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Test Report

Date: 13th Jul. 2020

Client name: JIANGSU EYOUNG MEDICAL DEVICES CO.,LTD

Client address: NO.1 DONGTANG ROAD, ZHENGLU TOWN, TIANNING COUNTY,CHANGZHOU CITY, JIANGSU PROVINCE

Assignment ID: 14A2002503

Sample No.: 14S20008009-02

Report on the submitted sample identified by the client as below:

Product Name	Disposable Medical Face Mask
Quantity Received	50pcs
Batch No.	20200503
Manufacturer	JIANGSU EYOUNG MEDICAL DEVICES CO.,LTD
Sample Receiving Condition	Room temperature
Sample Receiving Date	26th May.2020
Testing Period	11th Jun.2020 –12th Jun.2020

Test Requested, Test Method and Test Results:

Please refer to the following page(s), **Attachment 1**.

The above sample was submitted and identified by the client. The test was carried out by SGS subcontractor certified ISO17025 by CNAS. The results contained in this Report are in the scope of ISO 17025 certification.

Signed for and on behalf of SGS

Racy Li
Life Science Quality Assurance
Authorized Signature

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Attachment 1: Test for in vitro cytotoxicity (MTT cytotoxicity test)

SUMMARY

An in vitro cytotoxicity study was conducted to assess the potential for cytotoxicity of the test article: Disposable Medical Face Mask, based on the International Organization for Standardization ISO 10993-5:2009: Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity; ISO 10993-12:2012: Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials.

Four concentrations (100%, 75%, 50%, and 25%) of the test article extracts, the blank, 100% of the negative control and the positive control were prepared using Minimum Essential Medium (MEM) supplemented with 10% fetal bovine serum. The semi-confluent monolayers of L-929 mouse fibroblast cells were incubated with the test extract, the blank and two controls in a 96-well microplate respectively at 37°C under the condition of 5% CO_2. After 24 h, the MTT colorimetric assay was employed and the plate was read on a microplate reader at 570 and 650nm. Then the viability of cells was calculated.

Under the conditions of this study, the viability of 100% extract of the test article was 83%. It can be considered that the test article extracts had not a cytotoxic potential.

MATERIALS

The test article provided by the sponsor was identified and handled as follows:

Test Article:	Disposable Medical Face Mask
Sterilization Status:	Sterile
Storage Conditions:	Room temperature
Extract Vehicle:	GIBCO's Minimum Essential Medium supplemented with L-glutamine and 10% fetal bovine serum.
Test Extract Preparation:	According to the statement of the sponsor, the absorption capacity was 12ml/one piece [Volume of extraction vehicle to 3.3g of the test sample]. Based on the ISO 10993-12:2012, the ratio of 0.1g:1 ml (Weight of the test sample to volume of extraction vehicle), 3.3g of the whole test articles were covered with 33 ml extraction vehicle, then added an

additional 12ml of extraction vehicle under aseptic conditions for preparing the test extract at 37 ℃ for 24 hours with continuously agitation during extraction. The extract was used immediately after extraction.

Blank Preparation: The extraction vehicle not containing the test sample, retained in a vessel identical to that which holds the test article and subjected to conditions identical to those to which the test sample is subjected during its extraction.

Negative Control Preparation: Current SBRTC negative control, the ratio of 3 cm^2 high-density polyethylene: 1 ml (surface area of the test article to volume of extraction vehicle) was used and extracted at 37°C for 24 hours.

Positive Control Preparation: Current SBRTC positive control, the ratio of 6 cm^2 Polyurethane film containing 0.1% zinc diethyldithiocarbamate (ZDEC): 1 ml (surface area of the test article to volume of extraction vehicle) was used and extracted at 37 ℃ for 24 hours.

Condition of Extracts: All the extracts of the test and controls were clear and without any special treatments.

METHODS

Test System Management:

Mouse fibroblast cells (L-929, from the cell bank of Shanghai Institutes for Biological Sciences), were cultured in MEM with L-glutamine supplemented with 10% fetal bovine serum at 37 ℃ in a gaseous environment of 5% carbon dioxide (CO_2). A 96-well microplate method was employed for the MTT colorimetric assay. Each well was seeded 100 µL suspension of 1×10^4 cells, and incubated at 37 ℃ in 5% CO_2 atmosphere for 24 hours prior to use.

Experimental Procedure:

After incubation, the growth medium was replaced with 100 µL four concentrations (100%, 75%, 50%, and 25%) of the test extract, 100% of the negative control and the positive control, the blank (row 2 and

11) respectively. Six replicates were prepared for each group. The 96-well plate was incubated at 37 ℃ in 5% CO_2 for 24h.

After 24 h treatment, the culture medium was removed carefully from the plates. 50μL of the MTT (Sigma, 1mg/mL) solution was then added to each test well and the plates were further incubated for 2 h at 37 ℃ in a 5% CO_2 atmosphere. Then the MTT solution was removed and 100μL isopropanol per well was added and shake for 10 min gently. The plate was read on a microplate reader at 570nm (reference wavelength 650nm). The viability of the cells was calculated according to the formula below:

$Viab.\% = 100 \times OD_{570e}/OD_{570b}$

Where

OD_{570e} is the mean value of the measured optical density of the extracts of the test sample;

OD_{570b} is the mean value of the measured optical density of the blanks.

A test meets acceptance criteria if the left and the right mean of the blanks do not differ by more than 15% from the mean of all blanks. If the viability of the test sample was reduced to <70% of the blank, it had a cytotoxic potential. The 50% extract of the test sample should have at least the same or a higher viability than the 100% extract; otherwise the test should be repeated.

RESULTS

Group	The optical density (570nm-650nm)	Viab.%
100% of the negative control	0.804±0.033	100
100% of the test extract	0.663±0.019	83
75% of the test extract	0.705±0.018	88
50% of the test extract	0.732±0.024	92
25% of the test extract	0.760±0.033	95
100% of the positive control	0.038±0.006	5
The blank (row 2)	0.797±0.048	/
The blank (row 11)	0.802±0.051	/

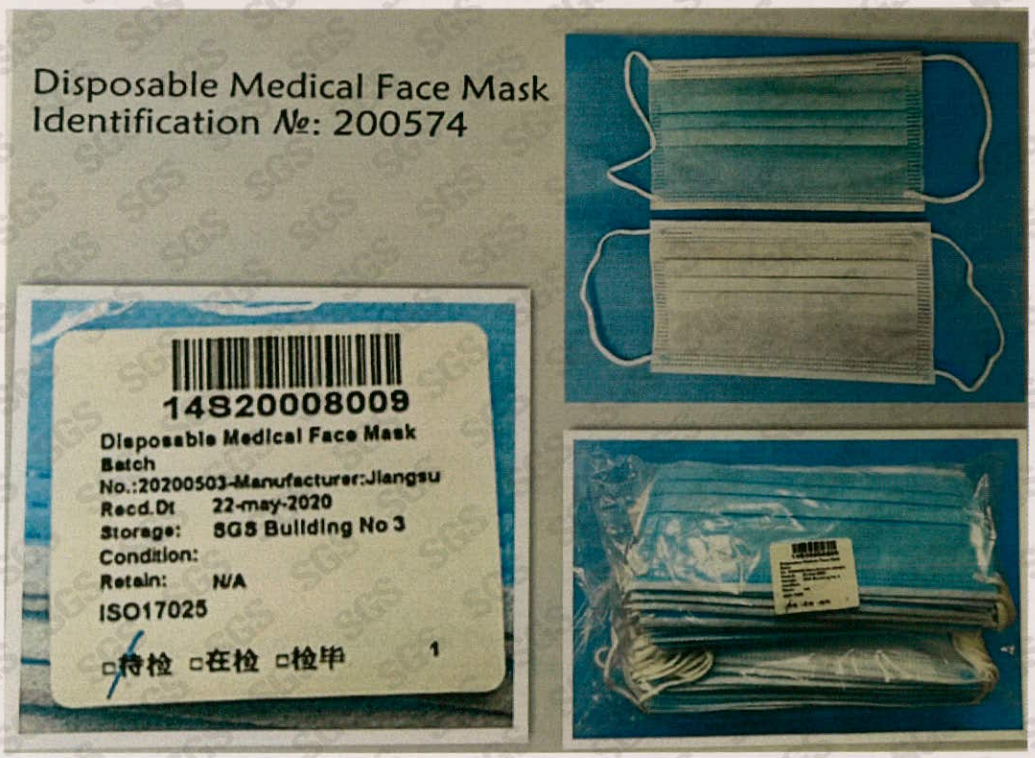
Note: n=6

The mean value of optical density of the blank was 0.800±0.047; both the left (row 2) and the right (row 11) mean of the blanks were less than 15% from the mean of all blanks.

CONCLUSION

Under the conditions of this study, the viability of 100% extract of the test article was 83%. It can be considered that the test article extracts had not a cytotoxic potential.

PHOTOGRAPH OF THE TEST ARTICLE



Remark: Results and conclusions apply only to the test article tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.

***End of Report ***