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Testing Center of Radiological Medical Research Institute, Soochow University

Test Report

SpO2 Finger Sensor

(Main parts including: soft and hard silicon pads, housing, cable, strain relief, and connector)

Cytotoxicity Test

Sample Supplier

ShenZhen Envisen Industry Co.,Ltd.

Supplementary Explanation

1. If demur at the analysis report please raise it within 15 days by receiving the report, otherwise will not be accepted.
2. Testing report is void without analysis center seal.
3. Valid report must be signed by ones who analyzed, reviewed and issued it.
4. Any erasure renders a report null and void.
5. Testing result of supply sample is only responsible for the provided sample.
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Cytotoxicity Test

Summary

The test article, SpO2 Disposal Sensor(Main parts including: soft and hard silicon pads, housing, cable, strain relief, and connector) was evaluated for cytotoxicity test in accordance with the ISO 10993-Part 5: Tests for cytotoxicity: in vitro methods. The testing sample solution is mixed with growing-well L-929 cell, and then incubated for 2 and 4 days. Observe the morphology and the cell growing on the culture bottle wall. The RGR (Relative Growth Rate) are 75% and 77% respectively by calculation on the basis of cell concentrations of different groups. The RGR of testing group is determined as Grade 1. This means the testing sample has no toxicity to L-929 cells.

Tested by:

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Date completed: Apr 14 , 2006

Introduction

The test article, SpO2 Disposal Sensor(Main parts including: soft and hard silicon pads, housing, cable, strain relief, and connector) were evaluated for cytotoxicity test in accordance with the ISO 10993-5-1999 Part 5: Tests for cytotoxicity: in vitro methods .The purpose of this study was to determine the potential cytotoxicity of the testing article to L-929 cell.

Materials

1. Test Sample:

1.1Sample Supplier: Shenzhen Envisen Industry Co.,Ltd.

1.2Sample Name: SpO2 Disposal Sensor(Main parts including: soft and hard silicon pads, housing, cable, strain relief, and connector)

1.3Size: /

1.4Lot No: /

1.5Receiving Date: Apr 4, 2006

2. Sample and Control Preparation:

2.1 Testing sample group

The testing sample is treated in accordance with experiment requirements followed by sterilization in autoclave.

24 hours prior to experiment, add liquid culture medium in the proportion of 1ml culture medium to 0. 2g testing sample, and then incubated at 37℃ for 24 hours. Thus, the sample solution is obtained.

2.2 For the positive controls, add con. 6.3% phenylhydroxide solution.

2.3 For the negative controls, add fresh 1640 liquid culture medium.

3. Culture medium:

RPMI 1640, calf serum, PBS, Pancreatin and double antibiotic.

Test method

1. Cell Strain: Recommended cell lines are American Type Culture Collection CCLI (NCTC clone 929).
2. Cell Culture

2.1 Take growing-well cell of strain L-929 to prepare cell soliquiod with concentration of 4×10^4 counts/ml in culture bottles. Proceed to next step after the cell grows up to monolayer.

2.2 Discard the liquid in culture bottles. In these culture bottles. Take testing group, add con. 50% sample solution, the positive control solution and the negative control solution. They are all incubated at 37℃. After 2 and 4 days incubation respectively, conduct the morphology evaluation and cell counting.

Results

The testing sample solution is mixed with growing-well L-929 cell, and then incubated for 2 and 4 days. Observe the morphology and the cell grow well sticking on the culture bottle wall. The RGR (Relative growth Rate) are 75% and 77% respectively by calculation on the basis of cell concentrations of different groups (the negative and positive controls).

Conclusion

By the experiment incubating L-929 cell using culture medium with sample solution, the RGR of testing group is determined as Grade 1. This means the testing sample has no toxicity to L-929 cell.

Table 1. Classification system for the RGR

Grade	RGR (%)	Reactivity
0	⩾100	none
1	75-99	slight
2	50-74	moderate
3	25-49	severe

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