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# Test Report

**TEST ITEMS**

Test for Irritation (Oral mucosa irritation 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**

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


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## SUMMARY

The extract of the test article, **Medical endoscope insertion tube,** was contacted with oral mucosal tissue, in order to assess the potential irritation to the oral mucosal membrane. The test was conducted based on the requirements for the International Organization for Standardization ISO 10993-23: 2021 Biological evaluation of medical devices Part 23: Tests for irritation; ISO 10993-12: 2021 Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

Six young adult Syrian hamsters were utilized. Both 0.9% sodium chloride injection (SC) and cotton seed oil (CSO) served as extraction vehicles. According to the sponsor's requirement,Oral mucosal tissue was directly exposed to the test extracts and the reagent controls (vehicles without test sample) respectively, 5min each hour, continuously for 4 fours. At 24h after the final treatment, injury to the epithelial layer of tissue and necrosis was examined macroscopically. The irritant effects including the status of epithelium, leucocyte infiltration, vascular congestion and oedema on oral mucosal tissue were evaluated microscopically. Finally for each extraction vehicle, the control group average score was subtracted from the test group average score to obtain the irritation index. According to the irritation index, degree of response was divided into 5 grades from non-irritant to severe irritant.

Under the conditions of this study, the macroscopic reaction of test extract was relatively similar to that of the reagent control. Microscopically, the SC extract and the CSO extract of the test sample were classified as non-irritant as compared to the reagent controls.

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Study Director: Sun Jiao, Ph.D.

Nov 3. 2023
Date Completed



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## INTRODUCTION

The purpose of the study was to evaluate the potential irritation response of the test extract contact with oral mucosa. This test was conducted based on the requirements of ISO 10993-23:2021 Biological evaluation of medical devices Part 23: Tests for irritation. The test article was received on Jul. 13, 2023. Treatment began on Aug. 14, 2023 and the final observations were concluded on Oct. 14, 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<br><Production date: 2023.7.1; Lot : 230701> |
| Identification No: | 230720 |
| Sterilization Status: | Non Sterile |
| Storage Conditions: | Room temperature |
| Extraction Vehicle: | 1）0.9% Sterile Sodium Chloride Injection (SC) <Anhui Double-Crane Pharmaceutical Co., Ltd.; LOT: 22051709A><br>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.<br>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. |
| Reagent Control: | 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. |


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## METHODS

Test System:

| | |
|---|---|
| Species: | Syrian hamster |
| Source: | Shanghai Songjiang Chedun Experimental Animal Breeding Farm Co., Ltd. |
| Sex: | Half males and half females (females were nonpregnant) |
| Age: | Young adult |
| Number of animals: | Six (three for the SC group; three for the CSO group) |

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 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 animals were selected. |

Experimental Procedure:

The animals were acclimatized to the laboratory condition for 5 days before the test. Before the test, the cheek pouches of the animalswere washed with SC carefully, and then were examined for any abnormality. A cotton-wool pellet was soaked approximate 0.2mlof the test extract was placed in the left side of cheek pouch in each animal for 5 min each hour. A cotton-wool pellet was soaked approximate 0.2ml extraction vehicle was placed in right side of cheek pouch correspondingly, which served as a reagent control. The above procedurewas repeated continuously for 4 hours.

Assessment of results:

The pouches were examined macroscopically following removal of the pellets each time, described the appearance of the cheek pouched for each animal and graded the pouch surface reactions for erythema and eschar formation according to the classification system given below: (see Table D.2)


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**Table D.2 — Macroscopic grading system for mucosal reactions**

| Reaction | Numerical grading |
|---|---|
| **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 |

At 24 hours after the final treatment, examined the cheek pouches macroscopically, and humanely killed the animals and removed the tissue samples from representative areas of the pouches. They were placed in an appropriate fixative prior to processing for histological examination. The irritant effects on oral tissue were evaluated and scored by a pathologist according to the system presented below (see Table D.3 and Table D.4):

**Table D.3 - Grading system for microscopic examination for mucosal tissue reaction**

| Reaction | Numerical grading |
|---|---|
| **Epithelium** | |
| Normal, intact | 0 |
| Cell degeneration or flatting | 1 |
| Metaplasia | 2 |
| Focal erosion | 3 |
| Generalized erosion | 4 |
| **Leucocyte infiltration (per high power field)** | |
| Absent | 0 |
| Minimal (less than 25) | 1 |
| Mild (26 to 50) | 2 |
| Moderate (51 to 100) | 3 |
| Marked (greater than 100) | 4 |
| **Vascular congestion** | |
| Absent | 0 |
| Minimal | 1 |
| Mild | 2 |
| Moderate | 3 |
| Marked, with disruption of vessels | 4 |
| **Oedema** | |
| Absent | 0 |
| Minimal | 1 |
| Mild | 2 |
| Moderate | 3 |
| Marked | 4 |

**Table D.4 - Irritation Index**

| Average score | Description of response |
|---|---|
| 0 | None |
| 1 to 4 | Minimal |
| 5 to 8 | Mild |
| 9 to 11 | Moderate |
| 12 to 16 | Severe |


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## DEVIATIONS

There were no deviations from the ISO 10993-23:2021.

## RESULTS

Clinical observations:
All animals appeared clinically normal throughout the duration of the study.

Macroscopic observations:
Compared the control cheek pouch with the test cheek pouch, there were no erythema and eschar formation.

Microscopic observations:
In the SC control group,no injury in the epithelium was observed. No leucocyte infiltration was found, and no vascular congestion or oedema was presented. In the SC test group, no injury in the epithelium was observed, and minimal leucocyte infiltration was foundoccasionally. No vascular congestion and no oedema were presented.
In the CSO control group,no injury in the epithelium was observed, and minimal leucocyte infiltration was foundoccasionally. No vascular congestion or oedema was presented. In the CSO test group, no injury in the epithelium was observed, and minimal leucocyte infiltration was found. No vascular congestion and no oedema were presented.

The scores of all the observation indexes and the average score were shown below:

| | Epithelium | Leucocyte infiltration | Vascular congestion | Oedema | Average score |
|---|---|---|---|---|---|
| SC Control | 0 | 0 | 0 | 0 | 0 |
| SC test extract | 0 | 1/3 | 0 | 0 | 1/3 |
| CSO Control | 0 | 1/3 | 0 | 0 | 1/3 |
| CSO test extract | 0 | 2/3 | 0 | 0 | 2/3 |

After the control group average score was subtracted from the test group average score, the irritation index of the SC group and the CSO group were both 0. The detailed data was given in the APPENDIX.

## CONCLUSION

Under the conditions of this study, the macroscopic reaction of test extract was relatively similar to that of the reagent control. Microscopically, the SC extract and the CSO extract of the test sample were classified as non-irritant as compared to the reagent controls.


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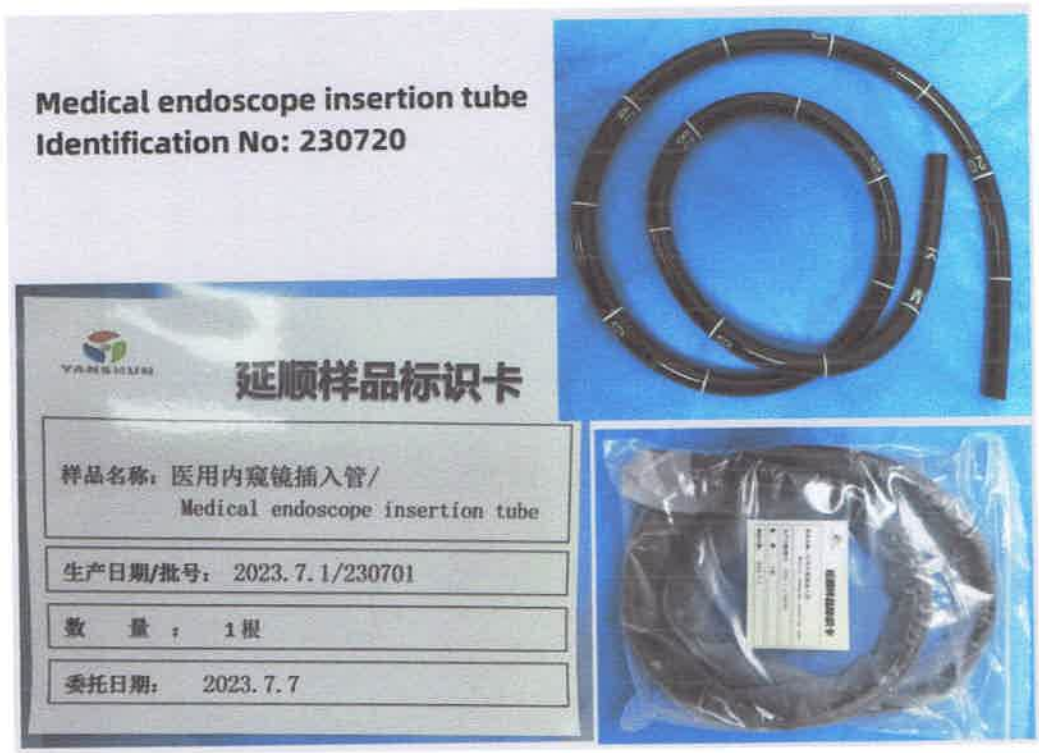
Results and conclusions applied only to the test article tested. No further evaluation of these results was made by Shanghai Biomaterials Research & Test Center.

## 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

Scores for SC group was given as below:

| SC GROUP | Animal Number | epithelium | Leucocyte infiltration | Vascular congestion | oedema | Score of each group (Average score) |
|---|---|---|---|---|---|---|
| Control | 1 | 0 | 0 | 0 | 0 | 0 |
| | 2 | 0 | 0 | 0 | 0 | |
| | 3 | 0 | 0 | 0 | 0 | |
| Score of each observation index | | 0 | 0 | 0 | 0 | |
| Test | 1 | 0 | 0 | 0 | 0 | 1/3 |
| | 2 | 0 | 0 | 0 | 0 | |
| | 3 | 0 | 1 | 0 | 0 | |
| Score of each observation index | | 0 | 1/3 | 0 | 0 | |

The irritation index of the SC group was 0.3 (regarded as 0).

Scores for CSO group was given as below:

| CSO GROUP | Animal Number | epithelium | Leucocyte infiltration | Vascular congestion | oedema | Score of each group (Average score) |
|---|---|---|---|---|---|---|
| Control | 4 | 0 | 0 | 0 | 0 | 1/3 |
| | 5 | 0 | 1 | 0 | 0 | |
| | 6 | 0 | 0 | 0 | 0 | |
| Score of each observation index | | 0 | 1/3 | 0 | 0 | |
| Test | 4 | 0 | 0 | 0 | 0 | 2/3 |
| | 5 | 0 | 1 | 0 | 0 | |
| | 6 | 0 | 1 | 0 | 0 | |
| Score of each observation index | | 0 | 2/3 | 0 | 0 | |

The irritation index of the SC group was 0.3 (regarded as 0).


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