Test Report

TEST ITEMS

Acute Systemic Toxicity Test

TEST ARTICLE

Non-absorbable Surgical Suture (model: PTFE)
<Specification: Z21302-60 (USP2-0/EP2.5)>

IDENTIFICATION №

150642

MANUFACTURER

Foosin Medical Supplies Inc., Ltd.

SPONSOR

TÜV SÜD Certification and Testing (China) Co., Ltd.
<Address: M Building, No.7 Wangjing Zhonghuan Nanlu, Chaoyang District, Beijing 100102, P.R.China>

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3. It will be invalid for the manual revision of the report.
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TABLE OF CONTENTS

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SUMMARY

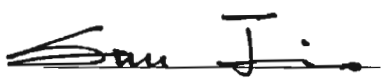
The purpose of the study was to determine whether the test article, Non-absorbable Surgical Suture (model: PTFE), would cause acute systemic toxicity following injection into mice. The test article was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO) respectively. These extracts were evaluated for acute systemic toxicity in accordance with the requirements of the ISO 10993-11:2006: Biological Evaluation of Medical Device, Part 11: Tests for Systemic Toxicity; ISO 10993-12:2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

Twenty ICR Mice with body weight range from 18.1 g to 20.7 g were utilized. The test article was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO) respectively. A single dose of the SC extract of the test article was injected by the intravenous route and the CSO extract of the test article was injected by intraperitoneal route respectively. Similarly, mice were dosed with corresponding reagent control. The animals were observed immediately at 4, 24, 48 and 72 hours after systemic injection. If during the 72h observation period none of the animals treated with the extract of the test article shows a substantially greater biological reaction than the animals treated with the reagent control, the extract of the test article meets the requirements of the test.

Under the conditions of this study, there was no mortality or evidence of acute systemic toxicity from the extract of the test article. The extract of the test article met the test requirement.

Study and Supervisory

Personnel: FEI Yun
YANG Fan
LU Hua

Study Director:  Nov 23. 2015

SUN Jiao, Ph.D. Date Completed

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INTRODUCTION

The purpose of the study was to determine whether the test extract would cause acute systemic toxicity following injection into mice. This test was conducted based on the requirements of ISO 10993-11:2006 Part 11: Tests for systemic toxicity. The test article was received on Jun. 16, 2015. Treatment began on Oct. 10, 2015, and the final observations were concluded on Oct. 16, 2015.

This study, initiated by protocol signature on Aug. 11, 2015, was completed in the Lab of Shanghai Biomaterials Research & Test Center (SBRTC) and was conducted in accordance with the provisions of the ISO/IEC 17025-2005.

MATERIALS

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

Test Article:	Non-absorbable Surgical Suture (model: PTFE) <Specification: Z21302-60 (USP2-0/EP2.5)>
Identification No:	150642
Sterilization Status:	Sterilized
Temperature Tolerance:	-25~+55℃(declaration from the sponsor)
Vehicles:	0.9% Sodium Chloride Injection (SC)<K15062018> Cotton seed oil (CSO)<MKBS9702V>
Test Article Preparation:	Based on the ISO ratio of 6cm^2/ml [Surface area of the test sample to volume of extraction vehicle], 91.3cm^2 of the test sample were covered 15.2ml of extraction vehicle under sterile conditions for preparing the SC or CSO test extract at 37℃ for 72 hours respectively in each phase. The extracts were used within 1 hour after extraction.
Reagent Control:	The extraction vehicle without the test article was similarly prepared.
Condition of extracts:	All the extracts of the test and controls were clear.

METHODS

Test System:

Species:	ICR Mouse
Grade:	SPF
Source:	Shanghai Jiesijie Experimental Animal CO., LTD
Sex:	Male
Body weight range:	18.1 g ~ 20.7 g
Number of animals:	Twenty

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Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2006: Biological evaluation of medical devices Part 2: Animal welfare requirements".
Food:	Diet was provided from SHANGHAI SLAC LABORATORY ANIMAL CO. LTD
Water:	Pure water
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 21℃ to 23℃. The room humidity range was from 57 % to 59 %. The light cycle was controlled using an automatic timer (12 hours light, 12 hours dark).
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy, unused animals were selected.

Experimental Procedure:

Prior to dosing, the mice were identified and weighed. Twenty mice were divided into four groups. Each group of five was injected respectively with the fresh extracts of CSO at a dose of 50ml/kg and the corresponding reagent control by the intraperitoneal route; each group of five was injected respectively with the fresh extracts of SC and the corresponding reagent control at a dose of 50ml/kg by the intravenous route.

Mice were observed for adverse reactions immediately after injection, again 4h after injection, and then 24, 48, and 72h, respectively, after injection for symptoms of slight, moderate, or marked toxicity or death. The body weights of all animals and the observations were recorded at 24, 48, and 72 h postinjection. The response to systemic injection assay was given below:

Response	Description
Normal, no symptoms	Mouse exhibits no adverse physical symptoms after injection.
Slight	Mouse exhibits slight but noticeable symptoms of hypokinesia, dyspnea, or abdominal irritation after injection.
Moderate	Mouse exhibits definite evidence of abdominal irritation, dyspnea, hypokinesia, ptosis, or diarrhea after injection. (Weight usually drops to between 15 and 17g.)
Marked	Mouse exhibits prostration, cyanosis, tremors, or severe symptoms of abdominal irritation, diarrhea, ptosis, or dyspnea after injection. (Extreme weight loss; weight usually less than 15g.)

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Dead, expired	Mouse dies after injection.

Interpretation of result:

If during the 72h observation period none of the animals treated with the extract of the test article shows a substantially greater biological reaction than the animals treated with the reagent control, the extract of the test article meets the requirements of the test.

DEVIATIONS

There were no deviations from the ISO 10993-11: 2006 and SBRTC-PROTOCOL-7-64.

RESULTS

Body weight data were acceptable. Individual observations were presented below:

Test Extract (SC)				Reagent Control			
№	Day 0	Day 3	Dead/Tested	№	Day 0	Day 3	Dead/Tested
1	18.4	21.7		1	19.6	22.9	
2	18.9	22.3		2	20.3	23.6	
3	19.7	23.2	0/5	3	20.2	23.5	0/5
4	20.7	23.3		4	18.4	21.6	
5	19.6	23.0		5	18.5	22.3	
Test Extract (CSO)				Reagent Control			
№	Day 0	Day 3	Dead/Tested	№	Day 0	Day 3	Dead/Tested
1	20.4	24.1		1	18.4	21.9	
2	18.3	21.9		2	18.2	21.5	
3	20.3	23.9	0/5	3	19.6	23.2	0/5
4	18.1	21.4		4	19.8	23.4	
5	20.1	23.2		5	19.3	22.5	

There was no mortality during the study. All animals appeared clinically normal throughout the study.

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

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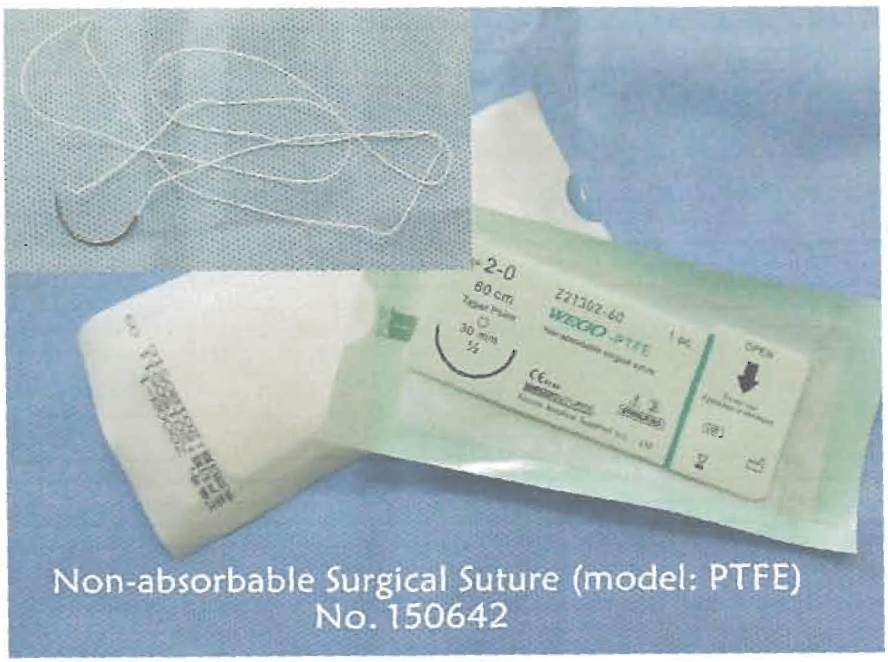
CONCLUSION

Under the conditions of this study, there was no mortality or evidence of acute systemic toxicity from the extract of the test article. The extract of the test article met the test requirement.

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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