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JIUZI DONGJING 208, FENGJING NORTH ROAD, SHANGCUN COMMUNITY, GONGMING STREET, GUANGMING DISTRICT, SHENZHEN CITY, CHINA

Sample Descriptions : SILICONE LEATHER

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

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Sample Receiving Date : May 19, 2025

Test Performing Date : May 19, 2025 to Jun 13, 2025

Test Performed : Selected test(s) as requested by applicant

Test Result(s) : For further details, please refer to the following page(s)

Test Requested	Result
ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	Showed no cytotoxic potential

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Joe Chow
Authorized Signatory

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Vitro cytotoxicity:

1.Summary

The test article was evaluated for potential cytotoxic effects. This study was conducted following the guidelines of ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity Appendix C. Following extraction, the test article and positive extract were diluted to obtain solutions of approximate concentrations of 100%, 50%, 25% and 12.5%. Triplicate monolayers of L929 mouse fibroblast cells were dosed with the full strength and diluted extracts and then incubated at 37 ℃ (humidified) in the presence of 5% CO2 for 24 hours. After incubation, the culture medium was replaced with 1 mg/mL MTT [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide] solution and incubated for an additional 2 hours. Then, the MTT solution was replaced with isopropanol. The percent viability for the test article was determined from the reagent control. A decrease in the number of living cells results in a decrease in the metabolic activity in the sample. This decrease directly correlates to the amount of blue-violet formazan formed, as monitored by the optical density at 570 nm. Each group shall have at least 6 reholes.

2. Identification of Test and Control Articles

2.1 Sample of test

The test articles provided by the sponsor were identified and handled as described below:

Test and Control Article Preparation: Before the experiment, after UV irradiation of the samples, the sample extraction was carried out according to Table 1 under sterile operation. The extract was continuously shaken during the extraction process.

Table 1 Extraction

Treatment Group	Extraction Ratio	Article Amount	Volume of Vehicle	Extraction Condition
Test Sample	6 cm^2/mL	36.0cm^2	6.0mL	37℃ 24 hours
Negative Control	3 cm^2/mL	18.0cm^2	6.0mL	
Positive Control	3 cm^2/mL	18.0cm^2	6.0mL	
Blank Control	--	--	3.0mL	

There appeared to be no visible changes to the test article during the extraction process. The extracts were stored in cold storage at 2-8℃， after completion of extraction and used within 2 hours. The extracts were not centrifuged, filtered, or otherwise altered prior to dosing.

2.2 Positive versus negative controls

Table 2 Control Sample

Group	Positive Control	Negative Control
Name	ZDBC	High Density polyethylene
Brand	Hantano Research Institute	Hantano Research Institute
Lot	B-202K	C-191

3. Test Method

3.1Test System

Mammalian cell culture monolayer consisting of L929 mouse fibroblast cells was used.

L929 cells were cultured in DMEM medium containing 10% fetal bovine serum and double antibody (penicillin 100 U/mL, streptomycin 100 μg/mL) in a 5% CO2 incubator at 37℃.

Test Procedure

Culture wells were selected which contained a semi-confluent cell monolayer. The growth medium contained in columns 2 and 11 of the 96- well plate was replaced with 100 μL of the reagent control. The growth medium in triplicate cultures was replaced with 100 μL of the test extract at the following approximate dilutions: 100% (full strength), 50%, 25% and 12.5%. Similarly, triplicate cultures were replaced with 100 μL of the negative control and positive control extract at the following approximate dilution: 100% (full strength) 50%, 25% and 12.5%. The wells were incubated at 37°C (humidified) in 5% CO_2 for 24 hours.

Following incubation, the cultures were examined under a phase contrast microscope to identify any systemic cell seeding errors, growth characteristics and changes in cell morphology. No determination of cytotoxicity was made from this examination.

The culture medium was replaced with 50 μL of a 1 mg/mL MTT [3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyltetrazolium bromide] solution and incubated at 37°C (humidified) in 5% CO_2 for 2 hours.

The MTT solution was replaced with 100μL of isopropanol. The optical density was measured at 570 nm (reference 650 nm).

3.3Evaluation and Statistical Analysis

The MTT Cytotoxicity Study is a colorimetric cytotoxicity test that quantitatively measures cell viability and proliferation following exposure to the test extract or solution. Tetrazolium salts are used to examine cell proliferation. Metabolically active cells reduce yellow-colored tetrazolium MTT [3-(4, 5-dimethylthiazol-2-yl)-2, 5-diphenyltetrazolium bromide] to insoluble purple-colored formazan crystals, due to the action of NADPH-oxidoreductase enzymes. The yellow-to-purple color change can be quantified by spectrophotometric analysis. Absorbance values that are lower than the control cells indicate a reduction in cell viability, whereas a higher absorbance indicates an increase in cell viability. A decrease in the number of living cells results in a decrease in the metabolic activity in the sample. This decrease directly correlates to the amount of blue-violet formazan formed, as monitored by the optical density at 570 nm. The percent viability is compared to the reagent control by using the following formula:

Percent Viability =(100 x OD_{570e})/OD_{570b}

OD_{570e} is the blank corrected mean value of the measured optical density of the test or control article extract.

OD_{570b} is the blank corrected mean value of the measured optical density of the reagent control.

The test results have satisfactory effect.

If the survival rate of test sample extract is less than 70%, it is judged to have cytotoxicity.

4.Results

Table 3 Cell survival rate and toxicity of each group

Treatment Group	Cell survival rate (%)	Cytotoxic Potential
Positive Control (ZDBC,100%,full strength)	29.38	Have Cytotoxic Potential
Negative Control (100%,full strength)	94.92	No Cytotoxic Potential
Test Article (100%,full strength)	74.58	No Cytotoxic Potential

Test Article (50%)	79.94	No Cytotoxic Potential
Test Article (25%)	88.42	No Cytotoxic Potential
Test Article (12.5%)	97.18	No Cytotoxic Potential

5. Conclusion

The test article extract (concentration 100%) met the requirements of the test since the viability of test article was more than 70%. According to ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity Appendix C, The extract of test article showed no cytotoxic potential to L929 mouse fibroblast cells.

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Remark:

Above tests were subcontracted to Guangdong Hua Wei Testing Co.,Ltd.

Sample Photo:

End of Report