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CNAS L2954

Final Report

Report Number: SDWH-M202101574-2(E)

Acute Systemic Toxicity of Disposable Nitrile Examination Gloves

According to ISO 10993-11:2017
Intraperitoneal
Sesame Oil Extract

Sponsor: Shandong Intco Medical Products Co.,Ltd

Address: No.9888,Qiwang Road,Naoshan Industry Park,Qingzhou,Shandong,China

检验检测专用章

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Content

Supplementary Explanation

(1) Please apply for rechecking within 15 days of receiving the report if there are any objections.

(2) Any erasure or without special inspection and testing seal renders the report null and void.

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Verification Dates

Test Article Receipt	2021-04-01
Protocol Effective Date	2021-04-09
Technical Initiation Date	2021-04-09
Technical Completion Date	2021-04-16
Final Report Completion Date	2021-04-28

Edited by: Wang Deheng 2021-04-25
Date

Reviewed by: Lu Chenxi 2021-04-28
Study Director Date

Approved by: Fang Jingyi 2021-04-28
Authorized Signatory Date

Sanitation & Environment Technology Institute, Soochow University

Summary

1 Test Article

Test Article Name	Disposable Nitrile Examination Gloves
Manufacturer	Shandong Intco Medical Products Co.,Ltd
Address	No.9888,Qiwang Road,Naoshan Industry Park,Qingzhou,Shandong,China
Model	N/A
Lot/Batch	N/A

2 Main Reference

ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

3 Test Method

The test article was extracted and the extract was evaluated to determine whether leachables extracted from the test article would cause acute systemic toxicity following injection into mice test in accordance with ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity.
Study protocol number: SDWH-PROTOCOL- M202101574-2.

4 Conclusion

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

Test Report

1 Purpose

The test article was extracted and the extract was evaluated to determine whether leachables extracted from the test article would cause acute systemic toxicity following injection into mice.

2 Reference

ISO 10993-11:2017 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity
ISO 10993-12:2021 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials
ISO 10993-2:2006 Biological evaluation of medical devices — Part 2: Animal welfare requirements

3 Compliance

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories (CNAS—CL01 Accreditation criteria for the competence of testing and calibration laboratories) China National Accreditation Service for Conformity Assessment LABORATORY ACCREDITATION CERTIFICATE Registration No. CNAS L2954.
RB/T 214—2017 Competence assessment for inspection body and laboratory mandatory approval—General requirements for inspection body and laboratory Certification and Accreditation Administration of the People's Republic of China INSPECTION BODY AND LABORATORY MANDATORY APPROVAL Certificate No. CMA 180015144061.

4 Identification of Test and Control Articles

4.1 Test Article

Test Article Name	Disposable Nitrile Examination Gloves
Manufacturer	Shandong Intco Medical Products Co.,Ltd
Address	No.9888,Qiwang Road,Naoshan Industry Park, Qingzhou,Shandong,China
Test Article Initial State	Non-sterile
CAS Number	Not supplied by sponsor (N/S)
Model	N/A
Size	N/A
Lot/Batch	N/A
Raw Material	Nitrile Latex（NBR）
Packaging Material	N/A
Physical State	Solid
Color	Blue
Density	N/A
Stability	N/A
Solubility	N/A
Storage Condition	Room temperature
Intended Use	It is mainly used for Patient Examination，to prevent possible cross infection between users and patients and prevent cross infection between patients.
Additional Information	N/A

The information about the test article was supplied by the sponsor wherever applicable.

4.2 Control Article

4.2.1 Negative Control

Article Name: Sesame Oil (SO)
Manufacturer: Ji'an Qingyuan District luyuanxiangliao. Co. Ltd
Size: 5kg
Lot/ Batch#: 20201218
Physical State: Liquid
Color: Light yellow
Storage Condition: Room Temperature

5 Equipment and Reagents

5.1 Equipment

Equipment Name	Equipment Number	Calibration Expire
Horizontal Large Capacity Constant Temperature Vibrator	SDWH2718	2021-08-10
Vertical pressure steam sterilizer	SDWH2097	2022-03-09
Steel straight scale	SDWH463	2021-07-06
Electronic scale	SDWH131	2021-12-08

5.2 Reagents

Reagent Name	Manufacturer	LOT
Sesame oil (SO)	Ji'an Qingyuan District luyuanxiangliao Co., Ltd.	20201218

6 Identification of Test System

Species: ICR mouse
Number: 10
Sex: Males
Initial body weight: Initial weight 18-22 g. The weight variation of animals used within a sex did not exceed ± 20 % of the mean weight.
Health status: Healthy, Young
Housing: Five animals per cage identified by a card indicating the lab number, test code, and first treatment date, etc.
Animal identification: Stain with picric acid
Cages: Plastic cages
Acclimation period: 7 days under the same conditions as for the actual test

7 Animal Care and Maintenance

Animal source: Provided by Zhejiang Vital River Laboratory Animal Technology Co. Ltd.; Permit Code SCXK（Zhe）2019-0001
Bedding: Corncob (Suzhou shuangshi laboratory animal feed science Co., Ltd)
Feed: Irradiation sterilization feed (Suzhou shuangshi laboratory animal feed science Co., Ltd)
Water: Sterile water
Animal room temperature: 20-26ºC
Animal room relative humidity: 30%-70%
Lights: 12 hours light/dark cycle, full spectrum lights
Personnel: Associates involved were appropriately qualified and trained.
Selection: Only healthy, previously unused animals were selected.

Device sterilization: All devices which will contact with the testing sample are subjected to steam sterilization in an autoclave at 121ºC for 30min.
There were no known contaminants present in the feed, water, or bedding expected to interfere with the test data.

8 Justification of Test System and Route of Administration

Mice have historically been used in biological evaluation studies. The species and number of animals as well as the route of administration used are specified in the current standard for evaluation of medical devices.
The test article was exposed to the test system through a solvent compatible with the test system following intraperitoneal administration (IP). This was the optimal route of administration available in this test system.

9 Experimental Design

9.1 Preparation of Extracts

9.1.1 Pretreatment

No pretreatment required.

9.1.2 Extraction

Under aseptic conditions, samples were taken according to the sampling method (Random sampling, calculating the combined area of all tissue contacting surfaces of each sample (one side) as the standard surface area of each sample). The extraction was performed with agitation in closed inert containers according to the extraction ratio listed in the following table(sample: extraction vehicle). The extraction vehicle was SO.

Samples	Actual Sampling	Extract Procedure			Final Extract
		Extract Ratio	SO	Condition	
Test	Surface area 60.0 cm^2	6 cm^2 : 1 mL	10.0 mL	50°C, 72 h	Clear
Negative Control	/	/	20.0 mL	50°C, 72 h	Clear

The state of the extract did not change after extraction. The extract was stored at room temperature, and tested within 24 h, without the process of adjusting its pH value, filtering, centrifuging, diluting, etc.
The vehicle (without the test article) was similarly prepared to serve as the control.

9.2 Experimental Procedure

9.2.1 Animal Preparation and Grouping

Prior to dosing, the mice were individually identified, weighed, and randomly assigned to a treatment group as shown below:

Group Name	Group Size	Sex	Dose Level	Route
Test	5 animals	Male	50 mL/kg	Intraperitoneal
Negative Control	5 animals	Male	50 mL/kg	Intraperitoneal

A single dose of test article extract was injected into the designated group of mice intraperitoneally at the dose level of 50 mL/kg bw. The negative control liquid was injected similarly into the separate group of designated control mice.
Mice were observed for any adverse clinical reactions immediately after injection, and then the animals were returned to their cages. The animals were observed for signs of systemic reactions at 4, 24, 48 and 72 hours after injection and weighed daily for three days after dosing. Any animal found dead or showed abnormal signs were subjected to gross necropsy.

9.3 Evaluation of Results

(1) If during the observation period of an acute systemic toxicity test none of the mice treated with the test article extract exhibited a significantly greater biological reactivity than control mice, the test article met the requirements. If two or more animals died, or if abnormal behavior such as convulsions or prostration occurs in two or more animals, or if body weight loss greater than 10 % occurs in three or more animals, the test article did not meet the requirements.
(2) If any animals treated with the sample exhibited only slight signs of biological reactivity, and no more than one animal showed gross symptoms of biological reactivity or died, repeat the testing using groups of ten animals. On the repeat test, if all ten animals treated with the test article extract exhibited no scientifically meaningful biological reactivity above the vehicle control animals during the observation period, the test article met the requirements.

10 Results

Clinical Observations
All animals appeared clinical normal throughout the study. The clinical observations are presented in Table 1 in the appendix.
Body Weight
Body weight data were acceptable and equivalent between the corresponding test and control treatment groups. Body weight data are presented in Table 2 in the appendix.

11 Conclusion

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

12 Record Storage

All the raw data and records pertaining to this study were retained in designated SDWH archive.

13 Confidentiality Agreement

Statements of confidentiality were as agreed upon prior to study initiation.

14 Deviation Statement

There were no deviations from the approved study protocol which were judged to have any impact on the validity of the data.

Annex 1 Test Data

Table 1 Clinical Observations

Treatment Group	Animal Number	Observation (after injection)				
		Immediate	4 Hours	24 Hours	48 Hours	72 Hours
Test	1	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	2	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	3	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	4	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	5	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
Control	6	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	7	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	8	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	9	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal
	10	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal	Appeared Normal

Table 2 Body Weight Data

Treatment Group	Animal Number	Initial Weight (g)	Weight after Injection (g)			
			4 Hours	24 Hours	48 Hours	72 Hours
Test	1	18.4	18.5	18.7	19.2	20.1
	2	20.4	21.0	20.6	21.1	22.0
	3	19.6	19.9	20.6	21.7	22.8
	4	19.5	20.0	20.0	20.5	21.7
	5	19.2	19.8	20.2	21.3	22.2
Control	6	19.2	19.5	19.9	20.5	21.6
	7	20.5	20.9	21.5	22.0	22.4
	8	20.7	21.4	21.4	22.4	23.2
	9	19.5	19.4	20.6	21.0	21.8
	10	20.4	20.9	21.0	22.0	22.9

Annex 2 Photograph of Test Article

Annex 3 Information Provided by Sponsor

1 Production Process

Not supplied by sponsor.

2 Other Information

Not supplied by sponsor.

End of Report