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Skin Irritation Test

Final Report

Verification

Report Number: CSTBB21031030

Article Name: Ostomy bag

Method Standard: ISO 10993-10: 2010

Sponsor

Zhejiang Ailebao Medical Technology CO.,LTD

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Abstract

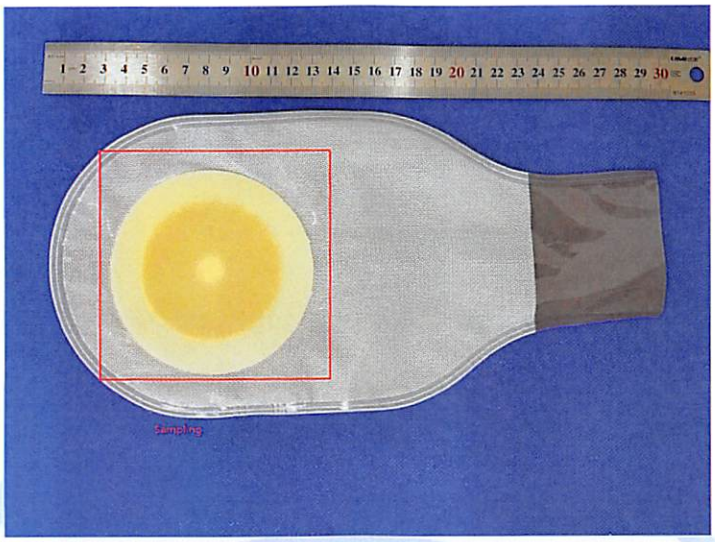
In this study, we took New Zealand white Rabbits to observe the skin irritation of the test article according to ISO 10993-10:2010.

Apply test article or control directly to the skin on each side of each rabbit, and then wrap the application sites with a bandage for a minimum of 4 h. At the end of the contact time, remove the dressing. The describe and score the skin reaction for erythema and oedema for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

The results showed that the rabbits in the negative control group (0.9 % Sodium Chloride Injection) retained a normal appearance throughout the test and showed no skin irritants. A severe skin reactions for erythema and oedema were shown in the positive control group (SDS). While in test article group, the response of skin on testing side did not exceed that on the control side. The skin reactions for erythema and oedema were not observed in test article group. The data of each group met the acceptance criteria, and the results of this test were considered valid.

Based on the above results, it can be concluded that under the experimental conditions, the test article has no potential skin irritation on rabbit in the method.

Study Verification and Signature



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Personnel Berry 2021-05-07
Date Completed

Approved Mengxuan Ye. 2021-05-07
Study Director
Date Completed

Supervisory
Test Facility Manager
Date Completed

CCIC Huatongwei International Inspection (Suzhou) Co., Ltd.

1.0 Purpose

To evaluate the potential skin irritation caused by test article contact with the skin surface of rabbits and extrapolating the results to humans, but it does not establish the actual risk of irritation.

2.0 Reference

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 (ISO 10993-10:2010)

Biological evaluation of medical devices-Part 12: Sample preparation and reference materialsy (ISO 10993-12:2021)

3.0 Test and control articles

Groups	Test article	Negative Control Article	Positive Control
Name	Ostomy bag	0.9% Sodium Chloride Injection(SC)	Sodium dodecyl sulfate (SDS)
Manufacture	Zhejiang Ailebao Medical Technology CO.,LTD	Guangxi Yuyuan Pharmaceutical Co., Ltd	Solarbio
Size	14.8*29.9cm	500 ml	500 g
Model	1OP60	/	/
Lot Batch#	Not provided	H20120305	1019Y032
Test Article Material	hydrocolloid、bag	/	/
Physical State	Solid	Liquid	Solid
Color	Pale yellow	Colorless	Colorless
Package material	PE bag	/	/
Sterilized or Not	Yes	/	/
Concentration	/	0.9 %	working concentration 10 %
Total Surface/Weight	442.52 cm^2 /15.12 g	/	/
Storage Condition	Room Temp.	Room Temp.	Room Temp.
The information about the test article was supplied by the sponsor wherever applicable.			

4.0 Identification of test system

4.1 Test animal

Species: New Zealand white Rabbit

Number: 3

Sex: either sex

Weight: >2 kg

Health status: Healthy, not previously used in other experimental procedures

Animal identification: Ear tattoo

Cages: Stainless steel cage

Acclimation Period: 7 days under the same conditions as for the actual test

4.2 Justification of test system

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 HTW with this method.

5.0 Animal Management

Animal purchase: Wuxi hengtai experimental animal breeding co., LTD SCXK (SU) 2020-0003

Feed: Experimental rabbits were fed a maintenance diet

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

Animal room temperature: 18-26 ℃

Animal room relative humidity: 30 %-70 %

Lights: 12 hours light/dark cycle, full-spectrum lighting

Personnel: Associates involved were appropriately qualified and trained

Selection: Only healthy, previously unused animals were selected

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

6.0 Equipment and reagents

6.1 Instruments

Electronic scale (SHB020, calibration data: 2021/03/11)

7.0 Experiment design

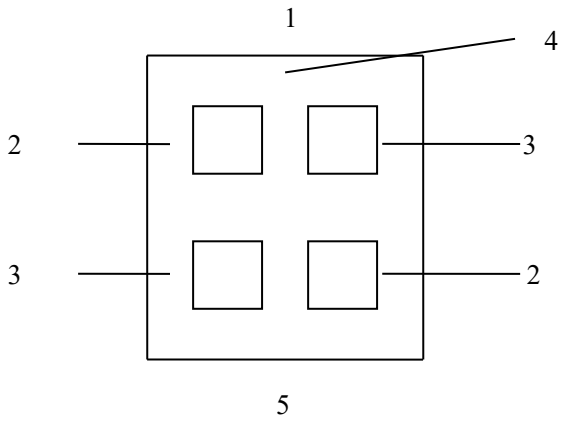
7.1 Sample preparation

The test articles were cut into 2.5 cm×2.5 cm and then used in test directly without any treatment. Use a volume of negative control article sufficient to saturate the gauze.

7.2 Test method

Use the rabbits with healthy intact skin. Fur was generally clipped within 4-24 h of testing on the backs of the rabbits, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10×15 cm).

Apply test article or control directly to the skin on each side of each rabbit as shown in Figure 1, and then wrap the application sites with a bandage (semi-occlusive or occlusive) for a minimum of 4h. At the end of the contact time, remove the dressing.



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

Figure1 Location of skin application sites

8.0 The results observed

The Describe and score the skin reaction for erythema and oedema according to the scoring system given in Table 1 for each application site at each time interval. Record the appearance of each application site at (1±0.1) h, (24±2) h, (48±2) h and (72±2) h following removal of the patches.

Table 1 Classification System for Skin Reaction

Erythema and Eschar Formation:	Numerical Grading
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
Edema Formation:	
No edema	0
Very slight edema (barely perceptible)	1
Well-defined edema (edges of area well-defined by definite raising)	2
Moderate edema (raised approximately 1mm)	3
Severe edema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	8
Irritation Response Categories in the Rabbit	
Response Category	Mean score
Negligible	0 to 0.4
Slight	0.5 to 1.9
Moderate	2 to 4.9
Severe	5 to 8

9.0 Evaluation criteria

Use only (24±2) h, (48±2) h and (72±2) h observations for calculation.

After the 72 h grading, all erythema grades plus oedema grades (24±2) h, (48±2) h and (72±2) h were totalled separately for each test article and blank for each animal. The primary irritation score for an animal was 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 article, add all the primary irritation scores of the individual animals and divide by the number of animals.

When blank or negative control was used, 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.

10.0 Results of the test

All animals were survived and no abnormal signs were observed during the study. According to what observed, the response of skin on testing side did not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 2.

11.0 Conclusion

The test result showed that the response of the test article extract was categorized as negligible under the test condition.

12.0 Record

All raw data pertaining to this study and a copy of the final report are retained in designated Huatongwei archive.

13.0 Confidentiality Agreement

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

14.0 Protocol amendment/deviations

There were no amendments or deviations that occurred during the course of this study.

Table 2 Skin irritation response observation

Rabbit No	Pretest weight(kg)	Finished weight(kg)	Group	Reaction	Interval (hours): score=left/right			
					1±0.1h	24±2 h	48±2 h	72±2 h
1	2.11	2.20	Test Article	Erythema	0/0	0/0	0/0	0/0
				Oedema	0/0	0/0	0/0	0/0
			Negative Control	Erythema	0/0	0/0	0/0	0/0
				Oedema	0/0	0/0	0/0	0/0
2	2.19	2.27	Test Article	Erythema	0/0	0/0	0/0	0/0
				Oedema	0/0	0/0	0/0	0/0
			Negative Control	Erythema	0/0	0/0	0/0	0/0
				Oedema	0/0	0/0	0/0	0/0
3	2.17	2.25	Test Article	Erythema	0/0	0/0	0/0	0/0
				Oedema	0/0	0/0	0/0	0/0
			Negative Control	Erythema	0/0	0/0	0/0	0/0
				Oedema	0/0	0/0	0/0	0/0
Primary irritation index					0			

Table 3 Positive control

Rabbit No	Group	Reaction	Interval (hours): score=left site/right site			
			1±0.1 h	24±2 h	48±2 h	72±2 h
1	Positive Article Group	Erythema	2/2	2/2	3/3	3/3
		Oedema	1/0	2/2	3/2	3/2
	Solution Control Group	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
2	Positive Article Group	Erythema	2/2	4/3	4/3	4/3
		Oedema	0/0	4/2	4/2	3/2
	Solution Control Group	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
3	Positive Article Group	Erythema	2/1	2/3	3/4	3/4
		Oedema	0/0	2/3	4/4	4/3
	Solution Control Group	Erythema	0/0	0/0	0/0	0/0
		Oedema	0/0	0/0	0/0	0/0
Primary irritation index			5.9			

Positive control performed once every six months see CSTBB21010001P1(Finish date：2021-01-15)