test location	3rd Floor, Building 7,166-1, Fengjin Road, Fengxian District, Shanghai.		
Test period	2026.01.05 to 2026.02.06		
Test item	Skin sensitization test		
Test criterion	ISO 10993-10: 2021		
Test conclusion	<p>Under the conditions of this experiment, the skin reaction grading of all animals in each period was grade 0, and the positive activation rate of the experimental group was 0%, indicating that the extract of the sample did not produce allergic reaction.</p> <p style="text-align: right;">Date of issue:</p>		
Implementation standard	ISO/IEC 17025: 2017		
Remarks	"/" in the report indicates that this item is blank		
Edited by	Checked by	Approved by (Authorized signatory)	

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1 Objective

The test was designed to evaluate the potential of a test article to cause skin sensitization using Guinea Pig Maximization Test.

2 Test method

Guinea Pig Maximization Test.

3 Test and control samples

3.1 Test samples

The information in the form is provided by the client.

Sample name	Medical-grade Poly(L-lacticacid)
Sterilization state	Unsterilized
Sterilization methods	/
Sample material	/
Application	/

3.2 Control samples

Polar negative control sample: 0.9%NaCl injection		
Manufacturer	Shandong Qidu Pharmaceutical Co., Ltd.	
Specification	500mL/bottle	
Batch No.	15B25061106	
Non-polar negative control: Cottonseed oil		
Manufacturer	Shanghai Macklin Biochemical Technology Co., Ltd	
Specification	13kg/drum	
Batch No.	C17831740	
Positive control sample: 1-Chloro-2,4-dinitrobenzene		
Manufacturer	Shanghai Aladdin Biochemical Technology Co., LTD	
Specification	25g/bottle	
Batch No.	D2420128	
solvent	Absolute ethanol、Watsons water	
Concentration	Intradermal induction phase	0.8%
	Topical induction phase	0.8%
	Challenge phase	0.2%

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4 Reagents and Instrument

4.1 Reagents

Name	Supplier
0.9% sodium chloride injection	Shandong Qidu Pharmaceutical Co., Ltd.
Cottonseed oil	Shanghai Macklin Biochemical Technology Co., Ltd
Complete Freund's Adjuvant	Sigma-Aldrich
SDS	Adamas-Beta®

4.2 Instrument

Name	Instrument ID	Calibration is valid until
Clean bench	WPE-TL0127	2026.09.16
Shaking incubator	WPE-TL0081	2026.09.16
Electronic balance	WPE-TL0029	2026.04.06
pH meter	WPE-TL0394	2026.10.15
Electronic counting scales	WPE-TL0055	2026.04.06

5 Test system

5.1 Test animal selection

The guinea pig is believed to be the most sensitive animal model for this type of study.

5.2 Test animal information

Species	Albino guinea pig
Number	30
Sex	Female
Weight	308~360g
Age	Early adulthood
Health condition	Healthy
Adaptation	5 days
Source	Shanghai Songjiang Chedundongwu Breeding Farm Co., Ltd, License No.: SCXK (Hu) 2022-0001, Quality Certificate No.: 20220001003364

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5.3 Feeding and management

Fodder	Pizhou Xiaohe Technology Development Co., Ltd., license number: Su Feed Certificate (2022) 03058
Bedding	Pizhou Xiaohe Technology Development Co., Ltd., Certificate Number: No.25057003
Water	Free access to water
Cage	Guinea Pig Housing Cage
Environment	General environment, animal room 326, the temperature range of 18~29°C, humidity range of 30~70%
Light	Control cycle light (12 hours light, 12 hours dark)
Veterinary	Give necessary veterinary attention
Raise	The animals were raised in accordance with the “Feeding and management procedures of the experimental animal guinea pig” in our Toxicology laboratory
Certification body	The animal laboratory of this institution shall be certified by Shanghai Laboratory Animal Center, and the certifying authority: Shanghai Municipal Department of Science and Technology. Experimental animal use License No. : SYXK (Hu) 2021-0023
Welfare	The IACUC established by the Institute confirmed that the experiment used a minimum number of animals without affecting the test results, and relevant documents were developed to safeguard animal welfare

6 Experimental content

6.1 Sample preparation

Samples were taken. The extraction solutions were prepared according to the methods listed in the table below. After extraction, the extraction solutions were examined for changes. The non-polar extraction solution was not centrifuged, while the polar extraction solution was centrifuged at 3000 rpm for 10 minutes and then filtered through a 0.22 μm membrane filter, with no pH adjustment performed. Control samples were prepared simultaneously.

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Table 6-1 Preparation of extracts

Extraction solvent	Stage	Actual sample	Sampling ratio	Solvent volume	Sampling condition	Whether it is clear	pH
0.9% NaCl injection	Intradermal induction phase	2.92g	0.2g: 1mL	14.60 mL	37°C 72h 60rpm	Turbid Layering	6.40(Before centrifugation) 6.44(After centrifugation)
	Topical induction phase	2.28g		11.40 mL		Turbid Layering	6.41(Before centrifugation) 6.43(After centrifugation)
	Challenge phase	2.14g		10.70 mL		Turbid Layering	6.44(Before centrifugation) 6.48(After centrifugation)
Cottonseed oil	Intradermal induction phase	3.02g	0.2g: 1mL	15.10 mL	37°C 72h 60rpm	Yes	5.45
	Topical induction phase	2.11g		10.55 mL		Yes	5.45
	Challenge phase	2.07g		10.35 mL		Yes	5.46

6.2 Test procedure

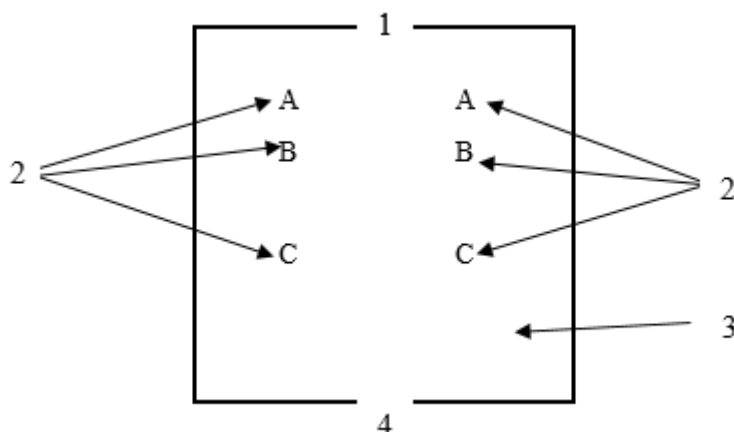
Before the experiment, the guinea pigs are marked and weighed. They are randomly divided into 0.9%NaCl injection test groups and control groups, Cottonseed oil test groups and control groups.

The skin reactions of guinea pigs are observed after 24h and 48h, and the body weight is recorded.

6.2.1 Intradermal induction phase

Make a pair of 0.1 mL intradermal injections of each of the following, into each animal, at the injection sites, as shown in Figure 1, in the clipped intrascapular region.

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1—cranial end; 2—0.1mL intradermal injections; 3—clipped intrascapular region; 4—caudal end; A, B, C—injection sites

Figure 1 — Location of intradermal injection sites

Site A: A stable emulsifier mixed by injection of Freund's complete adjuvant with 0.9%NaCl injection / Cottonseed oil solvent in 50:50 (volume ratio) ratio.

Site B: The test sample (undiluted extract); inject the control animals with the extraction vehicle/solvent alone.

Site C: The test sample at the concentration used at site B, emulsified in a 50:50 volume ratio stable emulsion of Freund's complete adjuvant and the solvent/extraction vehicle; inject the control animals with an emulsion of the blank liquid with adjuvant.

There was no irritation at the test site, and the test area was pretreated with 10% sodium dodecyl sulfate 0.5mL (24±2) h before the application of the local dressing, and massaged into the skin.

6.2.2 Topical induction phase

At (7±1) d after the intradermal induction phase, according to the concentration selected in the intradermal induction site B, using an area of about 8cm² of absorbent gauze was used to saturate the test sample to cover the induced injection point, followed by a single layer. The bandages were covered with cellophane, fixed with non-stimulating tape, and removed after (48±2) hours Patch of application.

6.2.3 Challenge phase

At 14±1d after completion of the topical induction phase, the control animals should be challenged with the undiluted extraction medium, while the test animals should be challenged with the undiluted test sample extract. The local sticker is applied to the unbound site during the induction phase, and then covered with a layer of glass paper, and then fixed with no stimulating tape. After (24±2) h, remove the

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bandaging band and apply the fillet.

6.3 Observation

Observe 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. Describe and grade the skin reactions for erythema and oedema according to the Magnusson and Kligman grading scale for each challenge site and at each time interval.

Table 6-2 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

6.4 Evaluation standard

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. 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. If the response is equivocal, rechallenge is recommended to confirm the results from the first challenge. The outcome of the test is presented as the frequency of positive challenge results in test and control animals. 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 can 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 naïve side on the animal.

7 Test result

The skin reaction grade and positive excitation rate of guinea pigs in this experiment are shown in Table 7-1, and the positive test results are shown in Table 7-2.

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Table 7-1 Result of skin sensitization reaction

Extraction solvent	Group	No.	Weight before test (g)	Weight after test (g)	Challenge phase grade		positive activation rate(%)	
					24h	48h		
0.9%NaCl injection	Control	1101	321	390	0	0	0	
		1102	344	412	0	0		
		1103	315	385	0	0		
		1104	317	380	0	0		
		1105	328	394	0	0		
	Sample	2101	342	418	0	0	0	
		2102	315	389	0	0		
		2103	313	387	0	0		
		2104	354	420	0	0		
		2105	360	423	0	0		
		2106	308	375	0	0		
		2107	322	394	0	0		
		2108	359	423	0	0		
		2109	334	410	0	0		
		2110	318	392	0	0		
	Cottonseed oil	Control	3101	330	401	0	0	0
			3102	345	413	0	0	
			3103	318	389	0	0	
			3104	347	411	0	0	
3105			322	388	0	0		
Sample		4101	350	418	0	0	0	
		4102	314	391	0	0		
		4103	322	394	0	0		
		4104	315	396	0	0		
		4105	347	420	0	0		
		4106	318	398	0	0		
		4107	330	403	0	0		
		4108	356	425	0	0		
		4109	324	397	0	0		
		4110	338	410	0	0		

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Table 7-2 Result of skin sensitization reaction in the positive control group

Group	No.	Weight before test (g)	Weight after test (g)	Challenge phase grade		positive activation rate(%)
				24h	48h	
Positive control	2001	356	420	1	2	100
	2002	337	408	1	2	
	2003	321	401	1	1	
	2004	345	424	2	2	
	2005	352	425	2	2	
	2006	344	427	2	2	
	2007	361	430	1	1	
	2008	314	394	2	2	
	2009	320	398	2	1	
	2010	318	395	1	2	
Remarks	Quote: report of project SHA-j-06-25050609 Test date: 2025.10.16-2025.11.09					

8 Deviations

The test was carried out in strict accordance with the standard operating procedures, and no deviation affecting the validity of the test data occurred.

9 Record Preservation

All raw data and records related to this test and copies of the final report are kept in the archives.

