CMA 190021344215

CNAS 中国认可 国际互认 检测 TESTING CNAS L9783

NEWAY TESTING LABORATORY

Testing Report

Skin Irritation Test ISO 10993-10:2010

（Single-exposure test）

Report No.: WT20010538-5

Test Sample: Conductive Hydrogel

Sponsor: DONGGUAN QUANDING MEDICAL SUPPLIES CO., LTD

Manufacturer: DONGGUAN QUANDING MEDICAL SUPPLIES CO., LTD

纽唯 Neway

Remarks

1. The results shown in this test report refer only to the sample(s) tested.
2. The content of this report is invalid if it is not presented as the entire report.
3. Any unauthorized alteration, forgery or falsification of the content or appearance of this report is unlawful and offenders may be prosecuted fully of the law.

Table of Contents

ABSTRACT 1

QUALITY ASSURANCE STATEMENT 2

PURPOSE AND SCHEDULE 3

PHOTO OF TEST SAMPLE 3

1. MATERIALS INFORMATION 4

- 1.1 Test Sample 4
- 1.2 Reagents 4
- 1.3 Equipment 4
- 1.4 Test Sample and Controls Preparation 4

2. EXPERIMENTAL DESIGN 5

- 2.1 Experimental System 5
- 2.1.1 Animals 5
- 2.2 Test Procedure 6
- 2.3 Observation of Animals 7
- 2.4 Evaluation of Results 7

3. TEST RESULTS 8

- 3.1 Observation 8
- 3.2 Calculation 9

4. CONCLUSION 10

5. ARCHIVING 10

ABSTRACT

Sponsor / Client: DONGGUAN QUANDING MEDICAL SUPPLIES CO., LTD.

Address: 3 YONGFA EAST ROAD, QISHI TOWN, DONGGUAN CITY, GUANGDONG, CHINA.

Manufacturer: DONGGUAN QUANDING MEDICAL SUPPLIES CO., LTD.

Address: 3 YONGFA EAST ROAD, QISHI TOWN, DONGGUAN CITY, GUANGDONG, CHINA.

Test Sample: Conductive Hydrogel, prepared two sample a pair , was subjected to animal skin irritation single-exposure test separately according to ISO 10993-10:2010.

The skin responses of application sites were observed and recorded in 1±0.1h, 24±2h, 48±2h and 72±2h respectively after removal of the test sample patches.

Conclusion:	The test sample induce negligible irritation in a rabbit skin single exposure test.

Study Director: _____ Date: NOV. 13. 2020

Xu Fengxia

Report Reviewer: _____ Date: Nov. 13, 2020

Wang Meng

Authorized Signatory: _____ Approval Date: NOV. 13, 2020

Xu Honglei

Report issued by:

GUANGDONG NEWAY QUALITY TECHNOLOGY SERVICE CO., LTD.

(Testing Stamp)

QUALITY ASSURANCE STATEMENT

These tests were audited by Quality Assurance (QA) personnel of NEWAY. The QA inspection includes review of study plan, result of a study-based audit and results of audit of raw data and study report.

The findings were reported to Study Director and NEWAY management.

QA manager:

Xu Honglei

NOV. 13, 2020

Date Completed

Inspection Type	Inspection Date	Testing Phase	Date to Facility Manager & Study Director
Study base	Sep. 21, 2020	Draft Protocol	Sep. 21, 2020
Study base	Oct. 19, 2020	Test Sample Preparation	Oct. 19, 2020
Study base	Oct. 23, 2020	Raw Data & Draft Final Report	Oct. 23, 2020

PURPOSE AND SCHEDULE

According to its nature and duration of the anticipated contact with human tissues when in use, medical device should be tested for biocompatibility to avoid potential physiological damage from irritative substances produced or contaminated during manufacturing.

In this study, skin irritation single-exposure test was performed to evaluate the possibility of skin irritation after single topical applications of the test sample patches on the skin of rabbits. These results provide practical information for assessing the risk of single-exposure skin irritation of the medical device.

Study schedule is as below:

Study Initiation Date: Sep. 21, 2020

Test Starting Date: Oct. 19, 2020

Test Completion Date: Oct. 23, 2020

PHOTO OF TEST SAMPLE

1. MATERIALS INFORMATION

1.1 Test Sample

Test Sample information was provided by sponsor and showed as below:

Test Sample Description:	Conductive Hydrogel
Specify the test parts or materials:	Conductive Hydrogel
Major ingredients:	Conductive Hydrogel
Intended Use:	Conducting electric current to the skin surface or transmitting human EMG or ECG signals to the machine.
Batch/Lot No.:	20200915
Model No.:	QD0.9A
Stability:	Not entrusted
Production date:	Sep. 15,2020
Expiration Date:	Sep. 14,2022
Storage Condition:	Ambient temperature
External Features:	Solid
Sterilization Method:	Non-Sterilized
Pre-treatment:	Non

1.2 Reagents

1.2.1 0.9% Sodium Chloride (Guangdong KELUN Lot：H18111406)

1.2.2 SDS (SIGMA Lot：STBG299IV)

1.3 Equipment

1.3.1 Electronic Scale (Shanghai Yaohua, C2016-02-01)

1.4 Test Sample and Controls Preparation

The sample (2.5cm*2.5cm) is applied to animal, the absorbent gauze

patches(2.5cm*2.5cm） containing 0.9% sodium chloride as the negative control and 20% SDS as the positive control.

2. EXPERIMENTAL DESIGN

2.1 Experimental System

2.1.1 Animals

a) Animal Species : New Zealand White Rabbit (Single strain)

b) Source: Guangzhou Huadu district huadong xinhua experimental animal farm, Experimental Animal Production Permit No.: SCXK(YUE) 2019-0023

c) Body Weights (Gender): Initial weight not less than 2kg (Female not pregnant)

d) Health Status: Healthy, previously unused young adult

e) Quarantine/acclimation: Animals are subjected to quarantine and acclimated for a week before treatment.

f) Animal Identification: Ear Marking

2.1.2 Animal Care and Management

a) Environment: Temperature 20-26℃, 40%-70% Relative Humidity

b) Housing: Animals are housed in groups in cages identified by a card indicating the lab number, test code and first treatment date.

c) Cage: Plastic Cage

d) Feed: Rabbit Diet, Guangdong Medical Laboratory Animal Center

e) Water: Drinking water met GB 5749 Standards for Drinking Water Quality

f) Lights: 12 hours light/dark cycle, full spectrum fluorescent lights.

2.1.3 Justification of experimental system: The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current ISO 10993-10:2010 standards.

2.1.4 Facility: Experimental facility is accredited in accordance with ISO/IEC 17025 by CNAS (China National Accreditation Service). CNAS registration Number: CNAS L9783.

2.1.5 Personnel: All relevant personnel are well trained and qualified.

2.1.6 Compliance: All activities of this study are carried out in compliance with the GLP (Good

Laboratory Practices) for U.S. Food and Drug Administration Good Laboratory Practice Regulations, 21 CFR Part 58 (1987).

2.2 Test Procedure

2.2.1 Preparation of animals

12h before testing, fur is generally clipped on the backs of the animals, a sufficient distance on both sides of the spine for application and observation of all test sites (approximately 10cm × 15cm)

2.2.2 Application of test sample and control

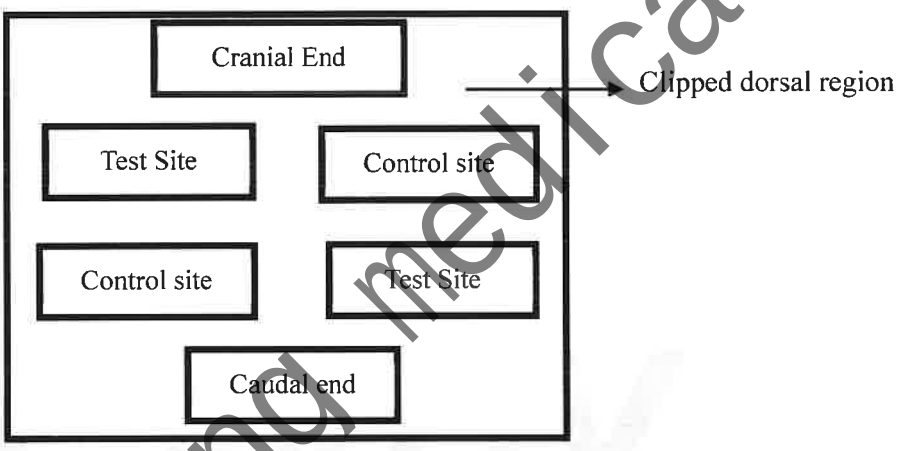

Figure 1 Location of skin application sites

The test sample apply the patch on each side of the animal as shown in Figure 1, and then wrap the application sites with occlusive dressing. Use a volume of 0.5mL 0.9% sodium chloride as the negative control, similarly apply on the animal only as shown in Figure 1. Use a volume of 0.5mL 20% SDS as the positive control, instead of test site. Wrap the application site with a bandage for 4 h. At the end of the contact time, remove the dressings and mark the positions of the sites with permanent ink. Wash with lukewarm water and careful drying.

2.3 Observation of Animals

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

Reaction	Irritation Score
Erythema and Eschar Formation (ER)	
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 (OD)	
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 1 mm)	3
Severe oedema (raised more than 1mm and extending beyond exposure area)	4
Maximal possible score for irritation	**8**
Note: Other adverse changes at the skin sites shall be recorded and reported.	

2.4 Evaluation of Results

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

2.4.2 After the 72 h grading, all erythema grades plus oedema grades of (24±2)h. (48±2)h and (72±2)h are totaled 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).

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

2.4.4 Calculate the primary irritation score for the controls and subtract the score from the score using the test samples to obtain the primary irritation score.

2.4.5 The primary irritation index is characterized by scores and description (response category)

given in Table 2.

Table 2 Primary irritation index categories in a rabbit

Mean Score	Response Category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

3. TEST RESULTS

3.1 Observation

According to what was observed, the response of skin on testing sides and control sides were recorded, see Table 3 for details. No other adverse changes at the skin sites was observed during the test.

Table 3 Dermal Observation

Application Site (Rabbit No.: 1#)	ER response / Score (1h	24h	48h	72h)	OD response / Score (1h	24h	48h	72h)
Test Site 1	0	0	0	0	0	0	0	0
Test Site 2	0	0	0	0	0	0	0	0
Control Site 1	0	0	0	0	0	0	0	0
Control Site 2	0	0	0	0	0	0	0	0

Application Site (Rabbit No.: 2#)	ER response / Score (1h	24h	48h	72h)	OD response / Score (1h	24h	48h	72h)
Test Site 1	0	0	0	0	0	0	0	0
Test Site 2	0	0	0	0	0	0	0	0
Control Site 1	0	0	0	0	0	0	0	0
Control Site 2	0	0	0	0	0	0	0	0

Application Site (Rabbit No.: 3#)	ER response / Score (1h	24h	48h	72h)	OD response / Score (1h	24h	48h	72h)
Test Site 1	0	0	0	0	0	0	0	0
Test Site 2	0	0	0	0	0	0	0	0
Control Site 1	0	0	0	0	0	0	0	0
Control Site 2	0	0	0	0	0	0	0	0

Application Site (Rabbit No.: 4#)	ER response / Score (1h	24h	48h	72h)	OD response / Score (1h	24h	48h	72h)
Positive Site 1	1	2	2	2	2	2	3	2
Positive Site 2	2	2	2	2	2	2	2	2
Control Site 1	0	0	0	0	0	0	0	0
Control Site 2	0	0	0	0	0	0	0	0

Application Site (Rabbit No.: 5#)	ER response / Score (1h	24h	48h	72h)	OD response / Score (1h	24h	48h	72h)
Positive Site 1	2	2	2	3	2	2	2	2
Positive Site 2	2	2	2	2	2	2	2	3
Control Site 1	0	0	0	0	0	0	0	0
Control Site 2	0	0	0	0	0	0	0	0

Application Site (Rabbit No.: 6#)	ER response / Score (1h	24h	48h	72h)	OD response / Score (1h	24h	48h	72h)
Positive Site 1	2	2	2	2	2	2	2	2
Positive Site 2	2	2	2	2	2	2	2	2
Control Site 1	0	0	0	0	0	0	0	0
Control Site 2	0	0	0	0	0	0	0	0

3.2 Calculation

The Primary Irritation Index of each extract was calculated separately, see Table 5 for details.

Table 4 Skin Irritation Category Evaluation

Rabbit No.	Total ER and OD score of Sample extract	Total ER and OD score of negative control	PII of Test Sample extract S_1	PII of negative control S_2	PII S_1-S_2	Response Category
1#	0	0	0	0	0	Negligible
2#	0	0				
3#	0	0				
4#	25	0	4.17	0	4.17	Moderate
5#	26	0				
6#	24	0				

4. CONCLUSION

Under the conditions of this study, the primary irritation index of the test sample is 0 Therefore, the test sample induce negligible irritation in a rabbit skin single-exposure test.

5. ARCHIVING

All the study-related raw data, records, protocol and the final report will be kept in NEWAY for 6 years from report issue date. For studies of more than 4 weeks duration, the test samples will also be in kept in NEWAY for 6 years from report issue date.

All the records and test samples were handled according to GLP Guidance. Agent authorized by the sponsor can apply for review according to NEWAY policy.

广东纽唯质量技术服务有限公司

NEWAY TESTING LABORATORY

地址: 广州市黄埔区敬业三街 1 号 H 栋 402A 房, 邮编:510663

Address: Rm.402A, Building H, No.1, Jingye 3rd Street, Huangpu District, Guangzhou, PR China, 510663.

电话 Tel: +86-020-82002131

传真 Fax: +86-020-82006951

主页: http://gdneway.com