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CNAS L1538

Test Report

TEST ITEMS

Test for irritation (Rectal irritation test)

TEST ARTICLE

mercury free clinical thermometer
<Sample Type: CR.W00; Lot No.: 20210501>

IDENTIFICATION No

210821

MANUFACTURER

Wuxi HongGuang Medical Equipment Co., Ltd.
<Address: No.21, Xixin Road, Xibei Town, Wuxi City, Jiangsu, China>

SPONSOR

TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch
<Address: 3-13, No.151 Heng Tong Road>

SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER

Page 1 of 8

Add: 201, Building 2, No. 427 Jumen Road, Shanghai, China

Zip Code: 200023

TEL: 0086-21-63034903

FAX: 0086-21-63011643

Web site: www.sbrtc.com

E-mail: biomatercenter@163.com



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TABLE OF CONTENTS

SUMMARY.....	4
INTRODUCTION.....	5
MATERIALS.....	5
METHODS.....	5
RESULTS.....	7
CONCLUSION.....	8
RECORD STORAGE.....	8
PHOTOGRAPH OF THE TEST ARTICLE.....	8

SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER

Page 3 of 8

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SUMMARY

The purpose of the study was to evaluate the potential irritation response of the extract of the test article, mercury free clinical thermometer, and contact with rectal tissue. This study was conducted based on the requirements for the International Organization for Standardization ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization; ISO 10993-12:2012 Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test extracts were contacted with rectal tissue once a day directly for five consecutive days. At 24h after the final treatment, the tissues were examined macroscopically and microscopically. The irritant effects on rectal tissue were evaluated and scored.

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

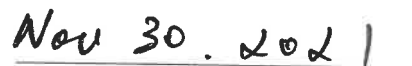
Study and Supervisory

Personnel: ZHANG Chengsi
CAI Zhenwei
LIU Xin
LU Hua

Study Director:



SUN Jiao, Ph.D.



Date Completed

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Page 4 of 8

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INTRODUCTION

The extract of the test article was contacted with rectal tissue, in order to assess the potential irritation to the rectal tissue. This study was conducted based on the requirements of ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization. The test article was received on Aug. 9, 2021. Treatment began on Aug. 16, 2021, and the final observations were concluded on Oct. 13, 2021.

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: 2017.

MATERIALS

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

Test Article:	mercury free clinical thermometer <Sample Type: CR.W00; Lot No.: 20210501>
Identification №:	210821
Sterilization Status:	NON STERILE
Storage Conditions:	Room temperature
Extraction Vehicles:	0.9% Sodium Chloride Injection (SC) Cotton Seed Oil (CSO)
Test Extract Preparation:	Based on the ISO 10993-12:2012, the ratio of 3cm ² /ml [Surface area of the test sample to volume of extraction vehicle], 73.6cm ² of the whole shell of the test samples were covered with 24.5ml of extraction vehicles under aseptic conditions for preparing test extracts at 37°C for 72h respectively with continuously agitation during extraction. The extracts were used after extraction.
Reagent Controls:	Two extraction vehicles without the test sample were similarly prepared respectively.
Condition of extracts:	All the extracts of the test samples and controls were clear, no suspended particulates and without any special treatments.

METHODS

Test System:

Species:	Rabbit
Strain:	New Zealand White
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FEILD
Sex:	female

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Page 5 of 8

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Number of animals: Twelve
Body weight range: 2.0 kg~2.2 kg
Age: Young adult

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 DOUBLE LION EXPERIMENTAL ANIMAL FEED TECHNOLOGY 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 range was from 20 °C to 26 °C. The room humidity range was from 50 % to 70 %.

Personnel: Associates involved were appropriately qualified and trained.

Selection: Only healthy, previously unused animals free of swelling or vaginal infection were selected for this test.

Experimental Procedure:

Before the test, each animal was checked for rectal discharge, swelling and other evidence of lower bowel infection, irritation and injury.

Each animal was secured by a restraining device, a separate syringe with attached a soft catheter was prepared for each animal. The animal's tail was grasped and raised to expose the perineum. The catheter was moistened with a lubricant and inserted deep into the rectum, entire 1 ml dose of the test extract or reagent control was deposited. The catheter was withdrawn and discarded. If there was anything expelled, removed gently with absorbent gauze patches. The above procedure was repeated at 24h intervals every day for five consecutive days.

Assessment of results:

At 24h after the initial application and immediately prior to each treatment, the appearance of the perineum for signs of discharge, erythema and irritation was noted and recorded. At 24h after the last dose, the animals were killed humanely. The entire lower bowel was dissected free and opened longitudinally. The signs of irritation, injury to the epithelial layer of tissue and necrosis were examined. Then the rectum and distal portion of the large bowel were fixed to processing for histological examination. The irritant effects on the rectal tissue were evaluated and scored by a pathologist according to the system presented in table 1.

The grades for microscopic evaluation for all the animals in the test group were added, and the sum was divided by the number of observations to obtain a test group average or control group average. The control group average score was subtracted from the test group average score to

obtain the Irritation Index.

Table 1 grading system for microscopic examination and irritation index

Reaction	Numerical grading
Epithelium	
Normal, intact	0
Cell degeneration or flattening	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

Irritation Index	
Average grade	Description of response
0	None
1 to 4	Minimal
5 to 8	Mild
9 to 11	Moderate
12 to 16	Severe

RESULTS

Clinical observations:

All animals appeared clinically normal throughout the duration of the study.

Macroscopic observations:

Compared the rectal tissue of the test rabbits with the rectal tissue of the control rabbits, there were no abnormality formation.

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Page 7 of 8

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Microscopic observations:

	Epithelium	Leucocyte infiltration	Vascular congestion	Oedema	Score
SC Control	0	0	0	1/6	1/6
SC test extract	0	1/6	0	0	1/6
CSO Control	0	2/6	0	0	2/6
CSO test extract	0	1/6	0	0	1/6

After the control group average score was subtracted from the test group average score, the irritation index of the test sample with extraction vehicle of SC was 0 and that of the test sample with extraction vehicle of CSO was -0.2(regarded as 0).

CONCLUSION

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

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**SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER**

Page 8 of 8

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Test Report

TEST ITEMS

Test for Irritation (Oral mucosa irritation test)

TEST ARTICLE

mercury free clinical thermometer
<Sample Type: CR.W00; Lot No.: 20210501>

IDENTIFICATION №

210821

MANUFACTURER

Wuxi HongGuang Medical Equipment Co., Ltd.
<Address: No.21, Xixin Road, Xibei Town, Wuxi City, Jiangsu, China>

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SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER

Page 1 of 9

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INTRODUCTION.....	5
MATERIALS.....	5
METHODS.....	5
RESULTS.....	7
CONCLUSION.....	8
RECORD STORAGE.....	8
PHOTOGRAPH OF THE TEST ARTICLE.....	9

SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER

Page 3 of 9

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SUMMARY

The extract of the test article, mercury free clinical thermometer, 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 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization; ISO 10993-12:2012 Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test extracts and the reagent controls were contacted with oral mucosal tissue once an hour for 4h totally. At 24h after the final treatment, the tissues were examined macroscopically and microscopically. The irritant effects on oral tissue were evaluated and scored.

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

Study and Supervisory

Personnel: LIU Siyuan
CAI Zhenwei
LIU Xin
LU Hua

Study Director:


SUN Jiao, Ph.D.

Nov 30, 2021
Date Completed

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Page 4 of 9

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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 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization. The test article was received on Aug. 9, 2021. Treatment began on Sep. 6, 2021, and the final observations were concluded on Oct. 15, 2021.

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: 2017.

MATERIALS

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

Test Article: mercury free clinical thermometer
<Sample Type: CR.W00; Lot No.: 20210501>

Identification №: 210821

Sterilization Status: NON STERILE

Storage Conditions: Room temperature

Extraction Vehicles: 0.9% sodium chloride injection (SC)
Cotton seed oil (CSO)

Test Extract Preparation: Based on the ISO 10993-12:2012, the ratio of 3cm²/ml [Surface area of the test sample to volume of extraction vehicle], 73.6cm² of the whole shell of the test samples were covered with 24.5ml of extraction vehicles under aseptic conditions for preparing test extracts at 37°C for 72h respectively with continuously agitation during extraction. The extracts were used after extraction.

Reagent Controls: Two extraction vehicles without the test sample were similarly prepared respectively.

Condition of extracts: All the extracts of the test samples and controls were clear, no suspended particulates and without any special treatments.

METHODS

Test System:

Species: Syrian hamster
Source: SHANGHAI SONGLIAN LAB ANIMAL-FEILD
Sex: 3 Males and 3 Females

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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 10993-2:2006 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 °C to 26 °C. 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 animals were washed with SC carefully, and then were examined for any abnormality. A cotton-wool pellet was soaked approximately 0.2ml of 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 approximately 0.2ml extraction vehicle was placed in right side of cheek pouch correspondingly, which served as a reagent control. The above procedure was repeated continuously once an hour for 4h totally.

Assessment of results:

The pouches were examined macroscopically following removal of the pellets each time, described the appearance of the cheek pouches 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

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Page 6 of 9

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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:

Reaction	Numerical grading
Epithelium	
Normal, intact	0
Cell degeneration or flattening	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

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

The irritation index was obtained by subtracting the score of the reagent control from the test extract score.

RESULTS

Clinical observations:

All animals appeared clinically normal throughout the duration of the study.

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Macroscopic observations:

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

Microscopic observations:

The scores of all the observation indexes and the average score were shown below. The irritation indexes were all 0 for the SC and CSO group, respectively.

	Epithelium	Leucocyte infiltration	Vascular congestion	Oedema	Score
SC Control	0	0	0	0	0
SC test extract	0	0	0	0	0
CSO Control	0	0	0	0	0
CSO test extract	0	0	0	0	0

CONCLUSION

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

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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Page 8 of 9

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PHOTOGRAPH OF THE TEST ARTICLE**SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER**

Page 9 of 9

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Test Report

TEST ITEMS

Test for irritation (Animal skin irritation test)

TEST ARTICLE

mercury free clinical thermometer
<Sample Type: CR.W00; Lot No.: 20210501>

IDENTIFICATION №

210821

MANUFACTURER

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<Address: No.21, Xixin Road, Xibei Town, Wuxi City, Jiangsu, China>

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SUMMARY.....	4
INTRODUCTION.....	5
MATERIALS.....	5
METHODS.....	6
RESULTS.....	8
CONCLUSION.....	8
RECORD STORAGE.....	8
PHOTOGRAPH OF THE TEST ARTICLE.....	8

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SUMMARY

The animal skin irritation test of the extract of the test article, mercury free clinical thermometer, was conducted to assess the potential of the material to produce irritation. This study was conducted based on the requirements of the International Organization for Standardization ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization; ISO 10993-12:2012 Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test article was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO). Each extract and corresponding reagent control was contacted on animal skin directly. Observations for erythema and edema were conducted at 24, 48 and 72 hours after contact.

Under the conditions of this study, there was no evidence of significant irritation from the test extracts to rabbits. The response category for the extracts of the test article was negligible.

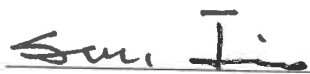
Study and Supervisory

Personnel: ZHANG Chengsi

YE Zhongjie

LU Hua

Study Director:



SUN Jiao, Ph.D.



Date Completed

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Page 4 of 8

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INTRODUCTION

This study was conducted to determine whether the test extract would cause local dermal irritant effects following contacted the rabbit skin. This study was conducted based on the requirements of ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization. The test article was received on Aug. 9, 2021. Treatment began on Sep. 3, 2021, and the final observations were concluded on Sep. 10, 2021.

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: 2017.

MATERIALS

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

Test Article:	mercury free clinical thermometer < Sample Type: CR.W00; Lot No.: 20210501>
Identification №:	210821
Storage Conditions:	Room temperature
Sterilization Status:	NON STERILE
Extraction Vehicles:	0.9% Sodium Chloride Injection (SC) Cotton Seed Oil (CSO)
Test Extract Preparation:	Based on the ISO 10993-12:2012, the ratio of 3cm ² /ml [Surface area of the test sample to volume of extraction vehicle], 73.6cm ² of the whole shell of the test samples were covered with 24.5ml of extraction vehicles under aseptic conditions for preparing test extracts at 37°C for 72h respectively with continuously agitation during extraction. The extracts were used after extraction.
Reagent Controls:	Two extraction vehicles without the test sample were similarly prepared respectively.
Condition of Extracts:	All the extracts of the test samples and controls were clear, no suspended particulates and without any special treatments.

In addition, according to the requirement of ISO 10993-10:2010, 10% Sodium Dodecyl Sulfate as a positive control was used previously for another study (2021.6.21-2021.6.25). 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.

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Page 5 of 8

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METHODS

Test System:

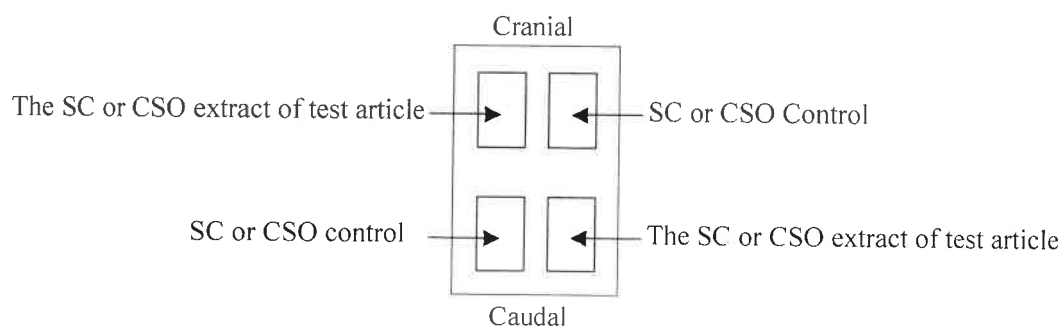
Species:	Albino Rabbit
Strain:	New Zealand White
Source:	SHANGHAI SONGLIAN LAB ANIMAL-FIELD
Sex:	Half males and half females
Body weight range:	2.5 kg ~ 2.7 kg
Age:	Young adult
Number of animals:	Six

Animal Management:

Husbandry:	Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities".
Food:	Diet was provided from DOUBLE LION EXPERIMENTAL ANIMAL FEED TECHNOLOGY 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 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, previously unused rabbits were selected.

Experimental Procedure:

On the day before the test, the rabbits were closely clipped the fur on the backs of the animals, and both sides of the spinal for application and observation of all test sites, approximately 10cm×15cm. A 25mm×25mm section of absorbent gauze patch was saturated with freshly prepared the extract, and then was applied to test sites. The extract of the test article and the reagent control were applied to the region as illustrated below:



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Page 6 of 8

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The application sites were covered with a gauze patch and then the application sites were wrapped with a semi-occlusive bandage for 24h. At the end of the contact time, the dressings were removed. A natural lighting was used to visualize the skin reactions. The skin reactions for erythema and oedema were described and scored at 1, 24, 48 and 72 hours following removed of the patches.

The tissue reaction for erythema and oedema were graded according to the classification system given below for each site and at each time observed, and the results were recorded.

Reaction	Primary Irritation Score
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
Oedema formation	
No oedema	0
Very slight oedema (barely perceptible)	1
Well-defined oedema (edges of area well-defined by definite raising)	2
Moderate oedema (raised approximately 1mm)	3
Severe oedema (raised more than 1mm and extending beyond exposure area)	4

Only the 24, 48 and 72hours observations were used for calculation. For each animal, the score both erythema and oedema at each time point were added together separately for each test extract and the corresponding reagent control. The primary irritation score for an animal was calculated by dividing the sum of all the scores by 6 (2 test sites $\times$ 3 time points). All the primary irritation scores of individual animals were added and divided by the number of animals, and then the primary irritation scores for each test extract were obtained. A similar calculation was made with the corresponding reagent control. The primary irritation index was obtained by subtracting the score of the corresponding reagent control from the test extract score and the response categories were given as below:

Mean score	Response category
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

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Page 7 of 8

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RESULTS

All animals appeared clinically normal throughout the study. All sites of the test extracts and the reagent controls appeared normal following removal the patches; the score of the test extracts and the reagent controls all were 0.

The Primary Irritation Index (PII) of each test extract was all 0.0.

CONCLUSION

Under the conditions of this study, there was no evidence of significant irritation from the test extracts to rabbits. The response category for the extracts of the test article was negligible.

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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CNAS L1538

Test Report

TEST ITEMS

Test for skin sensitization (Maximization test)

TEST ARTICLE

mercury free clinical thermometer
< Sample Type: CR.W00; Lot No.: 20210501 >

IDENTIFICATION №

210821

MANUFACTURER

Wuxi HongGuang Medical Equipment Co., Ltd.
<Address: No.21, Xixin Road, Xibei Town, Wuxi City, Jiangsu, China>

SPONSOR

TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch
<Address: 3-13, No.151 Heng Tong Road>

Page 1 of 9

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TABLE OF CONTENTS

SUMMARY	4
INTRODUCTION	5
MATERIALS	5
METHODS	6
RESULTS	8
CONCLUSION	8
RECORD STORAGE	8
PHOTOGRAPH OF THE TEST ARTICLE	9

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SUMMARY

A guinea pig maximization test of the test article, mercury free clinical thermometer, was conducted to evaluate the skin sensitizing potential. This study was based on the International Organization for Standardization ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization; ISO 10993-12:2012 Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test sample was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO). 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 at 24h and 48h after patch removal.

Under the conditions of this study, the SC and CSO extracts of the test samples showed no evidence of causing sensitization in the guinea pigs.

Study and Supervisory

Personnel: LIU Siyuan
YE Zhongjie
JIN Ruifen
LU Hua

Study Director:



SUN Jiao, Ph.D.



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 based on the requirements of ISO 10993-10:2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization. The test article was received on Aug. 9, 2021. Treatment began on Oct. 15, 2021, and the final observations were concluded on Nov. 12, 2021.

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: 2017.

MATERIALS

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

Test Article:	mercury free clinical thermometer <Sample Type: CR.W00; Lot No.: 20210501>
Identification №:	210821
Sterilization Status:	STERILE
Storage Conditions:	Room Temperature
Extraction Vehicles:	0.9% Sodium Chloride Injection (SC) Cotton seed oil (CSO)
Test Extract Preparation:	Based on the ISO 10993-12:2012, the ratio of 3cm ² /ml [Surface area of the test sample to volume of extraction vehicle], 73.6cm ² of the whole shell of the test samples were covered with 24.5ml of extraction vehicles under aseptic conditions for preparing test extracts at 37°C 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 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 ISO 10993-10:2010, 5% mercaptobenzothiazole (dissolved in DMSO) as a positive control was used previously for another study (2021.9.3 ~ 2021.9.28). 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:	SHANGHAI SONGLIAN LAB ANIMAL-FEILD
Sex:	Half males and half females (females were nulliparous and nonpregnant)
Body Weight Range:	311. 4g to 339. 1g
Age:	Young adult
Number of animals:	Thirty

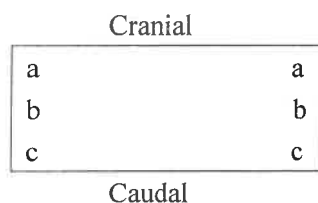
Animal Management:

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 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 °C to 26 °C . 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 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:



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

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 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 C, 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 and control animals was 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:

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.

RESULTS

Clinical Observation:

All animals appeared clinically normal throughout the study.

Dermal Observations:

No evidence of sensitization was observed. Individual results of dermal scoring for the challenge phase shown below:

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

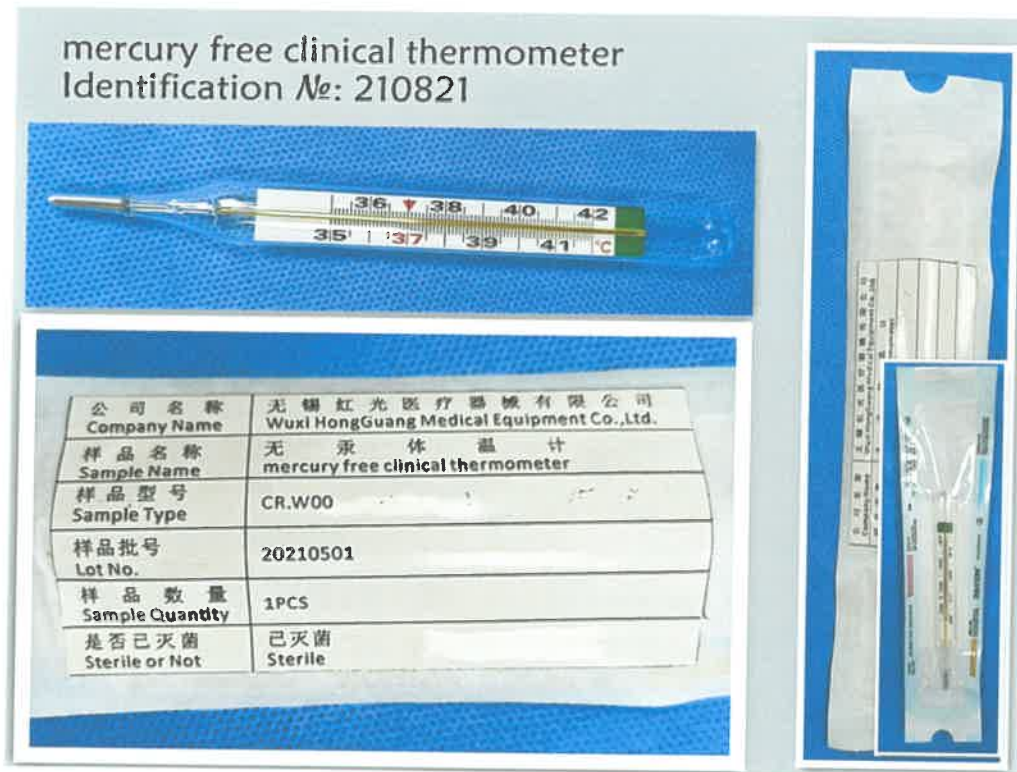
CONCLUSION

Under the conditions of this study, the SC and CSO extracts of the test samples showed no 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.

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**SHANGHAI BIOMATERIALS RESEARCH & TEST CENTER**

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Page 9 of 9

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Test Report

TEST ITEMS

Test for *in vitro* cytotoxicity (MTT cytotoxicity test)

TEST ARTICLE

mercury free clinical thermometer
<Sample Type: CR.W00: Lot No.: 20210501>

IDENTIFICATION No

210821

MANUFACTURER

Wuxi HongGuang Medical Equipment Co., Ltd.
<Address: No.21, Xixin Road, Xibei Town, Wuxi City, Jiangsu, China>

SPONSOR

TÜV SÜD Certification and Testing (China) Co., Ltd. Shanghai Branch
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TABLE OF CONTENTS

SUMMARY.....	4
INTRODUCTION.....	5
MATERIALS.....	5
METHODS.....	6
RESULTS.....	6
CONCLUSION.....	7
RECORD STORAGE.....	7
PHOTOGRAPH OF THE TEST ARTICLE.....	7

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SUMMARY

An *in vitro* cytotoxicity study was conducted to assess the potential for cytotoxicity of the test article, mercury free clinical thermometer, based on the International Organization for Standardization ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity; ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials.

Four concentrations (100%, 75%, 50%, and 25%) of the test sample extracts, the blank, 100% of the negative control and the positive control were prepared using Minimum Essential Medium (MEM) supplemented with 10% fetal bovine serum. The semi-confluent monolayers of L-929 mouse fibroblast cells were incubated with the test extract, the blank and other two controls, supplemented with 10% fetal bovine serum in a 96-well microplate respectively at 37°C under the condition of 5% CO₂. At 24h, the MTT colorimetric assay was employed and the plate was read on a microplate reader at 570 and 650 nm. The viability of the cells was calculated.

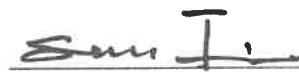
Under the condition of this study, the viability of 100% extract of the test sample was 77%. It can be considered that the test sample extracts had not a cytotoxic potential.

Study and Supervisory

Personnel: XU Yuan

HUANG Zhewei

Study Director:



SUN Jiao, Ph.D.



Date Completed

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INTRODUCTION

The study was performed in order to determine whether leachables extracted from the test article would cause cytotoxicity. This test was conducted based on the requirements of ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity. The test article was received on Aug. 9, 2021. The cells were first exposed to the extract on Oct. 12, 2021, and the final observations were concluded on Oct. 13, 2021.

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: 2017.

MATERIALS

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

Test Article:	mercury free clinical thermometer <Sample Type: CR.W00; Lot No.: 20210501>
Identification №:	210821
Sterilization Status:	Sterile
Storage Temperature:	Room Temperature
Extraction Vehicle:	gibco's Minimum Essential Medium supplemented with L-glutamine and 10% fetal bovine serum
Test Extract Preparation:	Based on the ISO 10993-12:2012, the ratio of 3cm ² /ml [Surface area of the test sample to volume of extraction vehicle], 73.6cm ² of the whole test sample (Sampling according to the requirement of the sponsor) was covered with 24.5ml of extraction vehicle under aseptic conditions for preparing the test extract at 37°C for 24 hours with continuously agitation during extraction. The extract was used immediately after extraction.
Blank Preparation:	The extraction vehicle not containing the test sample, retained in a vessel identical to that which holds the test sample and subjected to conditions identical to those to which the test sample is subjected during its extraction.
Negative Control Preparation :	Current SBRTC negative control, the ratio of 3cm ² High-density polyethylene film : 1ml [surface area of the test sample to volume of extraction vehicle] was used and extracted at 37°C for 24 hours.
Positive Control Preparation:	Current SBRTC positive control, the ratio of 6cm ² Polyurethane film containing 0.1% zinc diethyldithiocarbamate (ZDEC) : 1ml [surface area of the test sample to volume of extraction vehicle] was used and extracted at 37°C for 24 hours.
Condition of Extracts:	All the extracts of the test and controls were clear, no suspended particulates and without any special treatments.

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METHODS

Test System Management:

Mouse fibroblast cells (L 929, from the cell bank of Shanghai Institutes for Biological Sciences), were cultured in MEM supplemented with L-glutamine and 10% fetal bovine serum at 37°C in a gaseous environment of 5% carbon dioxide (CO₂). A 96-well microplate method was employed for the MTT colorimetric assay. Each well was seeded 100µl suspension of 1×10⁴ cells, and incubated at 37°C in 5% CO₂ atmosphere for 24h prior to use.

Experimental Procedure:

After incubation, the growth medium was replaced with 100µl four concentrations (100%, 75%, 50% and 25%) of the test extract, 100% of the negative control and the positive control, the blank (row 2 and 11) respectively. Six replicates were prepared for each group. The 96-well plate were incubated at 37°C in 5% CO₂ for 24h.

After 24 h treatment, the culture medium was removed carefully from the plates. 50µl of the MTT (1mg/mL) solution was then added to each test well and the plates were further incubated for 2 h at 37°C in a 5% CO₂ atmosphere. Then the MTT solution was removed and 100µl isopropanol per well was added and shake for 10min by gently. The plate was read on a microplate reader at 570 nm (reference wavelength 650 nm). The viability of the cells was calculated according to the formula below:

$$\text{Viab. \%} = \frac{100 \times OD_{570e}}{OD_{570b}}$$

Where

OD_{570e} is the mean value of the measured optical density of the extracts of the test sample;

OD_{570b} is the mean value of the measured optical density of the blanks;

A test meets acceptance criteria if the left and the right mean of the blanks do not differ by more than 15% from the mean of all blanks. If the viability of the test sample was reduced to <70% of the blank, it had a cytotoxic potential. The 50% extract of the test sample should have at least the same or a higher viability than the 100% extract; otherwise the test should be repeated.

RESULTS

Group	The optical density (570nm—650 nm)	Viab. %
100% of the negative control	0.790±0.031	99
100% of the test extract	0.612±0.022	77
75% of the test extract	0.659±0.024	83
50% of the test extract	0.700±0.020	88
25% of the test extract	0.738±0.024	93
100% of the positive control	0.034±0.005	4
The blank (row 2)	0.794±0.029	/
The blank (row 11)	0.800±0.029	/

Note: n=6

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The mean value of optical density of the blank was 0.797 ± 0.028 . Both the left (row 2) and the right (row 11) mean of the blanks were less than 15% from the mean of all blanks.

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

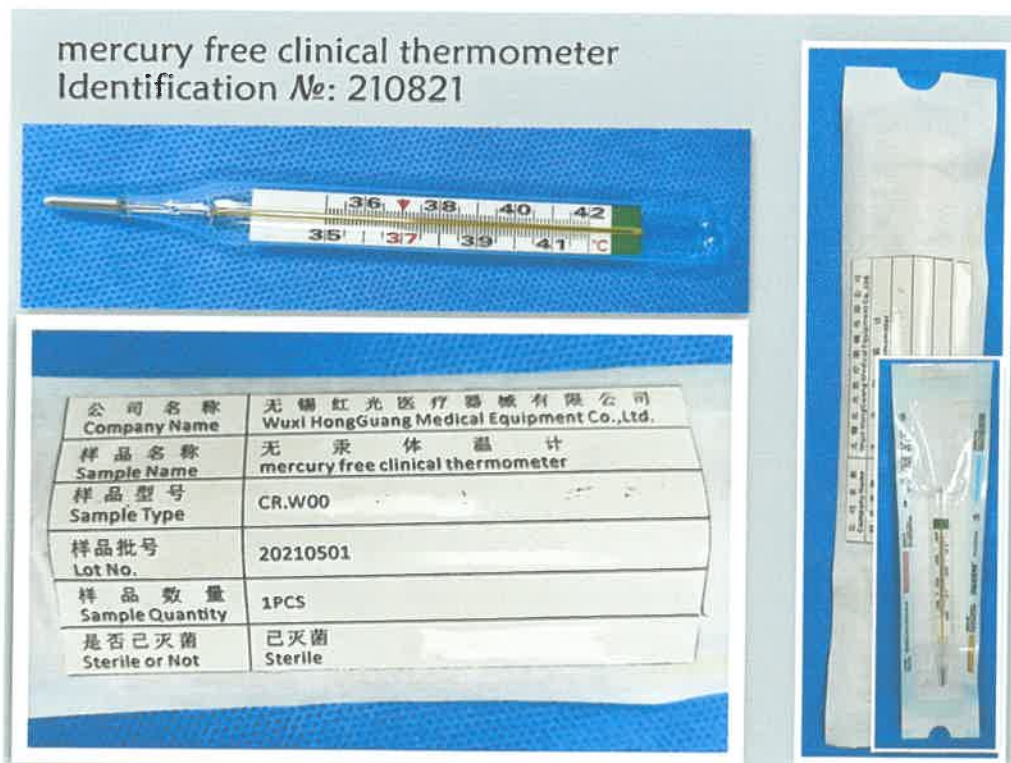
CONCLUSION

Under the condition of this study, the viability of 100% extract of the test sample was 77%. It can be considered that the test sample extracts had not a cytotoxic potential.

RECORD STORAGE

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PHOTOGRAPH OF THE TEST ARTICLE



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