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CNAS L2954

Final Report

Report Number: SDWH-M202007193-9(E)

Skin Irritation Test of 5040TPU Low noise medical cable

According to GB/T 16886.10-2017
0.9% Sodium Chloride Injection Extract

Sponsor: Shenzhen YONGQIANGFU Industrial CO.,Ltd

Address: 2Bldg,No.2 Industrial park,Xinwei Village ,Dalang LongHua Town,Shenzhen City

检验检测专用章 (2)

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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.

Quality Assurance Statement

The Quality Assurance Unit inspected/audited this study in compliance with the following GLP regulations:

Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA). The laboratory is exempt from the following provisions: 21 CFR Part 58.105 Test and Control Article Characterization, and Part 58.113 Mixtures of Articles with Carriers.

The Quality Assurance Unit conducted inspections on the following dates. The findings were reported to the Study Director and to the Testing Facility Management. The final report was reviewed by the Quality Assurance Unit. The final report accurately describes the test methods in accordance with standard operating procedures, and the results are consistent with raw data of non-clinical studies conducted according to the study protocol.

Inspections	Date of Inspection	Date Reported to Study Director	Date Reported to Testing Facility Management.
Study Protocol	2021-01-07	2021-01-07	2021-01-28
Study Procedure	2021-01-12	2021-01-12	2021-01-28
Raw Data	2021-01-28	2021-01-28	2021-01-28
Final Report	2021-01-28	2021-01-28	2021-01-28

Quality Assurance Unit: Zou Jing 2021-01-28

Quality Assurance Date

GLP Compliance Statement

This study was fully in accordance with the technical requirements of the study protocol.

This study was conducted in compliance with Good Laboratory Practice (GLP) Regulation 21 CFR Part 58, U.S. Food and Drug Administration (FDA).

The laboratory is exempt from the following provisions: 21 CFR Part 58.105 Test and Control Article Characterization, and Part 58.113 Mixtures of Articles with Carriers.

Verification Dates

Test Article Receipt	2020-12-24
Protocol Effective Date	2021-01-07
Technical Initiation Date	2021-01-07
Technical Completion Date	2021-01-15
Final Report Completion Date	2021-01-28

Edited by: Wang Deheng 2021-01-27
Date

Reviewed by: 2021-01-28
Study Director Date

Approved by: 2021-01-28
Authorized Signatory Date

Sanitation & Environment Technology Institute, Soochow University

Summary

1 Test Article

Test Article Name	5040TPU Low noise medical cable
Manufacturer	Shenzhen YONGQIANGFU Industrial CO.,Ltd
Address	2Bldg,No.2 Industrial park,Xinwei Village ,Dalang LongHua Town,Shenzhen City
Model	5040TPU
Lot/Batch	N/A

2 Main Reference

GB/T 16886.10-2017 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 GB/T 16886.10-2017 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization.
Study protocol number: SDWH-PROTOCOL- GLP-M202007193-5.

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

GB/T 16886 .10-2017 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
GB/T 16886 .12-2017 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
GB/T 16886.2-2011 Biological evaluation of medical devices — Part 2: Animal welfare requirements

3 Compliance

Good Laboratory Practice Regulations, 21 CFR, Part 58.
ISO/IEC 17025:2017 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	5040TPU Low noise medical cable
Manufacturer	Shenzhen YONGQIANGFU Industrial CO.,Ltd
Address	2Bldg,No.2 Industrial park,Xinwei Village ,Dalang LongHua Town,Shenzhen City
Test Article Initial State	Non-sterile
CAS Number	N/A
Model	5040TPU
Size	N/A
Lot/Batch	N/A
Raw Material	NA
Packaging Material	N/A
Physical State	Solid
Color	Green
Density	N/A
Stability	NA
Solubility	N/A
Storage Condition	Room temperature
Intended Use	N/A
Additional Information	N/A

The information about the test article was supplied by the sponsor wherever applicable.
The Sponsor is responsible for all test article characterization data as specified in the GLP

regulations.

4.2 Control Article

4.2.1 Negative Control

Name: 0.9% sodium chloride injection (SC)
Manufacturer: Guangxi Yuyuan Pharmaceutical Co., Ltd.
Size: 500mL
Lot/ Batch#: H20053105
Physical State: Liquid
Color: Colourless
Storage Condition: Room Temperature

4.2.2 Positive Control

Name: sodium dodecyl sulfate
Manufacturer: Ron reagent
Size: 500g
Lot/ Batch#: RH178474
Physical State: Powder
Color: White
Storage Condition: Room Temperature
Solvent: 0.9% sodium chloride injection (SC)
Concentration: 20%
Date prepared: 2020-12-29

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
Electronic Scale	SDWH2436	2021-05-21
Horizontal Large Capacity Constant Temperature Vibrator	SDWH2671	2021-12-23
Steel straight scale	SDWH463	2021-07-06
Vertical pressure steam sterilizer	SDWH2097	2021-03-25

5.2 Reagents

Reagent Name	Manufacturer	LOT
0.9% sodium chloride injection (SC)	Guangxi Yuyuan Pharmaceutical Co., Ltd.	H20053105
Sodium dodecyl sulfate (SDS)	Ron reagent	RH178474

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) 2020-0007>
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 (Randomly take the cable jacket only for test). The extraction was performed with agitation in closed inert containers according to the extraction ratio listed in the following table (sample: extraction vehicle). The extraction vehicle was SC.

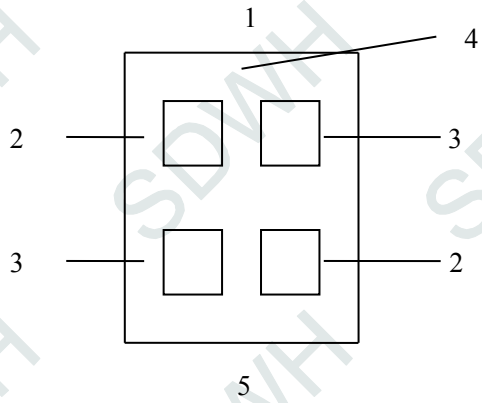
Test Period	Actual Sampling	Extract Procedure			Final Extract
		Extract Ratio	Extraction volume	Condition	
polar test extract	Surface area 30 cm^2	3 cm^2 : 1 mL	10.0 mL	50°C, 72 h	Clear
polar negative control	/	/	10.0 mL		Clear

The state of the extract did not change after extraction. The extract was stored at room temperature, 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 10cm×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 and washing with lukewarm water or other suitable nonirritating solvent and careful drying.



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 skin sites shall 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 did 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	2/2	3/3	3/3
			Oedema	3/3	4/3	4/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SC	2	Positive Control	Erythema	2/2	3/2	3/3
			Oedema	3/3	4/4	4/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
SC	3	Positive Control	Erythema	2/2	2/3	3/3
			Oedema	3/3	4/3	4/4
		Negative Control	Erythema	0/0	0/0	0/0
			Oedema	0/0	0/0	0/0
The primary irritation score.					6.1	

Note：Positive control performed once every six months, see SDWH-M202007070-1(Completed Date: 2021-01-01).

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