No.L1538

Test Report

TEST ITEMS

Test for irritation (Oral mucosa irritation test)

TEST ARTICLE

Insertion Tube & Universal tube for Flexible endoscope
(spec: BF-GIF-CF-LG)

IDENTIFICATION №

060506

SPONSOR

Shanghai Yanshun Scope Parts & Accessories Co., Ltd.

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SUMMARY

The test article, **Insertion Tube & Universal tube for Flexible endoscope (spec: BF-GIF-CF-LG)** was contacted with oral tissue, in order to assess the potential irritation to the oral tissue. The test was conducted based on the requirements for the International Organization for Standardization ISO 10993-10-2002: Biological evaluation of medical devices Part 10: Tests for irritation and delayed-type hypersensitivity.

Under the conditions of this study, the macroscopic and microscopic reaction was not significant as the negative control.

Study and Supervisory
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Date Completed

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INTRODUCTION

The purpose of the study was to evaluate the potential irritation response of the test article in direct contact with oral mucosa. The test article was received on May.16, 2006. Treatment began on Jun.8, 2006, and the final observations were concluded on Jun.26, 2006.

This study was completed in the Lab of Shanghai Biomaterials Research & Test Center (SBRTC). SBRTC was conducted in accordance with the provisions of the ISO/IEC 17025-2005.

MATERIALS

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

Test Article:	Insertion Tube & Universal tube for Flexible endoscope (spec: BF-GIF-CF-LG)
Identification №:	060506
Storage Conditions:	Room temperature
Test Article Preparation:	The black outer cover of the test article was cut to Φ5mm round sheet of surface area for testing.
Sample Disposition:	Any remaining sample was discarded

METHODS

Test System:

Species:	Syrian hamster
Source:	SHANGHAI INSTITUTE OF BIOLIGICAL PRODUCTS
Sex:	Male
Age:	Young adult
Number of animals:	Five

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities".
Food:	SONGLIAN's Animal Diet was provided daily

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Housing:	Animals were housed in groups in stainless steel suspended cages identified by a card indicating the Identification № of the test article and first treatment date.
Environmental:	The room temperature was monitored daily. The temperature range for the room was 22℃ to 23℃. The room humidity was monitored daily. The humidity range for the room was 40% 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 animals were washed with SC carefully, and then were examined for any abnormality. A sample of the test article was placed in left side of cheek pouch in each animal for 5 min. No sample was placed in right side of cheek pouch correspondingly, which served as a control. The above procedure was repeated continuously for 4 hours.

Assessment of results:

Examined the pouches 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:

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, killed the animals humanely 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:

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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

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:

	Test sample	Negative control
Epithelium	0	0
Leucocyte infiltration	0	0
Vascular congestion	0	0
Oedema	0	0

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

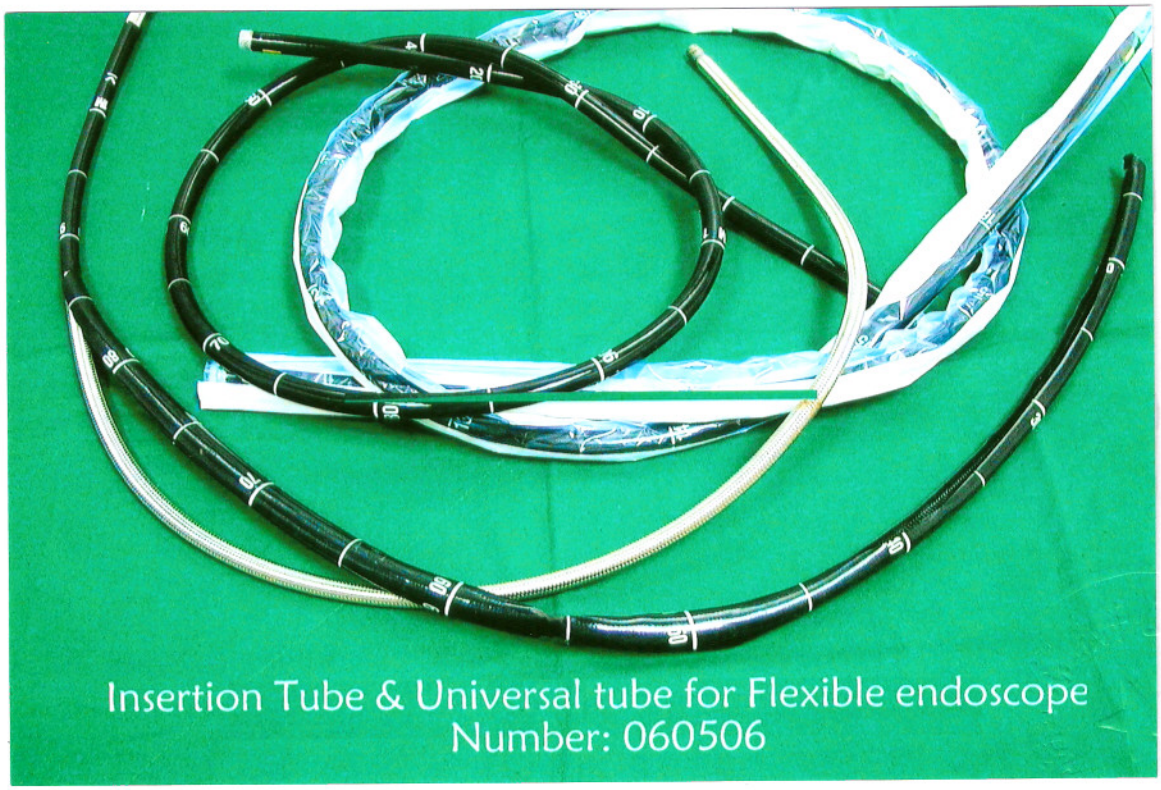
CONCLUSION

Under the conditions of this study, the macroscopic reaction of the test extract was not significant as compared to the negative control. Microscopically, the test extract was classified as a nonirritant as compared to the negative control.

RECORD STORAGE

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

PHOTOGRAPH OF THE TEST ARTICLE



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