Report No.: REP-26-003774EN-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:	Intracutaneous reactivity test
Date of Issue:	2026.02.28

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DECLARE

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Organization name: **Shanghai WEIPU Testing Technology Group Co., LTD.**

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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-lacticacid)	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 2026.01.15		
Test item	Intracutaneous reactivity test		
Test criterion	ISO 10993-23:2021		
Test conclusion	Under the test conditions, the final score of the polar extract of the sample was 0.0, and the final score of the non-polar extract was 0.0, which met the test requirements. Date of issue: 2026-02-28		
Implementation standard	ISO/IEC 17025: 2017		
Remarks	"/" in the report indicates that this item is blank		

Edited by	Checked by	Approved by (Authorized signatory)
2026-02-28	2026-02-28	2026-02-28

Catalogue

1 Objective

The relevant animal models are tested in the test for medical devices and materials. The injecting material is performed through the injection of the material to evaluate the potential of intracutaneous reactivity of the material under the test conditions.

2 Test method

Intracutaneous Reactivity 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 Co., Ltd.
Specification	13kg/drum
Batch No.	C17831740
Positive control sample：SDS	
Manufacturer	Adamas-Beta®
Specification	100g/bottle
Batch No.	P1782327

4 Reagents and Instrument

4.1 Reagents

Name	Supplier
0.9%NaCl injection	Shandong Qidu Pharmaceutical Co., Ltd.

Name	Supplier
Cottonseed Oil	Shanghai Macklin Biochemical Co., Ltd.

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 banlance	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 intracutaneous reactivity test of the rabbit's skin is the most sensitive method, and it has been widely used in evaluation of medical equipment/materials.

5.2 Test animal information

Species	New Zealand white rabbit
Number	3
Sex	Male
Weight	2.483~2.618kg
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

5.3 Feeding and management

Fodder	Pizhou Xiaohe Technology Development Co., Ltd. Certificate number: Jiangsu Feed License (2022) 03058
Water	Free access to water
Cage	Suspended stainless steel cage
Environment	General environment, animal room 322, the temperature range of 16~26℃, 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 rabbit” 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

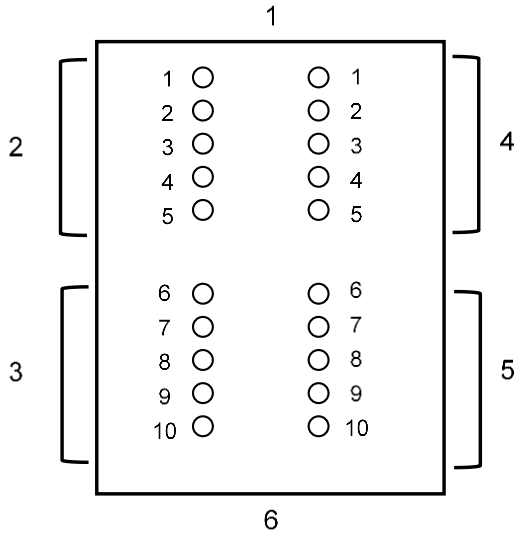
Samples were taken. The extraction solutions were prepared according to the methods listed in the table below. After extraction, the extraction solutions were examined for changes. The non-polar extraction solution was not centrifuged, while the polar extraction solution was centrifuged at 3000 rpm for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

Table 6-1 Preparation of extracts

Extraction solvent	Actually sample	Sampling ratio	Solvent volume	Sampling condition	Whether it is clear	pH
0.9%NaCl injection	2.92g	0.2g:1mL	14.60mL	37℃ 72h 60rpm	Turbid Layering	6.40(Before centrifugation) 6.44(After centrifugation)
Cottonseed Oil	3.02g		15.10mL		Yes	5.45

6.2 Test procedure

Fur was generally clipped and rabbits were weighed 4~18 h before testing on the backs of the rabbits, allowing a sufficient distance on both sides of the spine for injection of the extracts.



1—Cranial end; 2—0.2 ml injections of polar extract; 3—0.2 ml injections of Non-polar extract; 4—0.2 ml injections of polar solvent control; 5—0.2 ml injections of Non-polar solvent control; 6—Caudal end

Figure 1 Arrangement of injection sites

Intracutaneously inject 0.2 mL of polar extract at the first 5 points on the left side of the rabbit's back with appropriate intervals; then, following the same method, inject 0.2 mL of non-polar extract at the last 5 points.

Similarly, inject 0.2mL of the polar or non-polar solvent control on five sites of the contralateral side of each rabbit.

To observe the instant, (24±2) h, (48±2) h and (72±2) h reaction of local and surrounding skin tissue reactions including erythema, edema and necrosis and recorded.

Table 6-2 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-defined by definite raising)	2
Moderate oedema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Other adverse changes at the injection sites were recorded and are reported.	

6.3 Evaluation standard

After the (72±2) h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h are totalled separately for each test sample or blank for each individual animal. To calculate the score of a test sample or blank on each individual animal, divide each of the totals by 15 (3 scoring time points × 5 test or blank sample injection sites). To determine the overall mean score for each test sample and each corresponding blank, add the scores for the three animals and divide by three. The final test sample score can be obtained by subtracting the score of the blank from the test sample score. The requirements of the test are met if the final test sample 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.

7 Test result

Table 7-1 Scores for intracutaneous (intradermal) reaction

Extraction solvent	No.	Results											
		Sample group						Control group					
		24h		48h		72h		24h		48h		72h	
		Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema
0.9% NaCl injection	111	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
	112	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
	113	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
Final test sample score		0											
Cottonseed Oil	111	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
	112	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
	113	0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
		0	0	0	0	0	0	0	0	0	0	0	0
Final test sample score		0											

Table 7-2 Positive sample scores for intracutaneous (intradermal) reaction

Extraction solvent	No.	Results											
		Positive group						Control group					
		24h		48h		72h		24h		48h		72h	
		Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema	Erythema	Oedema
0.9%NaCl injection	101	2	2	3	2	3	3	0	0	0	0	0	0
		2	3	2	3	3	3	0	0	0	0	0	0
		2	2	3	3	3	3	0	0	0	0	0	0
		2	2	3	2	3	3	0	0	0	0	0	0
		2	2	2	2	3	3	0	0	0	0	0	0
	102	2	2	3	3	3	4	0	0	0	0	0	0
		3	2	3	3	3	4	0	0	0	0	0	0
		2	2	2	3	4	3	0	0	0	0	0	0
		2	3	3	3	3	3	0	0	0	0	0	0
		3	3	3	3	3	3	0	0	0	0	0	0
	103	2	2	3	3	3	3	0	0	0	0	0	0
		2	2	3	3	3	3	0	0	0	0	0	0
		2	2	2	3	3	3	0	0	0	0	0	0
		3	2	3	4	4	4	0	0	0	0	0	0
		3	2	3	3	3	4	0	0	0	0	0	0
Final test sample score		5.49											
Cottonseed Oil	101	2	2	3	3	3	3	0	0	0	0	0	0
		2	2	3	3	3	3	0	0	0	0	0	0
		3	3	3	3	3	3	0	0	0	0	0	0
		2	2	2	3	4	3	0	0	0	0	0	0
		2	3	3	3	3	3	0	0	0	0	0	0
	102	2	2	3	3	3	3	0	0	0	0	0	0
		2	2	3	4	3	4	0	0	0	0	0	0
		3	3	3	3	3	3	0	0	0	0	0	0
		3	2	3	3	3	4	0	0	0	0	0	0
		2	3	3	3	3	3	0	0	0	0	0	0
	103	2	3	3	3	3	3	0	0	0	0	0	0
		2	2	3	3	3	3	0	0	0	0	0	0
		3	3	3	3	4	3	0	0	0	0	0	0
		2	3	4	3	3	3	0	0	0	0	0	0
		3	2	3	3	3	3	0	0	0	0	0	0
Final test sample score		5.71											
Remarks		Test date: 2025.10.16 to 2025.10.19 The positive data comes from SHA-j-06-250100056											

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.

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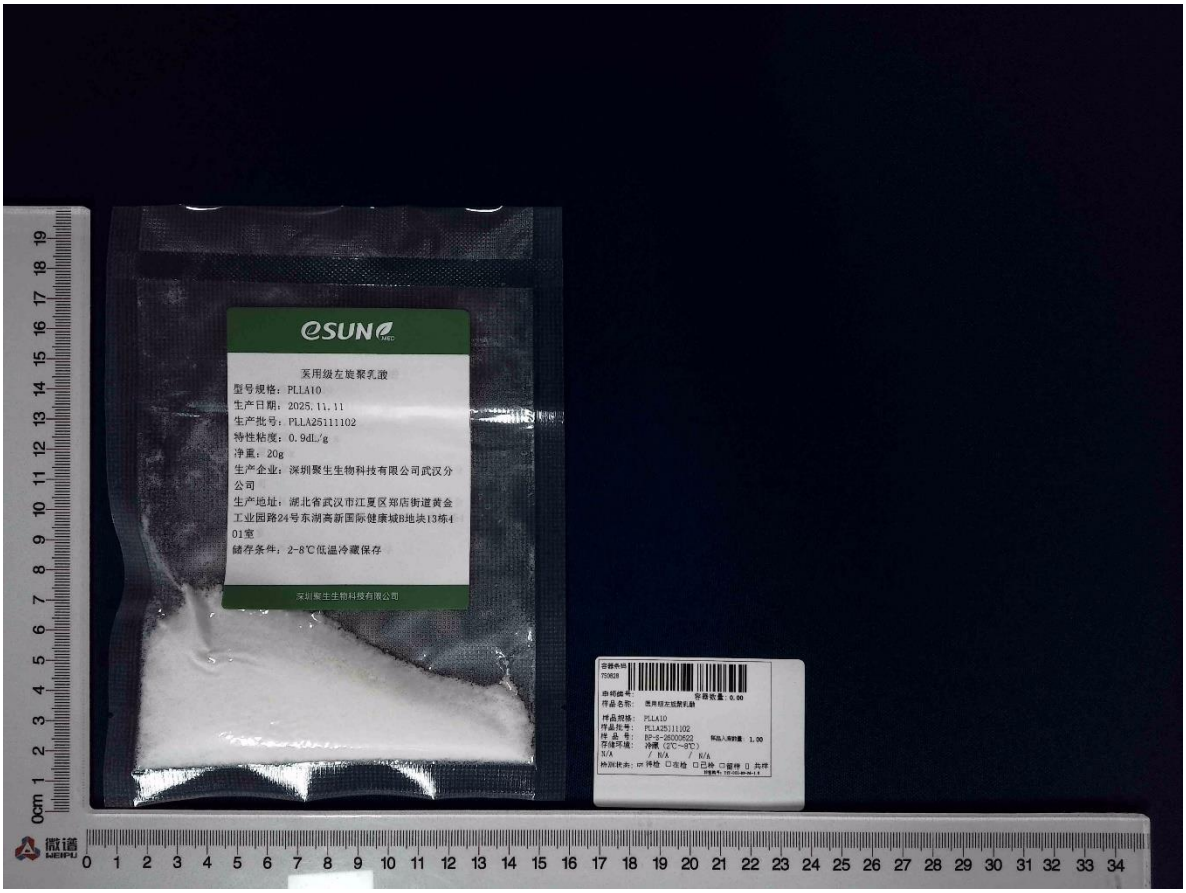
Test report photo page

Photos and descriptions

Test component description
Random Sampling
Model, specification or other description
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***** End of report *****