

检测报告

编号 : GZIN2108050369PC_CN

日期 : 2021-11-05

页码 : 1 of 5

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GZIN2108050369PC

客户名称: 迈高精细高新材料(深圳)有限公司
客户地址: 深圳市龙岗区坪地街道六联社区长山工业区 11 号

样品名称 : GF2071E
测试样品信息 : GF2071E
客户参考信息 : G(J)F(D,E)20XX(XX), G(J)F(D,E)95XX(XX), G(J)F(D,E)96XX(XX),
G(J)F(D,E)98XX(XX), G(J)F(D,E)99XX(XX), G(J)F(D,E)1XX(XX)

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样品描述: 片状

测试项目: 体外细胞毒性

测试方法: GB/T 16886.5-2017/ISO 10993.5-2009《医疗器械生物学评价 第5部分 体外细胞毒性试验》附录 C MTT细胞毒性试验

检测结论:

在本次试验条件下, 样品浸提液在 50%浓度下, 细胞活性 \geq 70%, 无细胞毒性。

一、测试系统及对照

1. 细胞类型: L929细胞
2. 完全培养基: 含 10%FBS的 DMEM培养基
3. 对照组: 完全培养基
4. 阳性对照: 5g/L苯酚
5. 阴性对照: 高密度聚乙烯
6. 浸提条件: 阴性对照, 以 0.2g/mL的浸提比例置于完全培养基中在 37.0°C浸提 24h。

样品以 1.25cm²/mL的浸提比例置于生理盐水中在 37.0°C浸提 24h。使用前, 取样品的生理盐水浸提液与培养基(2×) 1: 1混合, 再梯度稀释。

二、方法:

1. 检测方法: GB/T 16886.5-2017/ISO 10993.5-2009《医疗器械生物学评价 第5部分 体外细胞毒性试验》附录 C MTT细胞毒性试验
2. 培养环境: 37.0°C, 相对湿度: 饱和, CO₂浓度: 5.0%



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三、步骤

- 1.常规培养细胞。将细胞消化并重悬与培养液中。
- 2.调整细胞浓度为 1.0×10^5 /mL, 按每孔100 μ L细胞悬液接种于96孔板, 培养24h。
- 3.去除原培养液, 每孔加入100 μ L不同浓度样品浸提液和一系列对照组, 培养箱中暴露24h。
每组设置6个重复。
- 4.暴露结束, 各孔加入MTT溶液50 μ L, 放入培养箱中孵育3h。去除含MTT溶液, 加入100 μ L异丙醇, 避光震荡10min直至甲瓏完全提取, 在570nm波长下测定吸光度值, 以空白孔为参照。
- 5.细胞活性的计算和细胞形态学评价按下面进行。

$$\text{细胞活性 (\%)} = \frac{\text{OD}_{570 \text{ 样品}} - \text{OD}_{570 \text{ 空白}}}{\text{OD}_{570 \text{ 对照}} - \text{OD}_{570 \text{ 空白}}} \times 100$$

| 分级 | 反应性 | 浸提液细胞毒性形态学分级 |
|----|-----|---|
| 0 | 无 | 胞浆内有离散颗粒, 无细胞溶解, 无细胞增殖下降 |
| 1 | 轻微 | <20%细胞变圆和松散贴壁, 细胞质内未发现颗粒物质减少或形态异常; 偶有细胞溶解; 仅轻微细胞生长抑制。 |
| 2 | 轻度 | <50%细胞变圆, 细胞质内颗粒物质减少, 部分细胞溶解; <50%细胞生长抑制。 |
| 3 | 中度 | <70%细胞变圆或溶解; 细胞层尚未完全破坏, >50%细胞生长抑制。 |
| 4 | 重度 | 接近全部或全部细胞层破坏或细胞溶解。 |



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四、试验结果:

1.细胞形态学结果:

细胞形态学分级

| 组别 | | 暴露前 | 暴露 24h 后 |
|-------|---------|-----|----------|
| 对照组 | | 0 | 0 |
| 阴性对照组 | | 0 | 0 |
| 阳性对照组 | 5g/L | 0 | 4 |
| | 3.75g/L | 0 | 4 |
| | 2.5g/L | 0 | 4 |
| | 1.25g/L | 0 | 3 |
| 样品组 | 50% | 0 | 0 |
| | 37.5% | 0 | 0 |
| | 25% | 0 | 0 |
| | 12.5% | 0 | 0 |

2.细胞活性结果:

各组细胞活性结果 (均值)

| 组别 | | 细胞活性 (%) |
|-------|---------|----------|
| 对照组 | | 100.00 |
| 阴性对照组 | | 95.00 |
| 阳性对照组 | 5g/L | 0.81 |
| | 3.75g/L | 0.64 |
| | 2.5g/L | 0.83 |
| | 1.25g/L | 33.57 |
| 样品组 | 50% | 81.40 |
| | 37.5% | 98.15 |
| | 25% | 106.69 |
| | 12.5% | 102.43 |

五、结论:

在本次试验条件下, 样品浸提液在50%浓度下, 细胞活性 \geq 70%, 无细胞毒性。



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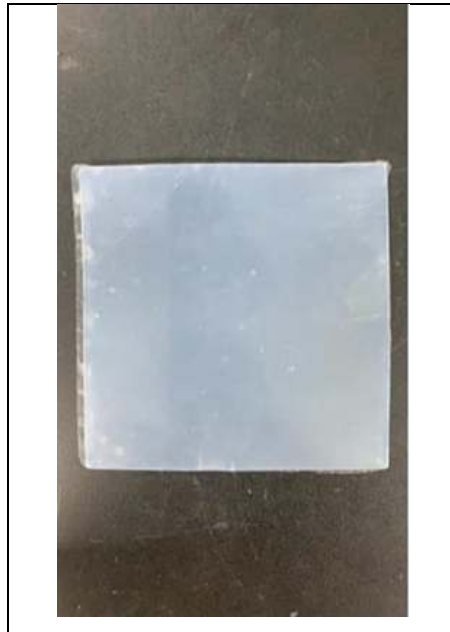
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样品图片:



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