210015344482

中国认可
国际互认
检测
TESTING
CNAS L13260

威科检测
WEIKE INSPECTION

Test Report

Sample name:Teflon medical heat shrinkable tube

Weike Inspection Group Co., Ltd

Notice

1. This test report is invalid without stamps of the test organization.

2. This test report is not allowed to be copied partially without written permission from the testing agency.

3. This test report is invalid without the signature of the approver.

4. The report is invalid if altered.

5. If there is any objection to the inspection report, it shall be submitted in written form to the inspection agency within 7 days from the date of receiving the report, and the late request will not be accepted;

6. This test report is only responsible for the test samples.

Add: Zone B, Floor 3, Factory Building 2, South China Modern Chinese Medicine City Science and Technology Park, Nanlang, Zhongshan, Guangdong

Tel: 0760-88337979

Fax: 0760-88337979

Postal Code: 528400

Website: www.weike1689.com

E-mail: gdwkjiance@163.com

Weike Inspection Group Co., Ltd

The First Page of Test Report

Sample Name	Teflon medical heat shrinkable tube	Sample Number	WT230992-1
Trademark	/	Model and Specification	KTFE-03-1.6-X
Client	Guangzhou Kaiheng Medical Equipment Co., LTD.	Test Category	Commission Inspection
Client's Address	Guangzhou Kaiheng Science and Technology Park, No.148 Changan, Guangshan Road, Huangpu District, Guangzhou	Product No. / batch number	YL230405
Production Unit	Guangzhou Kaiheng Medical Equipment Co., LTD.	Production Date	2023.4.5
Inspected Unit	Guangzhou Kaiheng Medical Equipment Co., LTD.	Sample Quantity	1
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	2023.05.10	Inspection Date	2023.05.24-2023.05.26
Inspection Basis	Biological evaluation scheme of Teflon medical heat shrinkable tube provided by Guangzhou Kaiheng Medical Equipment Co., LTD. ISO10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity		
Inspection Items	In vitro cytotoxicity test		
Test Conclusion	The results are included in the test report. (Special seal for test report or official seal of inspection unit) Issued Date: 二〇二三年六月十六日		
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 88.9%	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 is 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 88.9%, which was higher than 70%.

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

Test personnel: Zhu Yin Ying, He Xiao Ru

Test period:2023.05.24-2023.05.26

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: 8123151), with addition 10% FBS (manufacturing unit: Guangzhou Ruite Biotechnology Co., LTD; batch number: 20220814), containing 1% penicillin-streptomycin solution (manufacturing unit: gibco; batch number: 2441874)

2.3 Preparation of test sample: Under aseptic conditions, take 1.0 g of Teflon medical heat shrinkable tube and 5 mL of extraction medium was added at a ratio of 0.2 g/mL, extracted at 37℃ for 24 h as sample extract.

Negative control sample: Take the high-density polyethylene bottle, wash it with ultrapure water, dry it, and cut it into pieces after ultraviolet irradiation overnight. According to the proportion of surface area of 6 cm^2/mL, add 5 mL of the same batch of extraction medium into the high-density polyethylene bottle with surface area of 30 cm^2 and extract it at 37℃ for 24 h as the negative control solution.

Blank control sample: 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

Electronic balance WK-JY-096 Biological safety cabinet WK-JY-027

Carbon dioxide incubator WK-JY-104 Biochemical incubator WK-JY-106

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 CO_2 incubators 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.

Weike Inspection Group Co., Ltd
Test Report

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	0.615	0.589	0.576	0.615	0.668	0.658	0.643	0.157
Well 2	0.601	0.599	0.618	0.624	0.672	0.671	0.662	0.109
Well 3	0.621	0.627	0.613	0.612	0.648	0.688	0.660	0.126
Well 4	0.572	0.612	0.637	0.627	0.657	0.649	0.674	0.126
Well 5	0.602	0.621	0.627	0.607	0.679	0.686	0.683	0.127
Well 6	0.584	0.630	0.624	0.650	0.682	0.712	0.703	0.159
Average OD value	0.599	0.613	0.616	0.623	0.668	0.674		0.134
Viability	88.9%	90.9%	91.4%	92.3%	99.0%	100.0%		19.9%

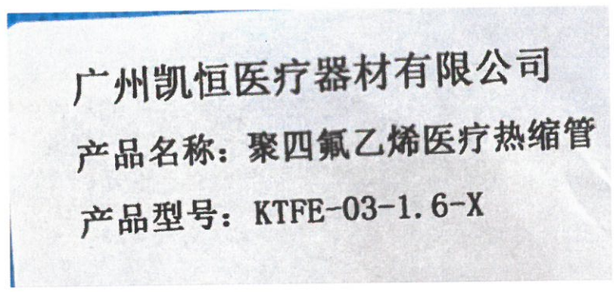
8. Conclusion

Under the conditions of this test, the viability of 100% test sample extract was 88.9%, the test sample extract did not show potential toxicity to cells.

Weike Inspection Group Co., Ltd

Photo Page of the Test Report

Photo and Profile



Sample profile
/
Model specifications or other instructions
Model specification:KTFE-03-1.6-X Production batch:YL230405 Production Date:2023.4.5

-End of the Report-