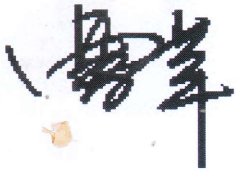
检 验 报 告

Report No.: WY20151196

SZYJ/JL-5.10-04-7.0

Test Article	TPE Medical Cable		
Model / Type	TP-001	Trade Mark	/
Test Type	Commission Test		
Sponsor	Shenzhen YONGQIANGFU Industrial CO., Ltd		
Applicant Address	2Bldg, No.2 Industrial park, Xinwei Village, Dalang LongHua Town, Shenzhen City		
Manufacturer	Shenzhen YONGQIANGFU Industrial CO., Ltd		
Lot No. / Identification No.	/	Date of Manufacturing	2015-6-25
Application Date	Aug. 13,2015	Accepting Date	Sept. 8,2015
Test Items	Skin Irritation Test		
Test in Accordance with	ISO 10993-10:2010 < Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization >		
Summary	The test article, TPE Medical Cable, was extracted in 0.9% sodium chloride injection and cottonseed oil respectively at 37℃ for 72h.The resulting extract was evaluated for skin irritation in accordance with the requirements of ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization. A 2.5cm×2.5cm patch of medical gauze, saturated with 0.5mL test article extract, was applied to the clipped area of rabbit. Similarly, the gauze saturated with negative control was patched on corresponding site on the same rabbit. The animal was wrapped with a bandage for 4h and then removed. The treatment sites were washed with warm water and marked. Observations for erythema and oedema were recorded at 1h, 24h, 48h, and 72h after removal, and the Primary Irritation Index for the extracts was calculated. Under the conditions of this study, the 0.9% sodium chloride and cottonseed oil test article extract showed no evidence of skin irritation to rabbit. The Primary Irritation Index for 2 extracts was 0 and irritation responses were negligible.		
Authorized Signatory		Date Completed	Nov.23,2015

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INTRODUCTION

The test article identified below was extracted and the extract was evaluated for skin irritation in accordance with the guidelines of the ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization. The test article was accepted on Sept. 8, 2015. The extraction was applied from Nov. 6, 2015 to Nov. 9, 2015. The treatment began on Nov. 9, 2015, and the observations were concluded on Nov. 12, 2015

MATERIALS

The sample provided by the sponsor was identified and handled as follows:

Test Article:	TPE Medical Cable
Identification No.:	/
Storage Conditions:	Room temperature
Extract Vehicle:	Polar solvent: 0.9% sodium chloride injection ChP (SC) Non-polar solvent: Cottonseed oil
Preparation:	Under aseptic conditions, 1.90g of test article which contacted body (as shown in Fig.2) was covered with 9.50mL of SC based on a ratio of 0.2g/mL. 2.07g of test article which contacted body was covered with 10.35mL of cottonseed oil in the same way. They were extracted at 37℃ for 72h. The vehicle without test article was similarly prepared to serve as the negative control. The extract of test article is transparent with no presence of particulates. The appearance of extract of test article and extract vehicle had no deference. The extract was used immediately.

METHODS

Test System:

Species:	Rabbit
Breed:	New Zealand White
Source:	Guangdong Animal Center of Medical Experimental
Sex:	Females, they should be nulliparous and not pregnant.
Body Weight Range:	2.3kg～2.9kg
Acclimation:	7 days
Number of Animals:	6

Animal Management:

Husbandry:	Conditions conformed to ISO 10993.2 Animal welfare requirements.
Food:	General rabbit diet was provided daily.
Water:	Freely available water was delivered.
Contaminants:	Reasonably expected contaminants in food or water supplies did not have the potential to influence the outcome of this test.
Housing:	Animals were individually housed in stainless steel suspended cages identified by a card indicating the sample number, animal number, test code, sex, and treatment date.
Environmental:	The room temperature and humidity were daily monitored. The temperature range for the room was within 20℃～25℃. The humidity range for the room was 40%～70%.

Facility: Shenzhen Testing Center of Medical Devices is a CNAS accredited facility.
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused animals were selected.

Experimental Procedure:

Six rabbits were randomly divided into polar and non-polar groups, which of groups were included 3 rabbits.

The day prior to treatment, each rabbit was weighed and clipped free of fur from the back and both sides of the spinal column to yield a sufficient area (about 10cm×15cm). A 2.5cm×2.5cm patch of medical gauze, saturated with 0.5mL test article extract, was placed on the area as illustrated in Fig.1. Similarly, the gauze saturated with negative control was patched on corresponding site on the same rabbit. And each animal was wrapped with a bandage for 4h and then removed. The treatment sites were washed with warm water to remove residual reagents and marked.

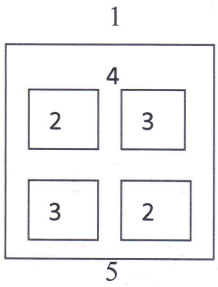

Fig.1 Location of skin application sites

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

Observations for erythema and oedema were recorded at 1h, 24h, 48h, and 72h after removal. The reactions were evaluated according to Table.1.

Table.1 Scoring system for skin reaction

Reaction	Primary 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	Score
No oedema	0
Very slight oedema(barely perceptible)	1

Well-defined oedema(edges of area well-define by definite raising)	2
Moderate oedema (raised approximately 1 mm)	3
Severe oedema(raised more than 1 mm and extending beyond exposure area)	4
Total possible score for irritation	8
Other adverse changes at skin sites shall be recorded and reported	

After the 72 h grading, all erythema grades plus oedema grades 24 h, 48h and 72h 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 (generally three). 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 index (PII).The PII is characterized by score and response category in Table 2.

Table.2 Irritation Response categories in 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

RESULTS

Results of scores for individual rabbits appear in Table 3.

Table 3. Skin Irritation Observations

Rabbit No.	Weigh (kg)	Group	Scoring Interval				Mean Score	Primary Irritation Score
			1 h (ER/OE)	24 h (ER/OE)	48 h (ER/OE)	72 h (ER/OE)		
1	2.6	Polar extracts	0/0	0/0	0/0	0/0	0	0
		Polar control	0/0	0/0	0/0	0/0	0	
2	2.7	Polar extracts	0/0	0/0	0/0	0/0	0	0
		Polar control	0/0	0/0	0/0	0/0	0	
3	2.5	Polar extracts	0/0	0/0	0/0	0/0	0	0
		Polar control	0/0	0/0	0/0	0/0	0	

4	2.7	Non-polar extracts	0/0	0/0	0/0	0/0	0	0
		Non-polar control	0/0	0/0	0/0	0/0	0	
5	2.9	Non-polar extracts	0/0	0/0	0/0	0/0	0	0
		Non-polar control	0/0	0/0	0/0	0/0	0	
6	2.3	Non-polar extracts	0/0	0/0	0/0	0/0	0	0
		Non-polar control	0/0	0/0	0/0	0/0	0	
Primary Irritation Index (Polar extracts)			0					
Irritation Response (Polar extracts)			Negligible					
Primary Irritation Index (Non-polar extracts)			0					
Irritation Response (Non-polar extracts)			Negligible					
Use only 24 h, 48 h and 72 h observations for calculations.								

ER/OE=Erythema/Oedema

Note: SDS (sodium lauryl sulphate) was the sensitizer for Rabbits. A SDS control test with the sensitizer was carried out on Sept. 21, 2015. The Primary Irritation Index for the SDS was 4.8 and irritation response was moderate.

CONCLUSION

Under the conditions of this study, the 0.9% sodium chloride and cottonseed oil test article extract showed no evidence of skin irritation to rabbits. The Primary Irritation Index for 2 extracts was 0 and irritation responses were negligible.

Results and conclusions apply only to the test article tested. No further evaluation of these results is made by our testing center. Any extrapolation of these data to other samples is the responsibility of the sponsor. All procedures were conducted in conformance with ISO 17025.

RECORD STORAGE

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

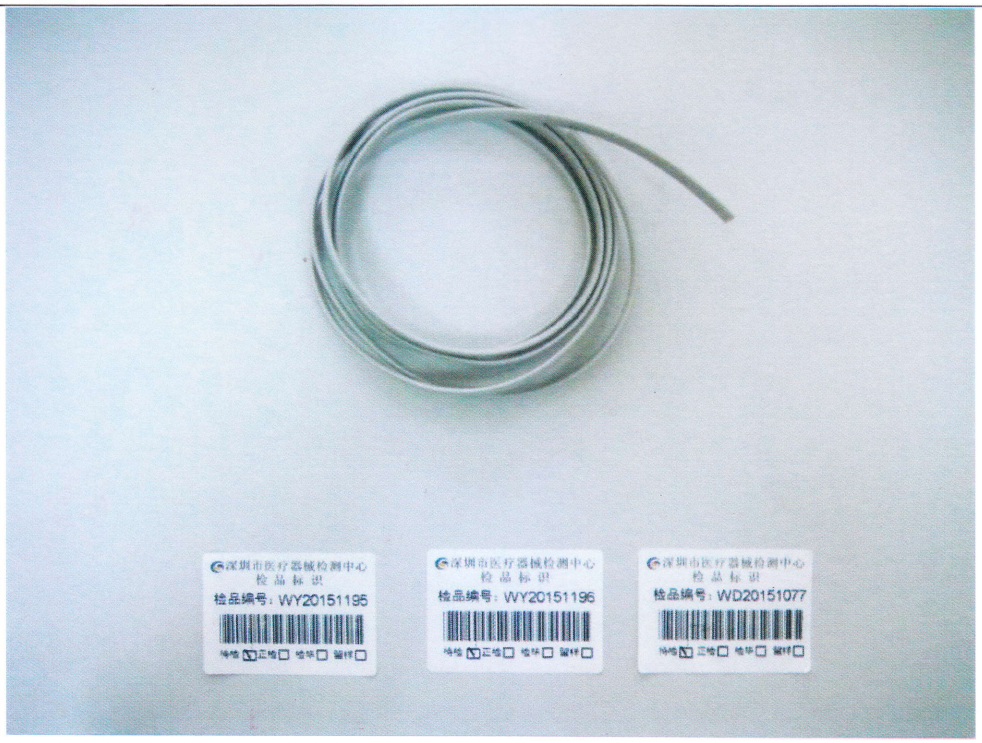

Fig.2 Test Article

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