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Final Report

Report Number: SDWH-M201905389-4(E)

Skin Irritation Test of Nerve and Muscle Stimulator

According to ISO 10993-10:2010
0.9% Sodium Chloride Injection Extract

Sponsor: Shenzhen XFT Medical Limited

Address: Room203, Building 1, Biomedicine Innovations Industrial Park, #14 Jinhui Road, Pingshan New District, Shenzhen, China

Sanitation & Environment Technology Institute, Soochow University

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Content

Supplementary Explanation

(1) Please apply for rechecking within 15 days of receiving the report if there are any objections.

(2) Any erasure or without special inspection and 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 results relate only to the articles tested.

(5) The report shall not be reproduced except in full without the written approval of the institute.

Verification Dates

Test Article Receipt	2019-12-12
Protocol Effective Date	2019-12-19
Technical Initiation Date	2019-12-20
Technical Completion Date	2019-12-27
Final Report Completion Date	2020-01-03

Edited by: Chen Yong Yong 2020-01-03
Date

Reviewed by: 2020-01-03
Study Director Date

Approved by: 2020-01-11
Authorized Signatory Date

Sanitation & Environment Technology Institute, Soochow University

Summary

1 Test Article

Test Article Name	Nerve and Muscle Stimulator
Manufacturer	Shenzhen XFT Medical Limited
Address	Room203, Building 1, Biomedicine Innovations Industrial Park, #14 Jinhui Road, Pingshan New District, Shenzhen, China
Model	XFT-2001E
Lot/Batch	Not supplied by sponsor (N/S)

2 Main Reference

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

3 Test Method

The extract of test article was evaluated for skin irritation. With ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Study protocol number: SDWH-PROTOCOL- M201905389-4.

4 Conclusion

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

Test Report

1 Purpose

The extract of test article was evaluated for skin irritation and extrapolating the results to humans, but it does not establish the actual risk of irritation.

2 Reference

ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
ISO 10993-12:2012 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
ISO 10993-2:2006 Biological evaluation of medical devices — Part 2: Animal welfare requirements

3 Compliance

ISO/IEC 17025:2005 General requirements for the competence of testing and calibration laboratories (CNAS—CL01 Accreditation criteria for the competence of testing and calibration laboratories) China National Accreditation Service for Conformity Assessment LABORATORY ACCREDITATION CERTIFICATE Registration No. CNAS L2954.
RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061.

4 Identification of Test and Control Articles

4.1 Test Article

Test Article Name	Nerve and Muscle Stimulator
Manufacturer	Shenzhen XFT Medical Limited
Address	Room203, Building 1, Biomedicine Innovations Industrial Park, #14 Jinhui Road, Pingshan New District, Shenzhen, China
Test Article Initial State	Not Sterilized
CAS Code	N/S
Model	XFT-2001E
Size	N/S
Lot/Batch	N/S
Test Article Material	N/S
Packaging Material	N/S
Physical State	Solid
Color	N/S
Density	N/S
Stability	N/S
Solubility	N/S
Storage Condition	Room Temperature
Intended Clinical Use	This device is intended to address the lack of ankle dorsiflexion in patients who have sustained damage to upper motor neurons or pathways to the spinal cord.

The information about the test article was supplied by the sponsor wherever applicable.

4.2 Control Article

4.2.1 Negative Control

0.9% sodium chloride injection (SC), storage condition: room temperature.

4.2.2 Positive Control

Sodium dodecyl sulfate (SDS), storage condition: room temperature.

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
Electronic Scale	SDWH442	2020-05-04
Horizontal Large Capacity Constant Temperature Vibrator	SDWH897	2020-05-04
Steel straight scale	SDWH463	2020-07-29
Autoclave	SDWH2097	2020-04-16

5.2 Reagents

Reagent Name	Manufacturer	LOT
0.9% sodium chloride injection (SC)	Guangxi Yuyuan Pharmaceutical Co., Ltd.	H19082605
Sodium dodecyl sulfate (SDS)	Sinopharm Chemical Reagent Co., Ltd	20181210

6 Identification of Test System

Species: New Zealand white Rabbit (single strain).
Number: 3
Sex: Female
Weigh: Initial body weight not less than 2kg
Health status: Healthy, not previously used in other experimental procedures, young adult, nulliparous and not pregnant.
Housing: Animals were housed in cages identified by a card indicating the lab number, test code and first treatment date.
Animal identification: Stain with dyeing liquid
Cages: Stainless steel cage
Acclimation Period: 7 days under the same conditions as for the actual test

7 Animal Care and Maintenance

Animal purchase: Provided by Suzhou Experimental Animal Sci-tech Co., Ltd. <Permit Code: SCXK (SU) 2015-0007>
Bedding: NA
Feed: Rabbit Diet, Suzhou Experimental Animal Sci-tech Co., Ltd.
Water: Drinking water met the Standards for Drinking Water Quality GB 5749-2006
Animal room temperature: 18-26°C
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 expected to interfere with the test data.

8 Justification of Test System and Route of Administration

The rabbit is specified as an appropriate animal model for evaluating potential skin irritants by the current testing standards. Positive control sodium dodecyl sulfate has been substantiated at SDWH with this method. See table 3.

The patches (about 2.5cm×2.5cm) which moistened by test article extract, and directly applying to the rabbit skin is considered to be the best mean of contact.

9 Experimental Design

9.1 Preparation of Extracts

9.1.1 Pretreatment

No pretreatment required.

9.1.2 Extraction

Under aseptic conditions, samples were taken according to the sampling method (Mix the four components by equal quantity and extract together (see the image in Annex 2), Total surface area data of the test article provided by the sponsor, 568 cm^2), and extracted in closed inert containers according to the extraction ratio of 3 cm^2: 1 mL (sample: extraction vehicle). The extraction vehicle was SC.

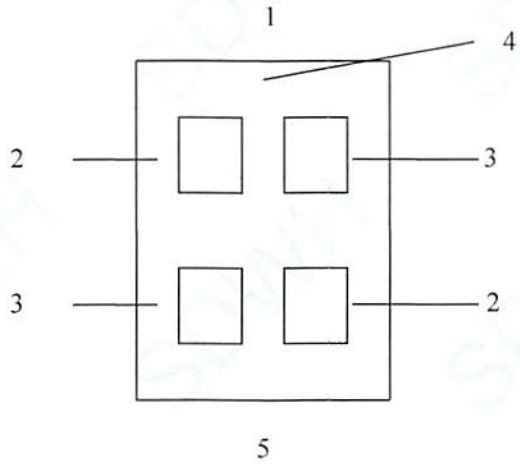
Test Period	Actual Sampling	Extract Procedure			Final Extract
		Extract Ratio	Extraction volume	Condition	
polar test extract	Surface area 568 cm^2	3 cm^2 : 1 mL	189.3 mL	37°C, 72 h	Not Clear
polar negative control	/	/	10.0 mL	37°C, 72 h	Clear

The extraction solvent was colorless and transparent pre- extraction and changed into slight rustiness suspension post-extraction. The extract was stored at 4°C, and tested within 24 h, without the process of adjusting its pH value, filtering, centrifuging, diluting, etc. The vehicle (without the test article) was similarly prepared to serve as the control.

9.2 Experimental Procedure

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 0.5 mL extract (s) 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 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 4 h. 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

9.3 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 — Scoring 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 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
Other adverse changes at the injection sites be recorded and reported	

9.4 Evaluation of Results

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 sample 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 is 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.

The primary irritation index (PII) for the test article was evaluated according to Table 2.

Table 2 — Primary or cumulative irritation index categories in a rabbit

Mean score	Response category
0~0.4	Negligible
0.5~1.9	Slight
2~4.9	Moderate
5~8	Severe

10 Results

All animals were survived and no abnormal signs were observed during the study. According to what observed, the response of skin on testing side does not exceed that on the control side. Thus, the primary irritation index for the test article was calculated to be 0. See table 4.

11 Conclusion

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

12 Record Storage

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

13 Confidentiality Agreement

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

14 Deviation Statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Annex 1 Test Data

Table 3 Positive control

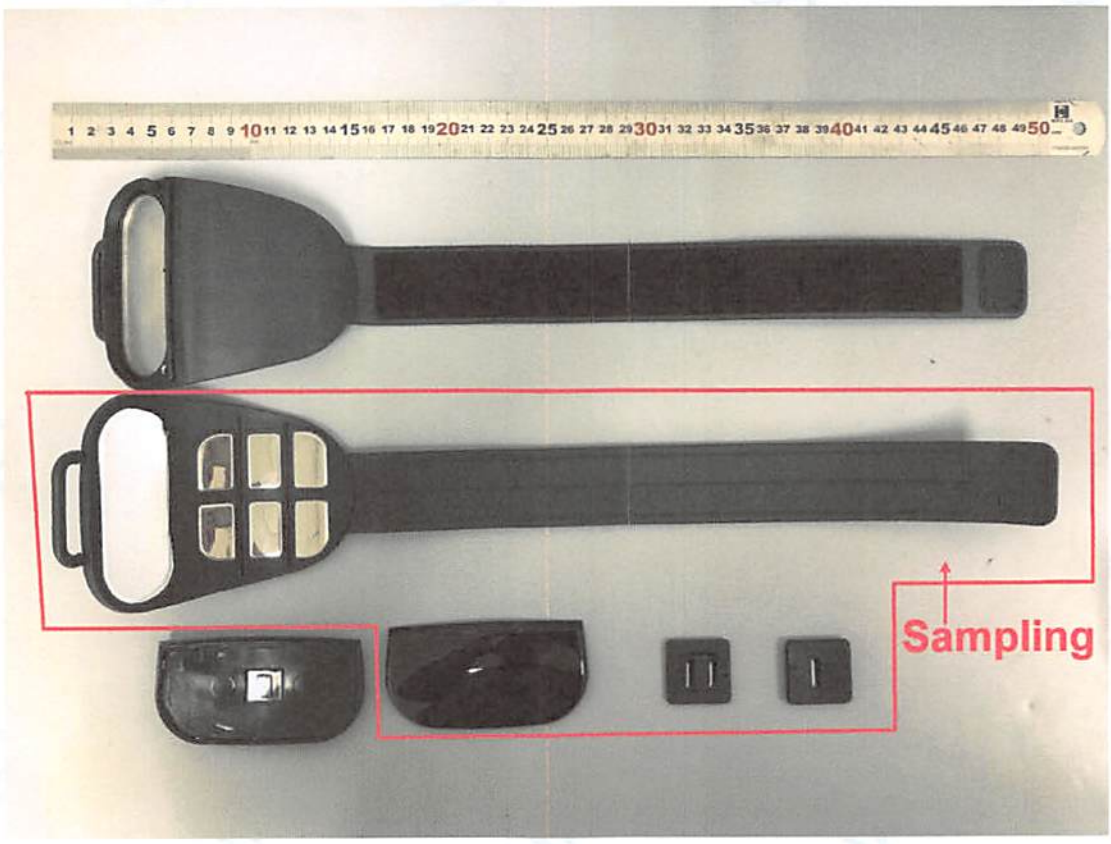
Extract	Rabbit No.	Group	Reaction	Interval (hours): score=left site/right site		
				24±2h	48±2h	72±2h
SC	1	Positive Control	Erythema	3/3	4/4	4/4
			Oedema	2/2	3/3	3/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SC	2	Positive Control	Erythema	2/3	3/3	4/4
			Oedema	3/3	3/3	4/3
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SC	3	Positive Control	Erythema	3/3	4/3	4/3
			Oedema	3/2	3/3	4/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
The primary irritation score.					6.4	

Note: Positive control performed once every six months, see SDWH-M201905450-1(Completed Date: 2019-12-27).

Table 4 Test Results of Dermal Observations

Extract	Rabbit No.	Group	Reaction	Interval (hours): score=left site/right site		
				24±2h	48±2h	72±2h
SC	1	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SC	2	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SC	3	Test Article	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
The primary irritation score.					0	

Annex 2 Photograph of Test Article



Annex 3 Information Provided by Sponsor

1 Production Process

Not supplied by sponsor.

2 Other Information

Not supplied by sponsor.

End of Report