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威科检测
WEIKE INSPECTION

Test Report

Sample name: SILICONE TUBE

Weike Inspection Group Co., Ltd

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Weike Inspection Group Co., Ltd

The First Page of Test Report

Sample Name	SILICONE TUBE	Sample Number	WT232340
Trademark	/	Model and Specification	Inner diameter 4 * outer diameter 7; Inner diameter 2 * outer diameter4
Client	SHENZHEN JIAJIE RUBBER & PLASTIC CO., LTD	Test Category	Commission Inspection
Client's Address	Floor 3, Building 1, San Fengyuan Park, NO.3, Datang Hongfa Street, Da Lingshan Town, Dongguan, Guangdong, China	Product No. / batch number	23102001A
Production Unit	SHENZHEN JIAJIE RUBBER & PLASTIC CO., LTD	Production Date	2023.10.20
Inspected Unit	SHENZHEN JIAJIE RUBBER & PLASTIC CO., LTD	Sample Quantity	10 meters
Sample Submission Mode	Delivering	Inspection Location	Zone B, Floor 3, Factory Building 2, South China Modern Chinese Medicine City Science and Technology Park, Nanlang, Zhongshan, Guangdong
Receiving Date	2023.10.25	Inspection Date	2023.10.31-2023.11.28
Inspection Basis	Biological evaluation scheme of SILICONE TUBE provided by SHENZHEN JIAJIE RUBBER & PLASTIC CO., LTD ISO 10993-5 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization		
Inspection Items	1. In vitro cytotoxicity test, 2. Skin sensitization test, 3. Skin irritation test		
Test Conclusion	The results are included in the test report. (Special seal for test report or official seal of inspection unit) Issued Date: 二〇二三年十一月七日		
Remarks	1) In this test report, "--"means the item is not applicable, and " / " means the item is blank;		

Approved by: Reviewed by: Inspected by:

Position:

No.	Test Items	Standard Terms	Standard Requirements	Test Results	Conclusion	Remarks
1	In vitro cytotoxicity test	/	Viability of 100% test sample extract should be higher than 70%	Viability of 100% test sample extract was 77.9%	Meet the acceptance criteria	
2	Skin sensitization test	/	The test shall be free of skin sensitization	The test sample had no guinea pig skin sensitization	Meet the acceptance criteria	
3	Skin irritation test	/	The test shall be a negligible of animal skin irritation	Skin irritation response type was a negligible reaction	Meet the acceptance criteria	
	The end					

Weike Inspection Group Co., Ltd
Test Report

In vitro cytotoxicity test

1. Overview

Purpose: In this test, the in vitro cytotoxicity test was carried out according to ISO 10993-5 2009 "Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity" to evaluate the potential toxicity of the test sample to cells.

Methods: The test sample extract was added into the cultured monolayer cells, after 24 h of culture in a carbon dioxide incubator at 37℃, the OD value was determined by MTT method and the relative survival rate of the cells was calculated.

Results: The viability of 100% test sample extract was 77.9%, which was higher than 70%.

Conclusion: The 100% test sample extract has no potential toxicity to cell.

Test personnel: Yinying Zhu, Xiaoru He

Test period: 2023.11.06～2023.11.08

2. Test materials

2.1 Test samples

Physical state: Solid, Insoluble in water

Storage condition: Normal temperature

2.2 Extraction Medium:

MEM medium (manufacturing unit: gibco; batch number: 8123623), with addition 10% FBS (manufacturing unit: Guangzhou Ruite BIOTECHNOLOGY Co., Ltd.; batch number: 20230316), containing 1% penicillin-streptomycin solution (manufacturing unit: gibco; batch number: 192814)

2.3 Preparation of test sample: Under aseptic conditions, take 30 cm^2 of SILICONE TUBE (Sampling model: Inner diameter 4 * outer diameter 7; Inner diameter 2 * outer diameter 4), and 5 mL of extraction medium was added according to the proportion of 6 cm^2 /mL and extracted at 37℃ for 24 h as sample extract.

Negative control sample: The high-density polyethylene bottle was washed with ultrapure water and dried. After ultraviolet irradiation overnight, it was cut into pieces. According to the proportion of surface area of 3 cm^2 / mL, 5 mL of the same batch of extraction medium was added to a high-density polyethylene bottle with a surface area of 15 cm^2 and extracted at 37 ℃ for 24 h as a negative control solution.

Blank control: 5 mL of the same batch of extraction medium was added at 37℃ for 24 h as blank control solution.

Positive control sample: Add 0.5 mL DMSO to 4.5 mL of the same batch of extraction medium, and extract at 37℃ for 24 h to obtain 10% DMSO, used as a positive control liquid.

2.4 Test liquid status:

Test sample: Clarification

3. Equipments

Vertical pressure steam sterilizer WK-JY-014 Digital display thermostat water bath WK-JY-101

Straight steel ruler WK-JY-151 Vertical constant temperature shaker incubator WK-JY-356

Carbon dioxide incubator WK-JY-342 Biological safety cabinet WK-JY-027

Inverted microscope WK-JY-109 Enzyme label analyzer WK-JY-115

4. Cell line

Using established cell lines and obtained from approved storage, recommended mouse fibroblasts ATCC

CCL1 (L-929).

5. Test system rationality

Mouse fibroblast ATCC CCL1 (L-929) is a commonly used cell line in in vitro mammalian cell research, which has a long application history in the toxicity evaluation of biomaterials and medical devices, and meets the requirements of ISO 10993-5 2009 "Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity".

6. Test methods

6.1 The suspended cells (1×10^5/mL) were dispensed at 100 μL per well in 96-well plate, the blank control, negative control, positive control and test groups are set and each group has at least 6 wells. And culture it in CO_2 incubators (5% CO_2, 37℃) for 24 h.

6.2 After 24 h, original culture solution was discarded. The blank control group was added with fresh cell culture solution, the negative control group was added with the negative control extract, the positive control group was added with the positive control solution or the positive control extract. The test group was then treated with 100 μL of extract of test sample(100%、75%、50%、25%). Incubate the 96-well plate at 37℃ in cell incubator of 5% CO_2 for 24 h.

6.3 24h after changing the culture medium, observe the cell morphology under a microscope. A 50 μL aliquot of MTT(1 mg/mL)was added to each well. The liquid in each well was tipped out after 2 hours and 100 μL isopropanol was added to each well,and oscillate on the oscillator.

Evaluate the suspension above with the measurement wavelength at 570 nm and reference wavelength at 650 nm by Enzyme label analyzer. Calculate the relative growth rate (RGR) according to the following formula:

$$\text{Viability}(\%) = \frac{100\times OD_{570e}}{OD_{570b}}$$

In this formula:

OD_{570e}--The average OD value of the 100% test sample extract;

OD_{570b}--The average OD value of the blank control extract;

When the survival rate is low, the potential cytotoxicity of test samples is high.

If viability is reduced to <70% of the blank, it has a cytotoxic potential.

7. Test results

	Test sample extract(100%)	Test sample extract(75%)	Test sample extract(50%)	Test sample extract(25%)	Negative control	Blank control		Positive control
Well 1	0.506	0.544	0.548	0.602	0.621	0.647	0.667	0.113
Well 2	0.531	0.540	0.568	0.604	0.612	0.658	0.651	0.115
Well 3	0.512	0.545	0.555	0.611	0.614	0.682	0.658	0.106
Well 4	0.501	0.536	0.570	0.619	0.601	0.640	0.678	0.114
Well 5	0.531	0.526	0.561	0.585	0.609	0.654	0.670	0.111
Well 6	0.504	0.524	0.587	0.601	0.615	0.659	0.657	0.104
Average OD value	0.514	0.536	0.565	0.604	0.612	0.660		0.111
Viability	77.9%	81.2%	85.6%	91.5%	92.7%	100.0%		16.7%

8. Conclusion

Under the conditions of this test, the viability of 100% test sample extract was 77.9%, the test sample extract did not show potential toxicity to cells.

Skin sensitization test (guinea pig maximum dose test (GPMT))

1. Overview

Purpose: The test was conducted according to the requirements of the maximum dose method for guinea pig skin sensitization test recommended in the national standard ISO 10993-10: 2010 "Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization", and to evaluate the potential of the sample to cause guinea pig skin sensitization reaction.

Methods: The sample was detected and the extraction solution was prepared with the extraction medium. The guinea pigs were induced by intradermal injection and local induction by closed application to produce sensitization. The animals in the control group were given blank extraction medium in the same way. After induction, the animals in the test group and the control group were stimulated with the corresponding sample extract and control solution. The skin reactions at the stimulated sites of all animals were graded 24 and 48 hours after the application was removed.

Results: There were no erythema and edema on the skin of the excited part of the animals in the test group.

Conclusion: Under the conditions of this test, the sample did not cause delayed type hypersensitivity in guinea pigs.

Test personnel: Chuhong Ji, Zijie Zhou

Test period: 2023.10.31～2023.11.28

2. Test materials

2.1 Test samples

Physical state: Solid, Insoluble in water

Storage condition: Normal temperature

2.2 Extraction medium :

Polar extraction medium: 0.9% sodium chloride injection(manufacturing unit: Guangdong Kelun Pharmaceutical Co., Ltd; batch number: H23061107)

Non-polar extraction medium: Cottonseed oil (manufacturing unit: Shanghai Maclin Biochemical Technology Co., Ltd.; batch number: C15476199)

2.3 Adjuvant: Freund's complete adjuvant manufacturing unit: SIGMA; batch number: SLCK7706)

2.4 10% sodium dodecyl sulfate (manufacturing unit: Shanghai Macklin Biochemical Technology Co., Ltd.; batch number: C11528388)

2.5 Sterile gauze (manufacturing unit: Nanchang Aokang Medical Instrument Co., Ltd; batch number: 20230708)

2.6 Preparation of test sample: Take 120 cm^2 of SILICONE TUBE (Sampling model: Inner diameter 4 * outer diameter 7; Inner diameter 2 * outer diameter 4), add 20 mL of extraction medium according to the proportion of 6 cm^2/mL , and extract at 37℃ for 72 h to prepare the sample extraction solution as the test sample. Each stage is tested with freshly prepared test solution.

2.7 Negative control sample: Take the extraction medium of the same batch number and prepare it under the same conditions.

2.8 Positive control sample: 0.1% 2,4 - dinitrochlorobenzene solution (DNCB) (manufacturing unit: Tokyo Chemical Industry Co., Ltd; batch number: WT6CA-LI)

This laboratory conducts a positive control test every 6 months. The time for this positive control test was:

2023.07.31 ~ 2023.08.27.

2.9 Test fluid status:

Test sample: Clarification; Positive control: Clarification

3. Experimental animals

3.1 Grade and strain: Common level Hartley guinea pig

3.2 Animal source: Longgui Xingke animal farm, Baiyun District, Guangzhou city. Laboratory animal qualification certificate number: SCXK (Guangdong) 2022-0042 (44817200002205).

3.3 Number of animals: 30

3.4 Gender: Male (male or female, female not pregnant).

3.5 Weight during test: 304 g to 350 g

3.6 Quarantine period: 7 days. After passing the quarantine, the animal can be used for testing.

3.7 Marking method: Cage sign method

3.8 Animal selection: Healthy and unused animals can only be used for testing after passing the quarantine.

3.9 Reasons for selecting test animals: Common level Hartley albino guinea pigs have been used to evaluate the risk of skin sensitization for a long time. Both international and national standards recommend that guinea pigs be used for skin sensitization test to evaluate the potential risk of skin sensitization of test materials under test conditions.

3.10 Animal feeding management

3.10.1 Feeding environment

Feeding room: Common level animal room, Number of Animal use permit: SYXK (Guangdong) 2023-0228

Temperature and humidity: Temperature (18 ~ 26)℃, Relative Humidity (40 ~ 70)%

Illumination: Automatic timer is used to control 12 hours of illumination and 12 hours of darkness

3.10.2 Feed

Type: Guinea pig maintenance formula feed

manufacturing unit: Jiangsu synergy pharmaceutical Bioengineering Co., Ltd

Production license No.: Susi license (2019) 01008

Feeding method: Free feeding at other times except the planned fasting date

3.10.3 Drinking water

Type: Clean domestic water

Water supply mode: Take water freely through automatic water supply system

3.10.4 Personnel: All the participants in the test have received training and obtained corresponding qualifications.

3.10.5 Animal ethics: This experiment was approved by the Animal Ethics Committee of our unit, and the relevant documents formulized by the Animal Ethics Committee were strictly implemented during the experiment to safeguard animal welfare.

4. Equipments

Straight steel ruler WK-JY-151 Vertical constant temperature shaker WK-JY-356

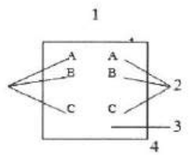
Electronic balance WK-JY-094

5. Test methods

5.1 Preparation before the test: One day before the test, each animal should be numbered and weighed, and the hair of the test site should be completely cut off with an electric razor. Observed the health status of each animal.

5.2 Intradermal induction: As shown in the figure below, paired intradermal injections of 0.1 mL were given at the inner part of the shaved scapula of each animal.

1 - Head
2 - 0.1ml intradermal injection point
3 - The inner part of the scapula with hair removed
4 - Tail



Site A: Injected a stable emulsifier mixed with Freund's complete adjuvant and selected solvent in a ratio of 50:50 (volume ratio).

Site B: Injected the test sample (undiluted extract); control animals were injected with corresponding extract medium only.

Site C: The test sample (concentration used in site B) was mixed with an emulsifier prepared from Freund's complete adjuvant and extraction medium (50%) at a volume ratio of 50:50, and then intradermal injection was performed; the control group was injected with emulsifier prepared by blank solution and adjuvant.

5.3 Local induction: In the 7 days after intradermal induction, no irritation occurred. 24 hours before application of topical application, the test area was pretreated with 10% sodium lauryl sulfate. After being massaged into the skin, the leaching solution was soaked with sterile gauze with an area of 8 cm^2, which was locally applied to the inside of the scapula of each guinea pig to cover the induction injection point. Secured with a closed bandage, remove the bandage and gauze block after 48 hours. In the same way, the control animals were operated with blank extraction medium.

5.4 Stimulation: On the 14th day after local induction, placed sterile gauze pieces in the test sample extract and control solution respectively for soakage, and apply them to the hair removal area of each animal's upper abdomen (the part not tested in the induction stage). Secured with a closed bandage, and remove the bandage and patch after 24 hours ± 2 hours.

5.5 Observation: At 24 and 48 hours after the patch was removed, the skin reactions of the experimental group and the control group were observed. The skin erythema and edema reaction at each excitation site and each observation time were described and graded according to Magnusson and Kligman grading standards.

Magnusson and Kligman Grading Standards

Reaction of application test	Grade
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

6. Test results

6.1 Body weight and clinical observation results: No abnormal performance was found in all animals during the test. See attached table 1 for details.

6.2 Sensitization results: No erythema and edema were found on the skin at the excitation site of animals in the test group, and no obvious sensitization symptoms were observed. See attached table 1 for details.

6.3 Erythema and edema can be seen on the skin at the excitation site of animals in the positive control group. See attached table 2 for details.

7. Conclusion

Under the test conditions, no erythema and edema were found on the skin of the excitation site of animals in each test group, which was rated as 0 according to Magnusson and Kligman grading standards. The results showed that the tested samples had no guinea pig skin sensitization.

8. Appendix

Attached table 1 Observation Results of Sensitization Test

Group category	Animal No.	Weight before test (g)	Observation of symptoms other than skin reactions	Grade of skin reaction results after stimulation	
				24 h	48 h
Test group (extraction medium:physiologic saline (0.9% NaCl))	1	310	Normal	0	0
	2	345	Normal	0	0
	3	320	Normal	0	0
	4	305	Normal	0	0
	5	312	Normal	0	0
	6	350	Normal	0	0
	7	332	Normal	0	0
	8	325	Normal	0	0
	9	311	Normal	0	0
	10	304	Normal	0	0
Negative control group (physiologic saline (0.9% NaCl))	1	309	Normal	0	0
	2	318	Normal	0	0
	3	333	Normal	0	0
	4	318	Normal	0	0
	5	321	Normal	0	0
Test group (extraction medium:cottonseed oil)	1	342	Normal	0	0
	2	330	Normal	0	0
	3	327	Normal	0	0
	4	335	Normal	0	0
	5	325	Normal	0	0
	6	331	Normal	0	0
	7	323	Normal	0	0
	8	346	Normal	0	0
	9	317	Normal	0	0
	10	308	Normal	0	0

Negative control group (cottonseed oil)	1	328	Normal	0	0
	2	342	Normal	0	0
	3	336	Normal	0	0
	4	314	Normal	0	0
	5	339	Normal	0	0

Attached table 2 Observation Results of Sensitization Test

Group category	Animal No.	Weight before test (g)	Observation of symptoms other than skin reactions	Grade of skin reaction results after stimulation	
				24 h	48 h
Positive control group (0.1%2.4-dinitrochlorobenzene solution (DNCB))	1	308	Normal	1	2
	2	343	Normal	2	2
	3	322	Normal	2	2
	4	341	Normal	2	1
	5	324	Normal	1	2
	6	338	Normal	1	1
	7	330	Normal	2	1
	8	315	Normal	1	2
	9	312	Normal	1	1
	10	337	Normal	2	2

Weike Inspection Group Co., Ltd
Test Report

Animal irritation test

1. Overview

Purpose: In this test, the skin irritation test on rabbits is carried out according to ISO 10993-10: 2010 "Biological Evaluation Of Medical Devices - Part 10: Tests for irritation and skin sensitization" to evaluate the potential reaction of skin caused by the test substance.

Methods: The test substances were applied to the test sites of the rabbit's back spine for at least 4 hours. The negative control group was treated the same way. Skin reactions were observed at 1 h, 24 h, 48 h and 72 h after the end of contact.

Results:PII of the skin in the test group was 0.

Conclusion: Under the conditions of this test, the skin showed a negligible reaction to the test substance.

Test personnel: Chuhong Ji, Zijie Zhou

Test period: 2023.11.12～2023.11.18

2. Test materials

2.1 Test samples

Physical state: Solid, Insoluble in water

Storage condition Normal temperature

2.2 Extraction medium:

Polar extraction medium: 0.9% sodium chloride injection (manufacturing unit: Guangdong Kelun Pharmaceutical Co., Ltd.; batch number: H23061107)

Non-Polar extraction medium: Cottonseed oil (manufacturing unit: Shanghai Maclin Biochemical Technology Co., LTD.; batch number: C15476199)

2.3 Sterilized gauze (manufacturing unit: Nanchang Aokang Medical Devices; batch number:20230708)

2.4 Preparation of test sample: Take 60 cm^2 of SILICONE TUBE (Sampling model: Inner diameter 4 * outer diameter 7; Inner diameter 2 * outer diameter 4), add 10 mL of extraction medium according to the proportion of 6 cm^2 /mL, extract at 37℃ for 72 h, and take 0.5mL dropped in 2.5cm × 2.5cm size of the gauze as a test sample.

2.5 Negative control sample: The same batch of extraction medium was taken and prepared under the same conditions, was dropped on a 2.5 cm × 2.5 cm gauze as a negative control.

2.6 Positive control sample: 20% Sodium Lauryl Sulfate (SLS) (manufacturing unit: Shanghai Macklin Biochemical Technology Co., Ltd; batch number: C11528388)

Drop 0.5 mL of the 20% Sodium Lauryl Sulfate (SLS) on a 2.5 cm×2.5 cm gauze as a positive control sample. This laboratory conducts a positive control test every 6 months. The time for this positive control test was: 2023.08.28~2023.08.31.

2.7 Test liquid status:

Test sample: Clarification; Positive control: Bubbles

3. Experimental animals

3.1 Grade and strain: Common level New Zealand white rabbit

3.2 Animal source: Longgui Xingke Animal Breeding Farm, Baiyun District, Guangzhou, Laboratory animal qualification certificate number: SCXK (Guangdong) 2022-0042 (44817200002174)

3.3 Number of animals: 6

3.4 Gender: Female (male or female, female not pregnant).

3.5 Weight during test: 2.3 kg to 2.6 kg

3.6 Quarantine period: 7 days. After passing the quarantine, the animal can be used for testing.

3.7 Marking method: Cage signing method

3.8 Animal selection: Healthy, unused animals have passed quarantine before use for testing.

3.9 Reasons for selection of test animals: Historically, New Zealand rabbits are used to assess the risk of skin irritation. Both international standards and national standards recommend using rabbits for skin irritation tests to evaluate the potential risk of skin irritation from test materials under test conditions.

3.10 Animal Management:

3.10.1 Raising environment

Feeding room: Common level animal room, Number of Animal use permit: SYXK (Guangdong) 2023-0228

Temperature and humidity: Temperature (18~26) ℃, Relative humidity (40~70)%

Light: Use an automatic timer to control 12 hours of light and 12 hours of darkness

3.10.2 Feed

Type: Experimental rabbit feed

Manufacturing unit: Jiangsu synergy pharmaceutical Bioengineering Co., Ltd

Production license No.: Susi license (2019) 01008

Feed method: Feed freely at other times except for the planned fasting date.

3.10.3 Drinking water

Type: Clean domestic water

Water supply mode: Free water intake through the automatic water supply system

3.10.4 Personnel: All the participants in the test have received training and obtained corresponding qualifications

3.10.5 Animal ethics: This experiment was approved by the Animal Ethics Committee of our unit, and the relevant documents formulized by the Animal Ethics Committee were strictly implemented during the experiment to safeguard animal welfare.

4. Equipments

Straight steel ruler WK-JY-151 Vertical constant temperature shaker WK-JY-356

Infant weighing scale WK-JY-111

5. Test methods

5.1 Preparation before the test: 4 h to 24h before the test, the animals were marked and weighed, and the fur on both sides of the spine of the back of the animals was removed (about 10 cm×15 cm) as the test and observation site.

5.2 Procedure: Applied the test substance to both sides of the rabbit's back spine, and the negative control substance was pasted on the control site in the same way. Apply the patch semi-occluded or occluded with a bandage for at least 4 hours After the contact period, removed the pad, marked the contact part with permanent ink, and removed the residual test material with warm water. The erythema and edema reactions at the contact point were observed and recorded at 24 h, 48 h and 72 h after exposure, according to the following scoring system:

Weike Inspection Group Co., Ltd
Test Report

The Skin Reaction scoring system

Erythema and eschar formation		Edema formation	
Reaction	Score	Reaction	Score
No erythema	0	No edema	0
Very slight erythema (barely perceptible)	1	Very slight oedema (barely perceptible)	1
Well-defined erythema	2	Well-defined oedema (edges of area wel-defined by definite raising)	2
Moderate erythema	3	Moderate oedema (raised approximately 1 mm	3
Severe erythema (beet-redness) to eschar formation preventing grading of erythema	4	Severe oedema (raised more than 1 mm and extending beyond exposure area)	4

5.3 Result evaluation: After 72 hours of scoring, all scores of erythema and edema of each animal test substance at (24±2) h, (48±2) h and (72±2) h were added up. Divide the sum of all scores by 6 (two test/observation sites, 3 time points) to calculate the Primary Irritation Index (PII) of an animal. Add all the PII scores of each animal and divide the sum of all PII scores by 3 (the total number of animals) to obtain the PII score of the test substance. Calculate the PII scores of the control groups in the same way, and subtract the PII scores of the control groups from the PII score of the test substance to obtain the primary irritation score. Then determine the type of reaction according to the following table:

Reaction types of skin irritation on rabbits

Average score	Type
0 to 0.4	Negligible
0.5 to 1.9	Slight
2 to 4.9	Moderate
5 to 8	Severe

6. Test results

The Primary Irritation Index (PII) of the polar extraction Medium group was 0, see attached table 1.

The Primary Irritation Index (PII) of the non-polar extraction Medium group was 0, see attached table 2.

7. Conclusion

Under the conditions of this test, the skin showed a negligible reaction to the test sample of the polar extraction medium group and a negligible reaction to the test sample of the non-polar extraction medium group as well.

8. Appendix

Attached table 1 Scores of Skin Reaction Results of Rabbits
(polar extraction medium: physiologic saline (0.9% NaCl))

Animal No.	Weight (kg)	Site	Test group								Control group							
			1 h		24 h		48 h		72 h		1 h		24 h		48 h		72 h	
			ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
1	2.4	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PII of a single animal (Test/Control)			S1=0								S2=0							
Other abnormalities			None															
2	2.5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PII of a single animal (Test/Control)			S3=0								S4=0							
Other abnormalities			None															
3	2.5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PII of a single animal (Test/Control)			S5=0								S6=0							
Other abnormalities			None															
PII =(S1+S3+S5)/3-(S2+S4+S6)/3			0															

Note: Only the observation data of (24±2)h, (48±2)h and (72±2)h are used for the calculation, and the 1h observation score is not included.

Primary irritation index (PII) = S(Test group)-S(Control group) = 0

Attached table 2 Scores of Skin Reaction Results of Rabbits
(non-polar extraction medium: cottonseed oil)

Animal No.	Weight (kg)	Site	Test group								Control group							
			1 h		24 h		48 h		72 h		1 h		24 h		48 h		72 h	
			ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
1	2.5	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PII of a single animal (Test/Control)			S1=0								S2=0							
Other abnormalities			None															
2	2.3	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PII of a single animal (Test/Control)			S3=0								S4=0							
Other abnormalities			None															
3	2.6	1	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
		2	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PII of a single animal (Test/Control)			S5=0								S6=0							
Other abnormalities			None															
PII =(S1+S3+S5)/3-(S2+S4+S6)/3			0															

Note: Only the observation data of (24±2) h, (48±2) h and (72±2) h are used for the calculation, and the 1 h observation score is not included.

Primary irritation index (PII) = S(Test group)-S(Control group) = 0

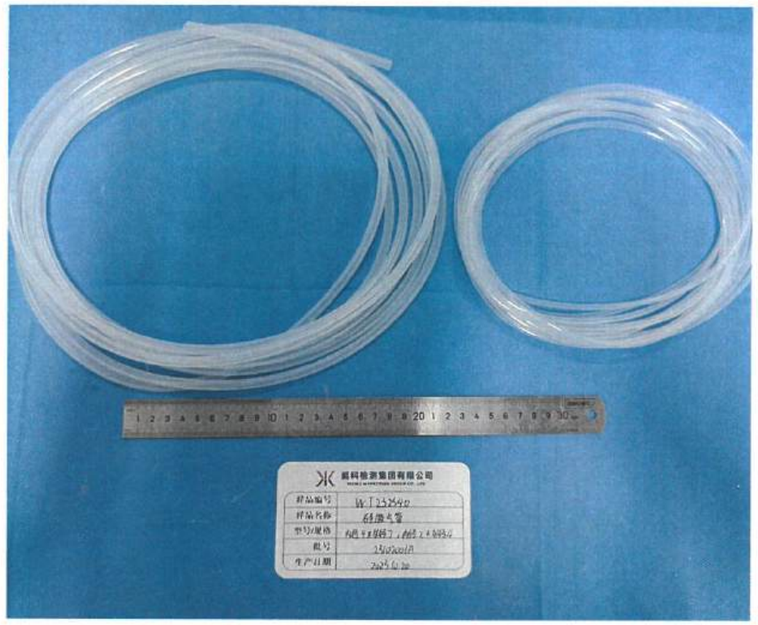
Attached table 3 Scores of Skin Reaction Results of Rabbits (Positive control group)

Animal No.	Weight (kg)	Site	Test group								Control group							
			1h		24h		48h		72h		1h		24h		48h		72h	
			ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED	ER	ED
1	2.6	1	1	1	2	2	3	2	3	2	0	0	0	0	0	0	0	0
		2	1	2	2	2	3	2	2	1	0	0	0	0	0	0	0	0
PII of a single animal (Test/Control)			S1=4.3								S2=0							
Other abnormalities			None															
2	2.5	1	2	2	2	2	2	2	3	2	0	0	0	0	0	0	0	0
		2	2	1	2	1	3	2	4	2	0	0	0	0	0	0	0	0
PII of a single animal (Test/Control)			S3=4.5								S4=0							
Other abnormalities			None															
3	2.8	1	2	1	2	2	3	3	3	2	0	0	0	0	0	0	0	0
		2	1	2	2	3	2	2	2	2	0	0	0	0	0	0	0	0
PII of a single animal (Test/Control)			S5=4.7								S6=0							
Other abnormalities			None															
PII =(S1+S3+S5)/3-(S2+S4+S6)/3			4.5															

Note: Only the observation data of (24±2) h, (48±2) h and (72±2) h are used for the calculation, and the 1 h observation score is not included.

Primary irritation index (PII) = S(Positive test group)-S(Negative control group) = 4.5

Photo and Profile



Sample profile

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Model specifications or other instructions

Model specification:Inner diameter 4 * outer diameter 7;
Inner diameter 2 * outer diameter4
Production batch:23102001A
Production Date:2023.10.20

-End of the Report-