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TESTING
CNAS L1538

Test Report

TEST ITEMS

Test for skin sensitization (Maximization test)

TEST ARTICLE

Medical endoscope insertion tube
<Production date: 2023.7.1; Lot : 230701>

IDENTIFICATION №

230720

MANUFACTURER

Changzhou Yanshun Optronics & Technology Co., Ltd.
<Address: No. 2965 Longcheng Rd. Luoxi Town Xinbei District ChangZhou>

SPONSOR

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2. It will be invalid for the report without the signature of study director.
3. It will be invalid for the manual revision of the report.
4. This English report "SBRTC-2023-0612-2" was replaced by "SBRTC-2023-0612-5". According to the requirement of the sponsor, the name of Manufacturer and Sponsor were modified in the reports because of the mistake in the client's contract.
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SUMMARY

A guinea pig maximization test of the test article, **Medical endoscope insertion tube**, was conducted to evaluate the skin sensitizing potential. This study was based on the International Organization for Standardization ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization; ISO 10993-12:2021 Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

30 healthy young adult albino guinea pigs (half males and half females) with body weight range from 315.8g to 340.7g were utilized. The test sample was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO) respectively. The test included intradermal induction phase, topical induction phase and challenge phase. In these phase, each extract was injected intradermally and patched occlusively to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and patched occlusively to five reagent control guinea pigs (per vehicle). Following a recovery period, the test and reagent control animals were received a challenge patch of the appropriated test sample extract and the reagent control. All sites were scored and the skin reactions for erythema and swelling were described and graded from 0-3 scale at 24h and 48h after patch removal. If the grades of less than 1 are seen in reagent control animals, grades of 1 or greater in the test group were generally indicated sensitization.

Under the conditions of this study, at 24h and 48h after the challenge phase, the skin sites of the test and reagent control animals had no visible changes. It could be concluded that neither SC extract nor CSO extract of the test samples had evidence of causing sensitization in the guinea pigs.

Study and Supervisory Personnel: LIU Siyuan
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Study Director: Sun Jiao, Ph.D.

Nov 3. 2023
Date Completed

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INTRODUCTION

A guinea pig maximization study of the test article identified below was conducted to evaluate the potential to cause contact sensitization. This test was conducted depending on the requirements of ISO 10993-10:2021 Biological evaluation of medical devices Part 10: Tests for skin sensitization. The test article was received on Jul. 13, 2023. Treatment began on Sep. 18, 2023, and the final observations were concluded on Oct. 16, 2023.

This study was completed in the Lab of Shanghai Biomaterials Research & Test Center (SBRTC) and was conducted in accordance with the provisions of the ISO/IEC 17025: 2017.

MATERIALS

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

Test Article:	Medical endoscope insertion tube <Production date: 2023.7.1; Lot : 230701>
Identification No:	230720
Sterilization Status:	Non Sterile
Storage Conditions:	Room temperature
Extraction Vehicles:	1）0.9% Sterile Sodium Chloride Injection (SC) <Anhui Double-Crane Pharmaceutical Co., Ltd.; LOT: 22051709A> 2）Sterile Cotton seed oil (CSO) <J&K Scientific, LOT: L390U137>
Test Extract Preparation:	According to the requirement of the sponsor, the test samples were cut into small pieces and sterilized at 121℃ for 30min before testing. Based on the ISO 10993-12:2021, the ratio of 0.2g/ml [Weight of the test sample to volume of extraction vehicle] was adopted for testing. 3g of the test samples (Sampling according to the statement of the sponsor) were submersed in 15ml of extraction vehicles separately under aseptic conditions for preparing the SC and CSO test extracts at 37 ℃ for 72h respectively with continuously agitation during extraction. The extracts were used after extraction. The extracts were freshly prepared for 3 times in the process of the whole experiment.
Reagent Controls:	Two extraction vehicles without the test sample were similarly prepared respectively.
Condition of extracts:	All the extracts of the test samples and the controls were clear, no suspended particulates and without any special treatments.
Additional materials:	Freund's Complete Adjuvant (FCA) was mixed 50:50 (v/v) with the vehicle. A 10% (w/w) sodium dodecyl sulfate suspension in paraffin.

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In addition, according to the requirement of the ISO 10993-10:2021, 5% mercaptobenzothiazole (dissolved in DMSO) as a positive control was used previously for another study this month. Saw the appendix Ⅰ. The method used in the positive control group was the same as the negative control group and test group. Complete data was traceable in laboratory records.

METHODS

Test System:

Species:	Albino guinea pig
Source:	Jiashan County Golden Rabbit Industry Professional Cooperative
Sex:	Half males and half females (females were nulliparous and nonpregnant)
Body Weight Range:	315.8 g to 340.7 g
Age:	Young adult
Number of animals:	Thirty

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2022: Biological evaluation of medical devices Part 2: Animal welfare requirements".
Food:	Diet was provided from DOUBLE LION EXPERIMENTAL ANIMAL FEED TECHNOLOGY CO., LTD.
Housing:	Healthy animals were acclimatized to the laboratory conditions for 5 days before the treatment, and then they were randomized and assigned to groups in cages identified by a card indicating the Identification № of the test article and first treatment date.
Environmental:	The room temperature and humidity were monitored daily. The room temperature range was from 20℃ to 26℃. The room humidity range was from 50 % to 70 %.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, unused animals were selected.

Experimental Procedure:

1. Intradermal induction phase (Induction I):

The day prior to treatment, the fur was clipped on all treatment sites with an electric clipper. The 1st day, the test animals were injected with the fresh extracts of test sample and the reagent control animals were injected with the reagent control. Three rows of intradermal injections (two per row) were given to each animal within an approximate 2cm×4cm boundary of the fur clipped area as illustrated below:

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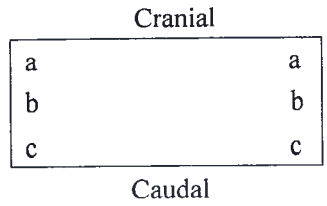

Test Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the chosen vehicle
b) 0.1ml of test extract
c) 0.1ml of 50:50(v/v) mixture of a and b

Reagent Control Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the chosen vehicle
b) 0.1ml of vehicle
c) 0.1ml of 50:50(v/v) mixture of a and b

Positive Control Animals:

a) 0.1ml of 50:50(v/v) mixture of FCA and the vehicle
b) 5% mercaptobenzothiazole (dissolved in DMSO)
c) 0.1ml of 50:50(v/v) mixture of a and b

2. Topical induction phase (Induction II):

At 7th day after completion of the intradermal induction phase, the same area was clipped free of fur and treat with 10% sodium dodecyl sulfate suspension in paraffin. The suspension was massaged into the skin over the injection site to provoke a mild acute inflammation. The area was left uncovered.

At 8th day, a 20mm×40mm section of absorbent gauze patch, saturated with the freshly prepared corresponding solution at the concentration of site b, and then was topically applied to the previously injected sites of the test animals. The reagent control animals were similarly patched with the appropriate reagent control. Each patch was secured with an occlusive dressing. The dressings and patches were removed after 48h.

3. Challenge phase

At 22nd day, the fur was clipped and shaved from the left flank areas. At 23rd day, absorbent gauze patches were soaked with the corresponding solution at the concentration of site b, and patched on the left upper flank of each animal in test and reagent control group. Then the animals were secured with an occlusive dressing. The dressings and patches were removed after 24h.

4. Observation of animals

The appearance of the challenge skin sites of the test animals, reagent control and positive control animals were observed respectively at 24h and 48h after removal of the dressing. The skin reactions for erythema and swelling were described and graded in according with the criteria shown below:

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

If the grades of less than 1 are seen in reagent control animals, grades of 1 or greater in the test group were generally indicated sensitization.

DEVIATIONS

There were no deviations from the ISO 10993-10:2021.

RESULTS

Clinical Observation:
All animals appeared clinically normal throughout the study. Individual body weights and clinical observations was given in APPENDIX II.

Dermal Observations:
No evidence of sensitization was observed. Individual results of dermal scoring for the challenge phase were shown as below. The detail data was given in the APPENDIX III.

	Hours following patch removal			
Time	24h		48h	
Vehicle	SC	CSO	SC	CSO
Test sample	0	0	0	0
Reagent Control	0	0	0	0

The result showed the skin sites of the test and reagent control animals had no visible changes at 24h and 48h after the challenge phase.

CONCLUSION

Under the conditions of this study, neither SC extract nor CSO extract of the test samples had evidence of causing sensitization in the guinea pigs.

Results and conclusions applied only to the test article tested. No further evaluation of these results was made by Shanghai Biomaterials Research & Test Center.

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RECORD STORAGE

All raw data pertaining to this study and a copy of the final report were stored in the designated archive files at Shanghai Biomaterials Research & Test Center.

PHOTOGRAPH OF THE TEST ARTICLE

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APPENDIX I

The result of controls in the guinea pig from the historical data in our center was showed as below:

Date: 2023.9.5 ~2023.9.30	Hours following patch removal (Hours)		
	Positive Control: 5% mercaptobenzothiazole LOT: MKCM9315		
Animal №	Pretreatment Body Weight (g)	24h	48h
1	325.4	2	3
2	317.0	2	2
3	329.4	2	2
4	331.2	2	3
5	317.5	2	3
	Negative Control: DMSO LOT:K2020036		
Animal №	Pretreatment Body Weight (g)	24h	48h
1	325.9	0	0
2	333.4	0	0
3	317.6	0	0
4	325.3	0	0
5	314.6	0	0

*This report is instead of SBRTC-2023-0612-2

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APPENDIX II

Individual body weights and clinical observations were given as below:

SC GROUP Individual Observation			CSO GROUP Individual Observation		
Animal Number	Pretreatment Body Weight (g)	Clinical Observations	Animal Number	Pretreatment Body Weight (g)	Clinical Observations
1 Test	319.4	Appeared normal	1 Test	318.9	Appeared normal
2 Test	322.8	Appeared normal	2 Test	340.7	Appeared normal
3 Test	319.6	Appeared normal	3 Test	320.4	Appeared normal
4 Test	321.5	Appeared normal	4 Test	337.2	Appeared normal
5 Test	326.4	Appeared normal	5 Test	330.7	Appeared normal
6 Test	325.8	Appeared normal	6 Test	323.3	Appeared normal
7 Test	336.4	Appeared normal	7 Test	328.1	Appeared normal
8 Test	324.1	Appeared normal	8 Test	321.0	Appeared normal
9 Test	335.8	Appeared normal	9 Test	327.5	Appeared normal
10 Test	332.9	Appeared normal	10 Test	315.8	Appeared normal
1 Control	321.7	Appeared normal	1 Control	327.5	Appeared normal
2 Control	330.4	Appeared normal	2 Control	331.4	Appeared normal
3 Control	325.9	Appeared normal	3 Control	329.6	Appeared normal
4 Control	320.8	Appeared normal	4 Control	327.5	Appeared normal
5 Control	326.9	Appeared normal	5 Control	323.8	Appeared normal

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APPENDIX III

Dermal observations were given as below:

SC GROUP Interval (hours)			CSO GROUP Interval (hours)		
Animal Number	24	48	Animal Number	24	48
1 Test	0	0	1 Test	0	0
2 Test	0	0	2 Test	0	0
3 Test	0	0	3 Test	0	0
4 Test	0	0	4 Test	0	0
5 Test	0	0	5 Test	0	0
6 Test	0	0	6 Test	0	0
7 Test	0	0	7 Test	0	0
8 Test	0	0	8 Test	0	0
9 Test	0	0	9 Test	0	0
10 Test	0	0	10 Test	0	0
1 Control	0	0	1 Control	0	0
2 Control	0	0	2 Control	0	0
3 Control	0	0	3 Control	0	0
4 Control	0	0	4 Control	0	0
5 Control	0	0	5 Control	0	0

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