Test Report

TEST ITEMS

Haemolysis test (Extraction Method)

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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2. It will be invalid for the report without the signature of study director.
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SUMMARY

This haemolysis test was conducted to determine whether the extract of the test article, Non-absorbable Surgical Suture (model: PTFE), would cause *in vitro* red blood cell hemolysis. It based on the requirements for the International Organization for Standardization ISO 10993-4: 2002+Amd 1: 2006: Biological Evaluation of Medical Devices, Part 4: Selection of tests for interactions with blood; ISO 10993-12:2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The fresh blood from a New Zealand White rabbits was used to prepare the fresh anticoagulant rabbit blood. The test extract, the negative control and positive control were contacted with the dilution of the fresh anticoagulant rabbit blood, at 37℃ for an hour, and then the supernatant of each group was get following centrifuging. The absorbance of each supernatant was determined by using a SHIMADZU UV-VISIBLE SPECTROPHOTOMETER at 545nm-test wavelength. The extent of haemolysis for the test article was calculated. If the extent of haemolysis was not more than 5%, the test article met the acceptable limits.

Under the conditions of this study, the extent of haemolysis for the test extract was 1 %, not more than 5%; the test extract met the test requirement. The negative control and the positive control performed as anticipated.

Study and Supervisory
Personnel: MA Jiadong
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Study Director: Sun Jiao
SUN Jiao, Ph.D.

Nov 23. 2015
Date Completed

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INTRODUCTION

The test article was conducted to determine whether leachables from the test extract would cause hemolysis *in vitro*. This test was conducted based on the requirements of ISO 10993-4: 2002+Amd 1: 2006: Biological Evaluation of Medical Devices, Part 4: Selection of tests for interactions with blood. The test article was received on Jun. 16, 2015. Treatment began on Oct. 16, 2015, and the final result was concluded on Oct. 19, 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>
Test Article Preparation:	Based on the ISO ratio of 6cm^2/ml [Surface area of the test sample to volume of extraction vehicle], 62.7cm^2 of the test sample were covered 10.45ml of extraction vehicle under sterile conditions for preparing the SC test extract at 37℃ for 72 hours respectively in each phase. The extracts were used within 1 hour after extraction.
Negative Control:	The extraction vehicles without test article were similarly prepared to serve as the test article.
Positive Control:	Distilled water <150907> without test article were similarly prepared to serve as the test article.
Condition of extracts:	The SC extract of the test was clear.

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METHODS

Test System:

Species:	Rabbit
Strain:	New Zealand White
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FIELD
Sex:	Male
Body weight range:	2.5 kg
Age:	Adult
Number of animals:	One

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.
Housing:	Healthy animals were acclimatized to the laboratory conditions for 7 days before the treatment, and then they were individually housed in stainless steel suspended 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 24℃. The room humidity was 56 %.
Personnel:	Associates involved were appropriately qualified and trained.
Selection:	Only healthy animals were selected.

The dilution of the fresh anticoagulant rabbit blood preparation:

10mL of fresh rabbit blood with 0.5mL of 20g/L potassium oxalate reagent was prepared for a fresh anticoagulant rabbit blood; then 4mL of fresh anticoagulant rabbit blood with 5mL 0.9% SC was prepared for the dilution of the fresh anticoagulant rabbit blood.

Experimental Procedure:

Three replicates were prepared per the test extract and controls respectively. Each of three tubes was added 10mL test extract as the test group. Each of three tubes was added 10ml SC as the negative control group; each of three tubes was added 10ml distilled water as the positive control group. All the tubes were put into a water-bath at 37℃ for 30min.

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After 30min, all tubes were added 0.2ml the dilution of the fresh anticoagulant rabbit blood, mixed gently and maintained a water-bath at 37℃ for 60min. The liquid in each tube was removed to the centrifugal tube respectively. Following all tubes was centrifuged for 5min at 800g, and an aliquot of each supernatant was carefully transferred to a cuvette. The absorbance of each supernatant was determined by using a SHIMADZU UV-VISIBLE SPECTROPHOTOMETER multipurpose recording spectrophotometer at 545nm-test wavelength, and averaged the replicate values. The absorbance of the negative control should not be more than 0.03 and the absorbance of the positive control should be 0.8±0.3, otherwise the test should be repeated. The extent of haemolysis was expressed as a percentage and calculated according to the formula:

$$\frac{Dt - Dnc}{Dpc - Dnc}$$

Where

D_t is the Absorbance of the Test Extract;

D_{nc} is the Absorbance of the Negative Control;

D_{pc} is the Absorbance of the Positive Control

If the extent of haemolysis was not more than 5%, the test extract met the acceptable limits.

DEVIATIONS

There were no deviations from ISO 10993-4: 2002+Amd 1: 2006 and SBRTC-PROTOCOL-18-48.

RESULTS

The absorbance of each supernatant was shown as below:

	The absorbance (545nm)			MEAN±SD
	1	2	3	
Test article	0.016	0.019	0.019	0.018±0.002
Negative control	0.008	0.011	0.009	0.009±0.002
Positive control	0.888	0.933	0.896	0.906±0.024

The extent of haemolysis for the test extract was 1 %.

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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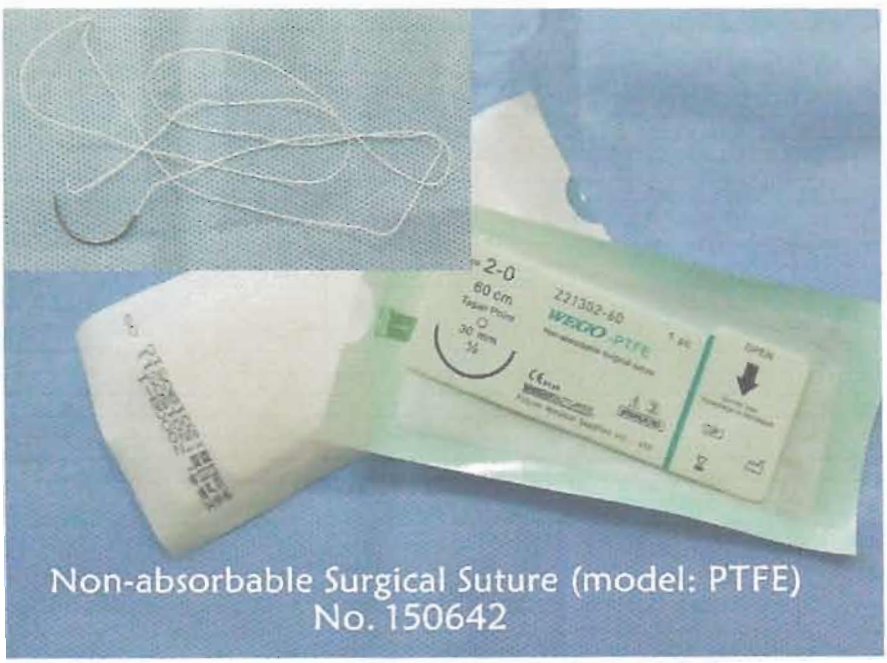
CONCLUSION

Under the conditions of this study, the extent of haemolysis for the test extract was 1 %, not more than 5%; the test extract met the test requirement. The negative control and the positive control performed as anticipated.

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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