中国认可
国际互认
检测
TESTING
CNAS L18131

# Test Report

Report Number: 26060536-04-R01EN

| | |
|---|---|
| Sponsor: | Shenzhen Zhongchuang 3D Technology Co., Ltd |
| Factory: | Dongguan Daji 3D Technology Co., Ltd. |
| Sample Name: | Permanent crown resin |
| Model/ Specification: | PRS-R-01 |
| Test Category: | Commission Test |

EPINTEK Guiyang Ltd.

# Declaration

1. The report is invalid without the special stamp for test report of the test facility.
2. Partial copy is invalid without written approval of the test facility.
3. Any copy is invalid without the special stamp of the test facility for test report.
4. The report is invalid without the signature of the authorized signatory.
5. The report is invalid once altered.
6. Any comment to the report should be submitted in writing to the test facility, otherwise it may not be accepted.
7. The results in this report are relevant only to the articles tested.
8. The sponsor is responsible for the authenticity of the sample and its information.

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# EPINTEK Guiyang Ltd.
# TEST REPORT

**Report Number: 26060536-04-R01EN**

| | | | |
|---|---|---|---|
| Sample Name | Permanent crown resin | Sample ID | 26060536 |
| Model/ Specification | PRS-R-01 | | |
| Sponsor | Shenzhen Zhongchuang 3D Technology Co., Ltd | | |
| Address | Room 204, Administration Building, Jia Tai Pharmaceutical, No.1 Industrial Zone,Tangwei Community, Fuhai Street, Bao'an District, Shenzhen City | | |
| Factory | Dongguan Daji 3D Technology Co., Ltd./Room 401, Building 2, No. 6 Xiyi Street, Xingfa South Road, Wusha, Chang'an Town, Dongguan City | | |
| Test Facility | EPINTEK Guiyang Ltd., Facility 1 | | |
| Test Category | Commission Test | Lot# | / |
| Produced Date | 2026.06.06 | Sample Quantity | 14 PCS |
| Received Date | 2026-06-17 | Test Date(s) | 2026-06-22~2026-06-26 |
| Test Item(s) | *In Vitro* Cytotoxicity Test | | |
| Test Method(s) | ISO 10993-5:2009<br>Biological evaluation of medical devices—Part 5: Tests for *in vitro* cytotoxicity | | |
| Conclusion | Under the conditions of this study, the test sample extract did not show a potential cytotoxicity to L-929 cells.<br>（Stamp for Test Report）<br>Issued Date： | | |
| Notes | "NA" means "not applicable","/"means "blank" | | |

Drafted by: _____ Reviewed by: _____

Sean Shao Pearl Tu

Approved by: _____ Position: Authorized Signatory

Aspenn Zeng

# EPINTEK Guiyang Ltd.
# TEST REPORT

**Report Number: 26060536-04-R01EN**

| No. | Item | Standard Method | Acceptance Criteria | Test Result | Conclusion | Note |
|---|---|---|---|---|---|---|
| 1 | *In Vitro* Cytotoxicity Test | ISO 10993-5:2009 MTT Method | If cell viability less than 70 %, the sample extract has a cytotoxic potential. | Under the conditions of this study, the 100% extracts of the test sample viability was 81.7%. | Under the conditions of this study, the test sample extract did not show a potential cytotoxicity to L-929 cells. | Details Shown in Annex |

# EPINTEK Guiyang Ltd.
# TEST REPORT

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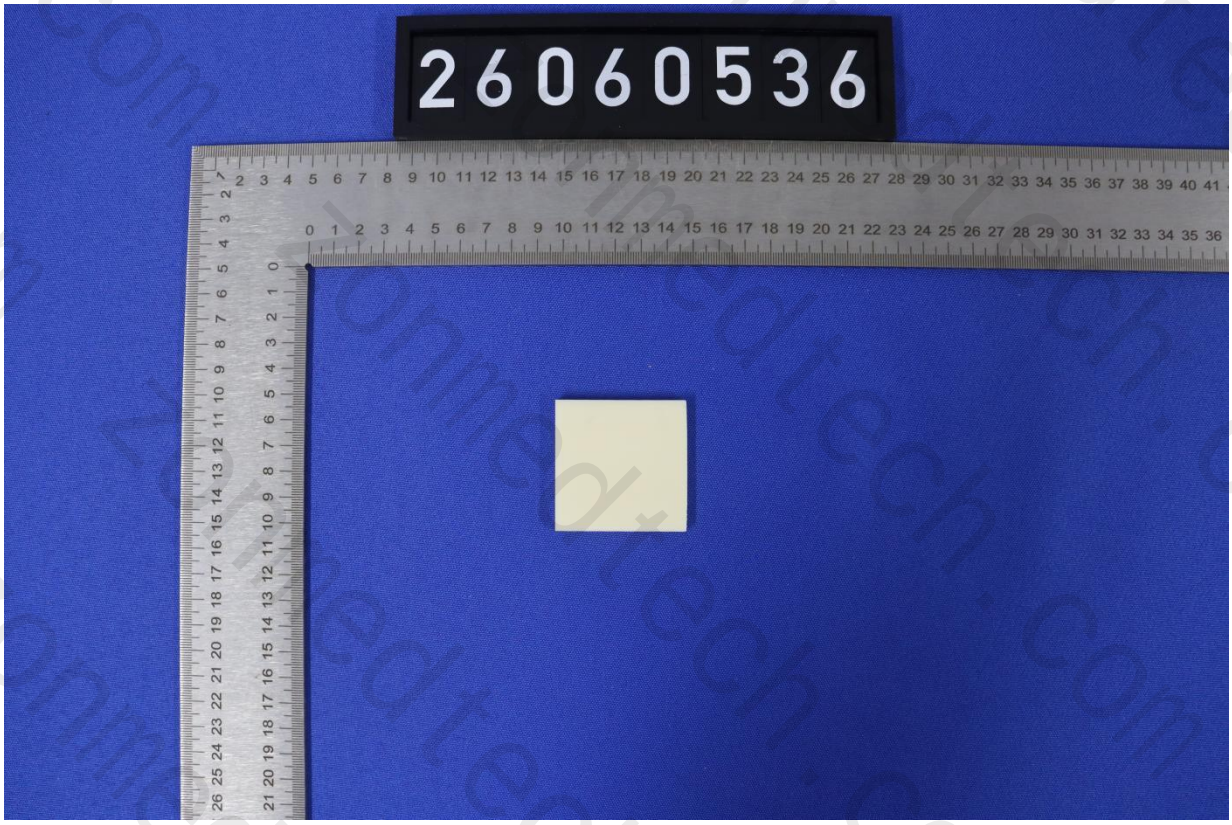
| Picture of Sample |
|---|
|   |
| Description for Sample, Model/Specification |
| Initial State: Unsterilized<br>Physical State: Solid<br>(Note: The above information was provided by the sponsor) |
| Misc |
| None |

# Annex of Test Report

## *In Vitro* Cytotoxicity Test- MTT Method

Study No.：26060536-003506

Model/ Specification：PRS-R-01

Lot#：/

**EPINTEK Guiyang Ltd.**

# SUMMARY

## 1. Purpose

The purpose of the test is to determine cytotoxic potential of the test sample extract on L-929 cells.

## 2. Test Procedure

The test sample (Overall sampling) is extracted in complete MEM medium supplemented with 10% fetal bovine serum (FBS) at an extraction ratio of 3 $cm^2$/ mL for 72 hours in a constant temperature shaking incubator at 37 °C. The negative control and positive control are extracted under identical incubation conditions at ratios of 3 $cm^2$/mL and 6 $cm^2$/mL respectively. The medium control is extracted alongside the test sample under the same conditions.

On Day 1, L-929 cell suspension is seeded into 96-well plates and incubated in an incubator (5% $CO_2$, 37 °C, relative humidity >90%) for 24 hours. On Day 2, the culture medium is aspirated, and serially diluted test sample extracts (100%, 75%, 50%, 25%) are added to each well separately. The plates are incubated for another 24 hours at 37 °C with 5% $CO_2$.

After the 24-hour incubation period, cell morphological observation is carried out first. Subsequently, 50 µL of MTT solution (1 mg/mL) is added to each well, followed by a 2-hour incubation, after which absorbance values are measured..

## 3. Test Result

The MTT test results showed that the cell viability of the 100% test sample extract was 81.7%. The results of control groups showed the test was valid.

## 4. Conclusion

Under the conditions of this study, the test sample extract did not show a potential cytotoxicity to L-929 cells.

# 1. Study Summaries

## 1.1. Purpose

The purpose of the test is to determine cytotoxic potential of the test sample extract on L-929 cells.

## 1.2. Deviation(s) and Incident(s) Procedure

If any deviation or incident has occurred in the test, the information will be recorded in a deviation report timely, and incorporated in this test report to evaluate the impact to final result(s).

## 1.3. Major Laboratory Personnel

| | |
|---|---|
| Study Director: | Eartha Zhang |
| Engineers: | Sean Shao |

## 1.4. Study Dates

| | |
|---|---|
| Test Start: | 2026-06-22 |
| Test End: | 2026-06-26 |
| Report Completed: | 2026-07-09 |

# 2. Testing Information

## 2.1. Blank Control

| | |
|---|---|
| Name: | MEM with 10% FBS |
| Manufacturer: | ExCell (FBS); HyClone (MEM) |
| Lot/ Batch#: | 012E-0515A (FBS); AL30859021 (MEM) |
| Size: | 500 mL (FBS); 500 mL (MEM) |
| Physical State: | Liquid |
| Color: | Red |
| Storage Condition: | (2~8) ℃ |
| Extracting Condition: | 37 ℃, 72 h, 60 rpm |

## 2.2. Negative Control

| | |
|---|---|
| Name: | High Density Polyethylene Film |
| Manufacturer: | Hatano Research Institute, FDSC |
| Lot/ Batch#: | C-212 |
| Size: | c.a.3 cm ×10 cm (5 sheets) |
| Physical State: | Solid |
| Color: | White |
| Storage Condition: | Room temperature |
| Extracting Ratio: | 3 $cm^2$/1 mL |
| Extracting Condition: | 37 ℃, 72 h, 60 rpm |

## 2.3. Positive Control

| | |
|---|---|
| Name: | No powder latex gloves |
| Manufacturer: | GFM World Sdn.Bhd. |
| Lot/ Batch#: | 202411DWL656 |
| Size: | S |
| Physical State: | Solid |
| Color: | White |
| Storage Condition: | Room temperature |
| Extracting Ratio: | 6 $cm^2$/1 mL |
| Extracting Condition: | 37 ℃, 72 h, 60 rpm |

## 2.4. Instruments and Reagents

### 2.4.1. Main Instruments

| Name | No. | Calibration Due Date |
|---|---|---|
| $CO_2$ Incubator | EPME-068 | 2027-04-08 |
| Clean Bench | EPME-108 | 2027-03-30 |
| Constant Temperature Shaking Incubator | EPME-061 | 2027-02-27 |
| Micro-plate Reader | EPME-063 | 2027-05-13 |
| Inverted Microscope | EPME-051 | Check qualified |

### 2.4.2. Main Reagents

| Name | Lot# | Manufacturer |
|---|---|---|
| Fetal bovine serum (FBS) | 012E-0515A | ExCell |
| Minimum essential medium (MEM) | AL30859021 | HyClone |
| Penicillin, Streptomycin | 20250911 | NCM Biotech |
| Trypsin | 2503821 | BLOEXPLORER |
| 3-(4,5-Dimethyl-2-Thiazolyl)-2,5-Diphenyl Tetrazolium Bromide (MTT) | C18575851 | MACKLIN |
| MEM (without phenol red) | 251130 | GenXion |
| Isopropanol | 20251129 | Fuyu |

# 3. Justification of the Test System

L-929 cells have been used for cytotoxicity because they demonstrate sensitivity to extractable cytotoxic samples.

# 4. Identification of the Test System

L-929 cells obtained from Procell Life Science& Technology Co.,Ltd.

# 5. Route of Exposure

Exposing the test sample to the test system via its extract (extracted using a carrier compatible with the test system) is regarded as the optimal contact route and is recommended by the standard.

# 6. Test Design

## 6.1. Preparation of Extracts

**Table 1 Extraction Condition**

| Aseptically Sampling | | | Media | Sterilization Method | Extract Condition[2)] |
|---|---|---|---|---|---|
| Ratio | Sampling Method[1)] | Sample Amount | | | |
| 3 cm²/ mL | Overall sampling | 50 cm² | MEM with 10% FBS | Alcohol disinfection（Soak） | 37 °C, 72 h, 60 rpm |

**Table 2 Extraction Details** [3)]

| Volume | pH | Clear | Color Change | Particle or precipitate | Centrifugation, Filtration or pH adjustment |
|---|---|---|---|---|---|
| 16.66 mL | 7.34 | Clear | Not | Not | Not |

1） Surface area of a single sample: 50 cm² (Provided by the sponsor), One sample was used in this test.

2） The extraction process was conducted in a shaking machine.

3） The result extracts were used immediately.

### 6.2. Preparation of MTT solution

MTT is dissolved in MEM without supplements and without phenol red at a concentration of 1 mg/mL. This solution is sterilized by filtering with 0.22 μm membrane, the solution should be used the same day.

### 6.3. Test Procedure

L-929 cells were cultured in MEM medium (10% FBS, Penicillin 100 IU/mL, Streptomycin 100 μg/mL) in cell incubator (5% $CO_2$, 37°C, >90% humidity), then digested with 0.25% trypsin to get single cell suspension. And obtained a $1\times10^5$ cells/mL suspension by centrifuging (200 g, 3 min) and re-suspended in MEM medium finally. The suspended cells were dispensed at 100 μL per well in 96-well plate, and cultured it in cell incubator (5% $CO_2$, 37℃, >90 % humidity) for 24h, cell morphology was evaluated to verify that the monolayer was satisfactory.

After the cells grew to form a monolayer, original culture medium was discarded. The 96-well plates were then treated with 100 μL extract of test sample (100%, 75%, 50%, 25%), blank control, negative control (100%) and positive control (100%) respectively. Incubated the 96-well plate in cell incubator (37℃, 5% $CO_2$, >90 % humidity) for another 24 h. Six parallel wells of each test were tested.

After 24 h incubation, take out the 96-well plate for cell morphology observation first, and then discard the original culture medium. 50μL aliquot of MTT (1 mg/mL) was added to each well and then incubated in cell incubator (37℃, 5% $CO_2$, >90% humidity) for 2 h. The supernatant in each well was tipped out and 100 μL isopropanol was added to each well.

Evaluated the absorbance value with a micro-plate reader with the measurement wavelength at 570nm and reference wavelength at 650nm.

# 7. Data analysis and calculation

Mean±standard deviation ($\overline{X}$±SD)

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

$OD_{570e}$—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.

# 8. Evaluation Criterion

- The lower the Viab.% value, the higher the cytotoxic potential of the test item is.
- If viability is reduced to 70 % of the blank, the test sample extract has 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.

# 9. Alteration and Deviation

No deviation affecting the validity of the test data occurred.

# 10. Results

## 10.1. Results of Cell Morphology

**Table 3 Observation of cell morphology**

| Group | Before treated with extract | 24 h after treatment |
|---|---|---|
| Blank control | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. |
| Negative control | | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. |
| Positive control | | Nearly complete or complete destruction of the cell layers. |
| 100% Test sample extract | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. | Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable. |
| 75% Test sample extract | | Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable. |
| 50% Test sample extract | | Not more than 20 % of the cells are round, loosely attached and without intracytoplasmatic granules, or show changes in morphology; occasional lysed cells are present; only slight growth inhibition observable. |
| 25% Test sample extract | | Discrete intracytoplasmic granules, no cell lysis, no reduction of cell growth. |

### 10.2. Results of Cell Vitality

**Table 4 Results of cell viability**

| Group | $\bar{X}$±SD | Viability |
|---|---|---|
| Blank control | 0.682±0.016 | 100.0% |
| Negative control | 0.668±0.005 | 97.9% |
| Positive control | 0.023±0.008 | 3.4% |
| 100% test sample extract | 0.557±0.007 | 81.7% |
| 75% test sample extract | 0.579±0.023 | 84.9% |
| 50% test sample extract | 0.595±0.026 | 87.2% |
| 25% test sample extract | 0.618±0.022 | 90.6% |

# 11. Conclusion

Under the conditions of this study, the test sample extract did not show a potential cytotoxicity to L-929 cells.

# 12. Archiving

All related documents, study protocol, test report and raw data, including the documentation, printouts of instruments and computers, are stored in the archiving room of the test facility.

……End of the Report……