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Test Report

Report Number: SSMT-R-2020-02364-02B

Sample Name: Sampling swab

Study Title: Intracutaneous Reactivity Test

Standard: ISO 10993-10:2010

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

C4 Building, No.9 Changyang Road, Wujin District, Changzhou, Jiangsu, China

Sponsor

Suzhou Shengtian Biotechnology Co. LTD

F3, B5, No. 35, Dongfu Road, SIP, Suzhou 215123, China

Contents

Explanation

1. Please apply for rechecking within 15 days of receiving the report if there is any objection.
2. Any erasure or without special testing seal renders the report null and void.
3. The report is only valid when signed by the persons who edited, checked and approved it.
4. The result relate only to the articles tested.
5. The report shall not be reproduced except in full without the written approval of the institute.
6. This experiment was carried out in the sub-site and the address is: No. 68, Yaoluo Road, Wujin District, Changzhou City.

Conclusion

The test article was evaluated for intracutaneous reactivity.

The test samples were extracted with 0.9 % sodium chloride injection and sesame oil respectively. The extracts and solvent control were injected intracutaneously in the animals . Record the appearance of each injection site immediately after injection and at 24 h, 48 h and 72 h after injection.

According to what was observed, the response of the polar test extract test group on testing side did not exceed that on the control side, the final test sample score was calculated to be 0. The response of the non-polar test extract test group on testing side did not exceed that on the control side, the final test sample score was calculated to be 0.

The test result showed that the test article did not induce intracutaneous reactivity in rabbit skin under the test condition.

Study verification and signature

The study was carried out in accordance with the standard operating procedure. The test process was conducted in compliance with the requirements of CNAS-CL01:2018 (ISO/IEC17025:2017, IDT) and RB/T214-2017.

Date Received	2020-08-10
Technical Initiation Date	2020-08-24
Technical Completion Date	2020-08-27
Final Report Completion Date	2020-09-15

Edited by Molly 2020.09.15 Date

Checked by Suri 2020.09.15 Date

Approved by Daisy 2020.09.16 Date
Authorized signatory

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

The rabbits were used to evaluate the potential risk of skin irritation caused by test article in this test.

2.0 Reference

Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization(ISO 10993-10:2010)

Biological evaluation of medical devices-Part 12:Sample preparation and reference materials(ISO 10993-12:2012)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (ISO 10993-2:2006)

3.0 Test and control articles

3.1 Test article (The information about the test article was supplied by the sponsor wherever applicable.)

Test article name: Sampling swab

Sterilization state: Sterilized, Irradiation

Model: AR150（main test）, ARY150（main test）, AR100(main test）， AR180, AR105, AR120, AR121,

Size: N/S

Lot/ Batch#: 20200603

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: Plastic rod, nylon

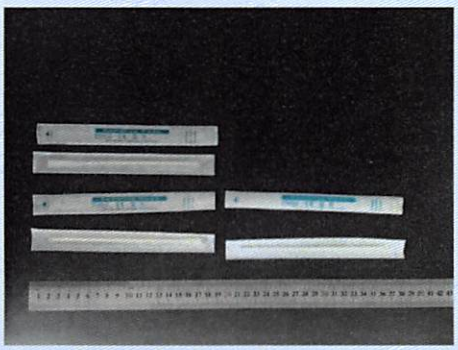
Packing Material: paper-plastic bag

Storage Condition: Room temperature

Manufacturer: Suzhou Shengtian Biotechnology Co. LTD

Manufacturer address: F3, B5, No. 35, Dongfu Road, SIP, Suzhou 215123, China

Sample photograph:



3.2 Control Articles

3.2.1 Polar control sample

Name: 0.9% sodium chloride injection (SC)

Manufacturer: Chenxin Pharmaceutical Co., Ltd.

Size: 250 ml

Physical State: Liquid

Color: Colourless

Lot/ Batch#: 1906112830

Storage Condition: Room Temperature

3.2.2 Non-polar control sample

Name: Sesame Oil (SO)

Manufacturer: Ji'an lvyuanxiangliao. Co., Ltd.

Size: 20 kg

Physical State: Liquid

Color: Light yellow

Lot/ Batch#: 20190516

Storage Condition: Room Temperature

4.0 Identification of test system

Species: New Zealand white rabbit (single strain)

Number: 3

Sex: Female

Weight: Initial body weight not less than 2.0 kg

Health status: Healthy, young adult, nulliparous and not pregnant.

Housing: Animals were housed in groups in cages identified by a card indicating the lab number and test code.

Animal identification: Cage card

The quarantine period: 5 days

5.0 Animal Care and Maintenance

Animal purchase: Provided by Tongxiang Yinhai Animal Husbandry Professional Cooperative <Permit Code: SCXK (ZHE) 2018-0002>

Bedding: NA

Feed: Rabbit Diet, Beijing Keao Xieli Feed Co., Ltd.

Water: Drinking water met the Standards for Drinking Water Quality (GB 5749-2006)

Cages: Stainless steel cage,Suzhou Fengqiao purification equipment Co.,Ltd.

Environment: Temperature 16-26℃, Relative humidity 40%-70%, Lights 12 hours light/dark cycle

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy animals were selected

Veterinarian: Vet takes care of the whole course

Ethics: Test methods of operation were reviewed and approved by the Commission on Science Standard animal ethics

There were no known contaminants present in the feed, water expected to interfere with the test data.

6.0 Justification of the test system

6.1 The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control 10 % sodium dodecyl sulfate has been substantiated at SSMT with this method. Positive control test is conducted every six months. In the last positive control test, the final score was 7.0 (polar test group) and 7.1 (non-polar test group). The data was from the report: SSMT-R-2020-01262-02 (Date: 2020-05-29).

6.2 The test article extract was directly applied to the rabbit skin, which is considered to be the best mean of contact.

7.0 Instruments

Water bath thermostatic oscillator (SSMT-150)

Electronic balance (SSMT-075)

Electronic balance (SSMT-147)

Clean bench (SSMT-187)

8.0 Experiment design and dose

8.1 Sample preparation

The test article was extracted as Table 1. Extract was checked and used immediately after extraction without the process of filtering, centrifugation, dilution, etc. The pH of the extract was not adjusted prior to testing. The preparation process was aseptic. The control article was prepared under the same condition.

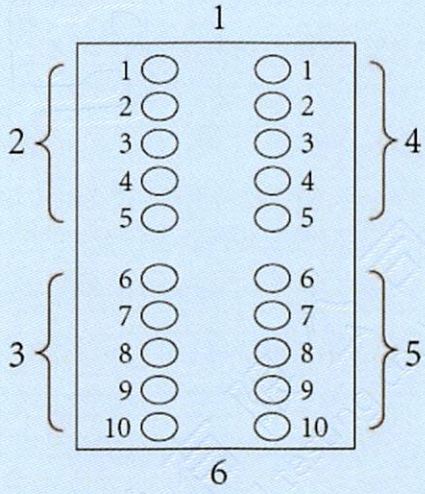
Table 1 Sample Preparation

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container			Final Extract
Sampling Manner	Actually Sampling	Ratio	Solvent	Condition	Clear or Not
Take the whole. Take one sample of AR150, ARY150 and AR100 respectively in every test group.	2.48 g	0.2 g : 1 ml	SC 12.4ml	37 ℃, 72 h	Clear
	2.65 g	0.2 g : 1 ml	SO 13.2 ml	37 ℃, 72 h	Clear

8.2 Test method

Fur was generally clipped 16 h before testing on the backs of the rabbits, allowing a sufficient distance on both sides of the spine for injection of the extracts.

Choose 10 points on the rabbit back at one side in interval appropriate. Inject 0.2 ml polar extract or non-polar extract each point (five points for polar extract and five points for non-polar extract). Choose 10 points on the rabbit back on the other side. Inject 0.2 ml corresponding solvent control each point（five points for polar solvent control and five points for nonpolar solvent control).



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

8.3 Observation of animal

To observe the instant, 24 h, 48 h and 72 h reaction of local and surrounding skin tissue reactions including erythema, edema and necrosis and recorded. According to the occurrence of erythema, edema can score for the 0, 1, 2, 3, 4 standard score level. See table 2.

Table 2 Grading system for intracutaneous (intrademal) reactions

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.	

9.0 Evaluation criteria

Use only 24 h, 48 h and 72 h observations for calculation.

All erythema grades plus oedema grades 24 h, 48 h and 72 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.

10.0 Results of the test

According to what was observed, the response of the polar test group on testing side did not exceed that on the control side, the final test sample score was calculated to be 0. The response of the non-polar test group on testing side did not exceed that on the control side, the final test sample score was calculated to be 0. See table 3.

Table 3 Test results of dermal observations

Extract solvent	Rabbit No.	Group	Reaction	24 h	48 h	72 h	Points
SC	J1501	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	
	J1502	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	
	J1503	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	
SO	F1501	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	
	F1502	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	
		Negative Control	Erythema	0	0	0	0

			Oedema	0	0	0	
	F1503	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	

Under this test condition, the extract of test article did not induce intracutaneous reactivity in rabbit skin.

11.0 Deviation statement

There was no deviation from the standard operating procedure which were judged to have any impact on the validity of the data.

12.0 Record

All the original data and records related to this test and copies of the final report are retained in the archives of Science Standard Medical Testing.

13.0 Confidentiality agreement

Statements of confidentiality were as agreed upon prior to study initiation.