# Test Report

| | |
|---|---|
| Sample Name: | PLGA |
| 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: | 2025.04.17 |

**Shanghai WEIPU Testing Technology Group Co., LTD.**

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| | | | |
|---|---|---|---|
| Task No. | / | Detection category | Commission test |
| Sample No. | BP-S-25013885 | Sample source | Sent by client |
| Sample name | PLGA | Batch number | PLGA50502411271 0011100 |
| Specification | 50:50 | Sample number | 1pc |
| Model | / | | |
| 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 | 2025.03.05 | | |
| Test location | 3rd Floor, Building 7,166-1, Fengjin Road, Fengxian District, Shanghai | | |
| Test period | 2025.03.05 to 2025.03.14 | | |
| 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.<br>Date of issue: 2025.04.17 | | |
| Implementation standard | ISO/IEC 17025: 2017;<br>RB/T214—2017 | | |
| Remarks | "/" in the report indicates that this item is blank | | |

| Edited by | Checked by | Approved by (Authorized signatory) |
|---|---|---|
| 唐芳<br>Date: 2025.04.17 | 郭和平<br>Date: 2025.04.17 | 张鹏<br>Date: 2025.04.17 |

# 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 | PLGA |
| Sterilization state | Unsterilized |
| Sterilization methods | / |
| Sample material | PLGA |
| Application | / |

### 3.2 Control samples

| | |
|---|---|
| Negative control sample：0.9%NaCl injection | |
| Manufacturer | Shandong Qidu Pharmaceutical Co., Ltd. |
| Specification | 500mL/bottle |
| Batch No. | 15B24051403 |
| Negative control sample：Cottonseed Oil | |
| Manufacturer | Shanghai Macklin Biochemical Co., Ltd. |
| Specification | 13kg/drum |
| Batch No. | C17477820 |
| Positive control sample：SDS | |
| Manufacturer | Adamas-Beta® |
| Specification | 100g/bottle |
| Batch No. | P1880796 |

## 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 | 2025.10.09 |
| Shaking incubator | WPE-TL0081 | 2025.10.09 |
| Electronic balance | WPE-TL0029 | 2025.04.10 |
| pH meter | WPE-TL0394 | 2025.11.20 |
| Electronic counting scales | WPE-TL0055 | 2025.04.10 |

## 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 | 2.210~2.291kg |
| Age | Early adulthood |
| Health condition | Healthy |
| Adaptation | 5 days |
| Source | Jiashan Shengwang Ecological Farm, License number: SCXK（Zhe）2023-0010，Quality Certificate No. : 20250307Cezz06000000053 |

5.3 Feeding and management

| | |
|---|---|
| Fodder | Wuhan Wanqian Jiaxing Biotechnology Co., Ltd., license number: SCXK (E) 2021-0011 |
| 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

Take the sample, the extracts were prepared according to the method in the table below. After the extraction, the changes of the extracts were checked. The extracts were not centrifuged and etc. The pH was not adjusted. Negative control sample was prepared by the same method.

**Table 6-1 Preparation of extracts**

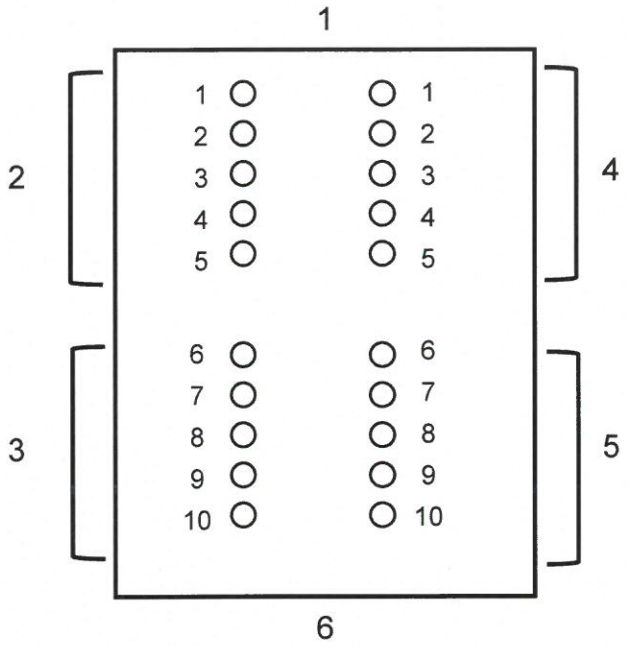
| Extraction solvent | Actually sample | Sampling ratio | Solvent volume | Sampling condition | Whether it is clear | pH |
|---|---|---|---|---|---|---|
| 0.9%NaCl injection | 2.32g | 0.2g: 1mL | 15.31mL[a] | 37℃ 72h 60rpm | Yes | 6.17 |
| Cottonseed Oil | 2.16g | | 12.96mL[b] | | Yes | 5.31 |

a: Sample absorption rate is 1.60mL/g.

b: Sample absorption rate is 1.00mL/g.

### 6.2 Test procedure

Fur was generally clipped and rabbits were weighed 4h~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 |

| 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 | 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 | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 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 | 101 | 3 | 3 | 3 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 3 | 3 | 3 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 3 | 3 | 3 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 2 | 3 | 3 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 2 | 3 | 3 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| 0.9% NaCl injection | 102 | 4 | 3 | 4 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 4 | 3 | 4 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 4 | 3 | 4 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 3 | 3 | 4 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 4 | 3 | 4 | 3 | 4 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 103 | 4 | 2 | 4 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 4 | 2 | 4 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 3 | 3 | 4 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 4 | 2 | 4 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 4 | 3 | 4 | 3 | 4 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| Final test sample score | | 6.64 | | | | | | | | | | | |
| Cottonseed Oil | 101 | 2 | 3 | 3 | 3 | 3 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 2 | 2 | 3 | 3 | 3 | 4 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 2 | 3 | 3 | 3 | 3 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 2 | 2 | 3 | 3 | 3 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 2 | 2 | 3 | 3 | 3 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | 102 | 2 | 2 | 3 | 3 | 3 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 3 | 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 | 3 | 3 | 3 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | 3 | 2 | 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 |
| | | 3 | 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 | 3 | 3 | 3 | 3 | 0 | 0 | 0 | 0 | 0 | 0 |
| Final test sample score | | 5.47 | | | | | | | | | | | |
| Remarks | | Test date: 2024.12.05 to 2024.12.08<br>The positive data comes from SHA-j-06-24110083-01-BC-01 | | | | | | | | | | | |

## 8 Deviations

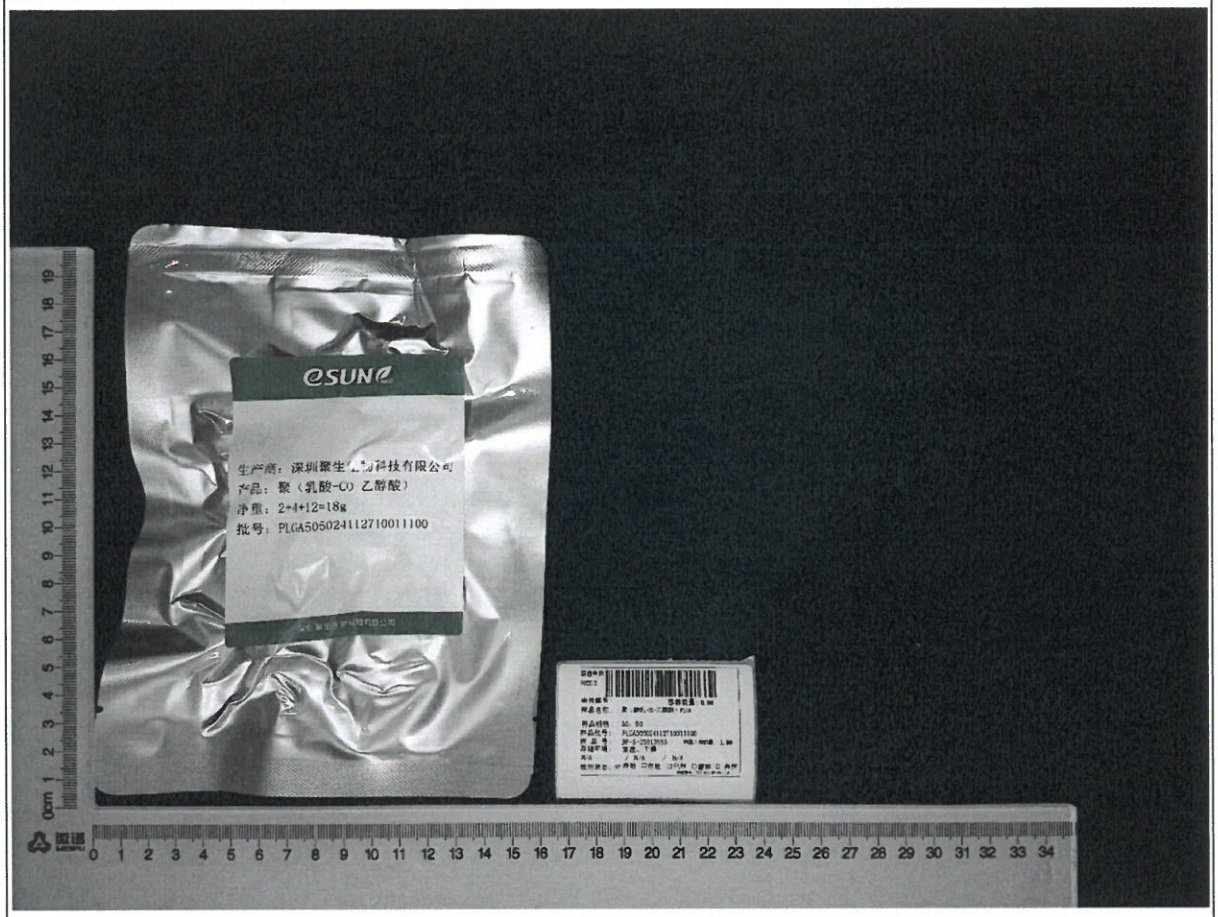
The test was carried out in strict accordance with the standard operating procedures, and no deviation affecting the validity of the test data occurred.

## 9 Record Preservation

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

**Shanghai WEIPU Testing Technology Group Co., LTD.**

# Test report photo page

| Photos and descriptions |
|---|
|  |
| Test component description |
| Random sampling |
| Model, specification or other description |
| / |

***** End of report *****