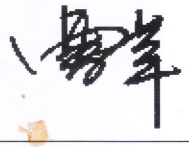
检 验 报 告

Report No.: WY20150747 Page 1 of 6

SZYJ/JL-5.10-04-7.0

Test Article	Silicone Medical Cable		
Model / Type	SP-001	Trade Mark	/
Test Type	Commission Test		
Sponsor	Shenzhen YONGQIANGFU Industrial CO., Ltd		
Applicant Address	2Blg,No. 2 Industrial park, Xinwei Village, Dalang LongHua Town, Shenz6hen City		
Manufacturer	Shenzhen YONGQIANGFU Industrial CO., Ltd		
Lot No. / Identification No.	/	Date of Manufacturing	2015-5-08
Application Date	May. 20,2015	Accepting Date	June. 16,2015
Test Items	Skin sensitization tests		
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, Silicone Medical Cable, was extracted in 0.9% sodium chloride injection and cottonseed oil respectively at 37℃ for 72h. The resulting extract was evaluated the potential for delayed dermal sensitization in accordance with the maximization test requirements of ISO 10993-10:2010 Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization. The test article extract was intradermally injected and occlusively patched to ten test guinea pigs in an attempt to induce sensitization. The negative control were similarly injected and occlusively patched to ten control guinea pigs respectively. Following a recovery period, the test and control animals received a challenge patch of the appropriate test article extract and negative control. All sites were scored at 24h and 48h after patch removal. Under the conditions of this study, the 0.9% sodium chloride and cottonseed oil test article extracts showed no evidence of causing skin sensitization in the guinea pig.		
Authorized Signatory		Date Completed	Aug.14,2015

INTRODUCTION

A guinea pig maximization test of the test article identified below was conducted to evaluate the potential to cause skin sensitization. This study was conducted based on the maximization test requirements 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 June. 16, 2015. The extraction was applied from July. 10, 2015 to July. 13, 2015. The treatment began on July. 13, 2015, and the observations were concluded on Aug. 9, 2015.

MATERIALS

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

Test Article:	Silicone 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:	Prior to use, based on a ratio of 0.2g/mL, a quantity of the test article (as show in fig.2) was covered with different vehicles respectively under sterile condition, 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 difference. The extract was used immediately.
Additional material:	Freund's Complete Adjuvant (FCA, SIGMA, Batch No.: SLBH1431V) was mixed 50:50(v/v) with the chosen vehicle and used at Induction I. A 10% sodium lauryl sulphate (SLS) suspension in petrolatum was used for Induction II

METHODS

Test System:

Species:	Guinea pig
Breed:	Albino
Source:	Guangdong Animal Center of Medical Experimental
Sex:	Males and nonpregnant nulliparous Females.
Body Weight Range	300g to 400g
Age:	Young Adults
Acclimation:	Minimum 3 days
Number of Animals:	forty

Animal Management:

Husbandry:	Conditions conformed to ISO 10993.2 Animal welfare requirements.
Food:	General Guinea pig 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 housed in groups in stainless steel suspended cages identified by a card indicating the sample number, animal numbers, test code, sex and first 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 and registered with the State Food and Drug Administration of China.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy, previously unused animals were selected.

Experimental Procedure:

4h prior to treatment, each animal was weighed, identified and clipped free of fur over the dorsoscapular region.

Induction I:

The test animals were injected with the test article extract and the control animals were injected with the control. Three rows of intradermal injections (two per row) were given to each animal within an approximate 4cm×6cm boundary of the fur clipped area as illustrated below:

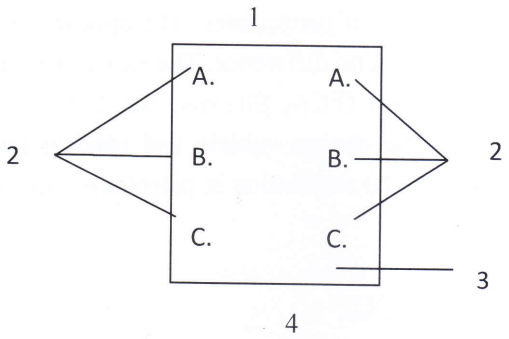


Fig.1 Location of intradermal injection sites

1-Cranial end

2- 0.1mL intradermal injections

3- Clipped intrascapular region without hair

4- Caudal end

Negative Control Animal:

A. 0.1 mL of 50:50 (v/v) mixture of FCA and the chosen vehicle

B. 0.1 mL of vehicle

C. 0.1 mL of a 1:1 mixture of the 50:50 (v/v) vehicle/ FCA mixture and the vehicle

Test Animal:

A. 0.1 mL of 50:50 (v/v) mixture of FCA and the chosen vehicle

B. 0.1 mL of test extract

C. 0.1 mL of a 1:1 mixture of the 50:50 (v/v) vehicle/ FCA mixture and the test extract

Induction II

6 days after the injections, the same area used during Induction Iwas clipped free of fur and treated with 10% sodium lauryl sulphate (SLS) suspension in petrolatum. The suspension was massaged into the skin over the injection site to provoke a mild acute inflammation. The area was left uncovered for 24h. Then 8cm^2 section of medical gauze, saturated with the test article extract, was applied to the previously injected sites of the test animals. The control animals were similarly patched with the appropriate negative control. The trunk of each animal was wrapped with an elastic bandage. After 48h, the binders and patches were removed.

Challenge:

At 15 days after the removal of the induction patch, a 2.5cm×2.5cm patch of medical gauze, saturated with the test article extract or negative control. All patches were applied to flank areas. The trunk of each animal was wrapped with a bandage for 24h and then removed.

Observations for dermal reactions were conducted at 24h and 48h after challenge patch removal. Scores were recorded in accordance with the criteria below:

Table 1 Magnusson and Kligman scale

Patch test reaction	Grading scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

Magnusson and Kligman grades of 1 or greater in the test group generally indicate sensitization, provided grades of less than 1 are seen in negative control animals. If grades of 1 or greater are notes in the negative control animals, then the reactions of test animals that exceed the most severe reaction in negative control animals are presumed to be due to sensitization.

RESULTS

Individual body observations are presented in Table 2.

The negative control group and the test article group was a grade 0 during observation period.

Table 2 Individual observations

Polar control	Animal No.	1	2	3	4	5	6	7	8	9	10
	weight(g)	306	322	328	316	326	320	319	316	322	325
	24h	0	0	0	0	0	0	0	0	0	0
	48 h	0	0	0	0	0	0	0	0	0	0
Polar extracts	Animal No.	11	12	13	14	15	16	17	18	19	20
	weight(g)	329	326	330	319	331	326	318	319	311	310

	24h	0	0	0	0	0	0	0	0	0	0
	48 h	0	0	0	0	0	0	0	0	0	0
Non-polar control	Animal No.	21	22	23	24	25	26	27	28	29	30
	weight(g)	315	316	319	315	305	309	312	316	308	306
	24h	0	0	0	0	0	0	0	0	0	0
	48 h	0	0	0	0	0	0	0	0	0	0
Non-polar extracts	Animal No.	31	32	33	34	35	36	37	38	39	40
	weight(g)	306	325	327	304	323	318	318	306	303	305
	24h	0	0	0	0	0	0	0	0	0	0
	48 h	0	0	0	0	0	0	0	0	0	0

Note: 0.1% 1-chloro-2,4-dinitrobenzene was the sensitizer for guinea pigs. A positive control test with the sensitizer was carried out on Mar. 5, 2015. The positive control group was a grade 2~3 during observation period.

CONCLUSION

Under the conditions of this study, the 0.9% sodium chloride and cottonseed oil test article extracts showed no evidence of causing skin sensitization in the guinea pig.

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

（Blank Below）