CMA
180015344189

ilac-MRA CNAS
中国认可
国际互认
检测
TESTING
CNAS L10066

Test Report

Report Number: SSMT-R-2020-03009-02B

Sample Name: Menstrual cup

Study Title: Skin Irritation Test

Standard: ISO 10993-10:2010

GB/T 16886.10-2017

Test facility

Jiangsu Science Standard Medical Testing Co., Ltd.

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

Sponsor

Xi'an Furuize Biotechnology Co., Ltd.

Room 11131, Building 3, i Duhui, No.11, Tangyan South Road, Zhangba Street Office, High-tech Zone, Xi'an City, Shaanxi, China.

Contents

Explanation....3
Conclusion....4
Study verification and signature....5
1.0 Purpose....6
2.0 Reference....6
3.0 Test and control articles....6
4.0 Identification of test system....7
5.0 Animal Care and Maintenance....7
6.0 Justification of the test system....8
7.0 Instruments....8
8.0 Experiment design and dose....8
9.0 Evaluation criteria....10
10.0 Results of the test....10
11.0 Deviation statement....11
12.0 Record....11
13.0 Confidentiality agreement....11

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 animal skin irritation test was conducted to assess the potential irritation of the test article or material.

The test sample was extracted with 0.9% sodium chloride injection and sesame oil respectively. The patches (about 2.5 cm×2.5 cm) which moistened by 0.5 ml extract of test article were directly applied to the rabbit skin for 4 hours. Observation for erythema and edema were conducted at 1 h, 24 h, 48 h and 72 h after removal of the patches.

The primary irritation indexes of the polar and non-polar test group were both calculated to be 0. The test result showed that the extract of the test article did not induce skin irritation in rabbit 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/IEC 17025:2017, IDT) and RB/T 214-2017.

Date Received	2020-10-15
Technical Initiation Date	2020-10-26
Technical Completion Date	2020-10-29
Final Report Completion Date	2020-10-30

Edited by Molly Liu 2020.10.30
Date

Checked by Suri Han 2020.10.30
Date

Approved by Daisy Zhang 2020.10.30
Authorized signatory Date

Jiangsu Science Standard Medical Testing Co., Ltd.

1.0 Purpose

New Zealand rabbits were used to evaluate the potential of skin irritation of samples under the condition of 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)

Biological evaluation of medical devices-Part 10:Tests for irritation and skin sensitization(GB/T 16886.10-2017)

Biological evaluation of medical devices-Part 12:Sample preparation and reference materials(GB/T 16886.12-2017)

Biological evaluation of medical devices-Part 2: Animal welfare requirements (GB/T 16886.2-2011)

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: Menstrual cup

Sterilization state: Unsterilized

Model/Size: N/S

Lot/ Batch#: N/S

Physical State: Solid

Color: See the photo

Density: N/S

Stability: N/S

Solubility: N/S

Test Article Material: Silica gel

Packing Material: N/S

Storage Condition: Room temperature

Manufacturer: Xi'an Furuize Biotechnology Co., Ltd.

Manufacturer address: Room 11131, Building 3, i Duhui, No.11, Tangyan South Road, Zhangba Street Office, High-tech Zone, Xi' an City, Shaanxi, China.

Sample photograph:



3.2 Control Articles

3.2.1 Polar Negative Control: 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 Negative Control: Sesame Oil (SO)

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

Size: 20 kg

Physical State: Liquid

Color: Pale yellow

Lot/ Batch#: 20190516

Storage Condition: Room Temperature

4.0 Identification of test system

Species: New Zealand white rabbit (single strain)

Number: 6 (3 for polar test group and 3 for non-polar group)

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, test code and first treatment date.

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 15% sodium dodecyl sulfate has been substantiated at SSMT with this method. Positive control tests are conducted every six months. The last irritation index of polar test group was 6.0. The last irritation index of non-polar test group was 5.7. The data was from the report SSMT-R-2020-01262-01 (Date: 2020-05-29).

6.2 The test article extract was directly applied to the rabbit skin, which was suggested by the standard.

7.0 Instruments

Digital oscillation incubator (SSMT-300)

Electronic balance (SSMT-075)

Steel Straight Scale (SSMT-210)

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.

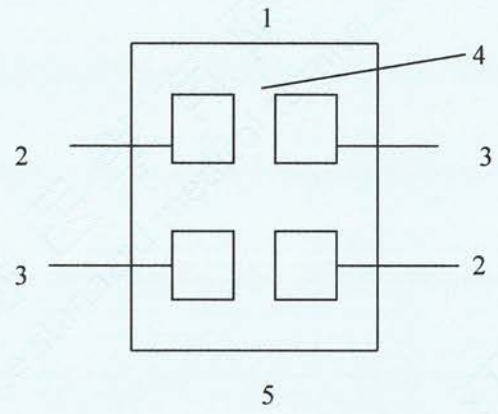
Table 1 Sample Preparation

Aseptic Sampling		Aseptic Agitation Extraction In Inert Container				Final Extract
Sampling Manner	Actually Sampling	Extraction solvent	Extraction ratio	Solvent volume	Condition	Clear or Not
Take the whole. One test sample was used in each group.	14.18 g	0.9% sodium chloride injection	0.2 g : 1 ml	70.9 ml	50 ℃, 72 h	Clear
	12.13 g	Sesame oil	0.2 g : 1 ml	60.6 ml	50 ℃, 72 h	Clear

8.2 Test method

Use the rabbits with healthy intact skin. Fur is generally clipped on the back of the rabbits 16 h before testing, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10 × 15 cm).

Apply 0.5 ml extract of test article or control to 2.5 cm × 2.5 cm absorbent gauze patches, and then apply the patch soaked with the extract of test article or control directly to the skin on each side as shown in Figure 1. And then wrap the application site with a bandage (semi-occlusive) for 4 h. At the end of the contact time, remove the dressings.



1- Cranial end, 2- Test site, 3- Control site, 4- Clipped dorsal region, 5- Caudal end

Figure1 Location of skin application sites

8.3 Observation of animal

Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 2 for each application site at each time interval. Record the appearance of each application site at 1 h, 24 h, 48 h and 72 h following removal of the patches.

Table 2 Classification System for Skin Reaction

Reaction	Irritation score
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**

NOTE: Other adverse changes at the skin sites were recorded and are reported.

8.4 Result calculation

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

After the 72 h grading, all erythema grades plus oedema grades 24 h, 48 h and 72 h are totalled separately for each test sample and blank for each animal. The primary irritation score for an animal is calculated by dividing the sum of all the scores by 6 (two test/observation sites, three time points).

To obtain the primary irritation index for the test sample add all the primary irritation scores of the individual animals and divide by the number of animals.

Calculate the primary irritation score for the controls and subtract that score from the score using the test material to obtain the primary irritation score.

9.0 Evaluation criteria

The primary irritation index is characterized by number (score) and description (response category) given in Table 3.

Table 3 Primary irritation index categories in a rabbit

Mean score	Response category
0-0.4	Negligible
0.5-1.9	Slight
2.0-4.9	Moderate
5-8	Severe

10.0 Results of the test

According to what observed, the response of skin on testing side did not exceed that on the control side. See Table 4 .

Table 4 Dermal observations

Extraction solvent	Rabbit No.	Group		Interval			
				1h	24h	48h	72h
0.9% sodium chloride injection	J1501	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	J1502	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	J1503	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
Sesame oil	F1501	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0

	F1502	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0
	F1503	Test Article	Erythema	0	0	0	0
			Oedema	0	0	0	0
		Negative Control	Erythema	0	0	0	0
			Oedema	0	0	0	0

The primary irritation indexes of the polar and non-polar test group were both calculated to be 0. Under the conditions of this study, the extract of the test article did not induce skin irritation.

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.