

功效检测报告

COSMETIC EFFICACY TEST REPORT

报告编号 Report No: RG240337-5CE

客户名称 The name of
the customer: 聚磷锡创生物科技（无锡）有限公司
Polyphosphate Xichuang Biotechnology
(Wuxi) Co., Ltd.

客户联络信息 Customer
contact information: 无锡市锡山区安镇街道东安路 88 号 1 层 103B
103B, 1st Floor, No. 88 Dong'an Road,
Anzhen Street, Xishan District, Wuxi City

样品名称 Sample name: 多聚磷酸钠 (PolyP45)

申请项目 Test Item: 口腔修护 Oral repair

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Reporting: 2024.11.05

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广州华测品鉴生物技术有限公司

CTI Pinjian Biotechnology (Guangzhou) Co.Ltd.

页码 1 / 10
检验检测专用章
Inspection & Testing Services

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Report description

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The results and conclusions in this report only represent the samples tested.

5. 客户送检样品, 我司仅对收到的样品负责。

If the customer sends the sample for inspection, our company is only responsible for the sample received.

6. 对本报告有疑议, 请在收到报告的 10 个工作日内与本公司联系。

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9.因报告中所用语言产生的歧义,以中文为准。

Any ambiguity arising from the language used in the report shall prevail in Chinese.

广州华测品鉴生物技术有限公司

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检测结果
Test results

样品信息 Sample information	样品名称 Name of Sample	多聚磷酸钠 (PolyP45)	样品来源 Sample Source	客户送检 The customer sends the sample
	样品规格 Sample Specification	100 g	批号 Sample Batch	N/A
	生产日期 Production date	N/A	保质期/限期使用日期 Shelf life/expiration date	N/A
	样品性状 Sample Properties	固体粉末 Solid powder	样品保存条件 Save the condition	4 度保存 Save at 4 degrees
	生产厂家 Manufact	聚磷锡创生物科技（无锡）有限公司 Polyphosphate Xichuang Biotechnology (Wuxi) Co., Ltd.		
	生产厂家地址 Manufacturer's address	无锡市锡山区安镇街道东安路 88 号 1 层 103B 103B, 1st Floor, No. 88 Dong'an Road, Anzhen Street, Xishan District, Wuxi City		
	其他信息 Additional Information	N/A		
客户信息 Customer Information	客户名称 The name of the customer	聚磷锡创生物科技（无锡）有限公司 Polyphosphate Xichuang Biotechnology (Wuxi) Co., Ltd.		
	客户联络信息 Customer contact information	无锡市锡山区安镇街道东安路 88 号 1 层 103B 103B, 1st Floor, No. 88 Dong'an Road, Anzhen Street, Xishan District, Wuxi City		
样品来源为客户送检时，以上信息由客户提供，我司不对信息的有效性和真实性负责。 When the sample source is sent by the customer for inspection, the above information is provided by the customer, and our company is not responsible for the validity and authenticity of the information.				
表 1 检测信息 Table 1 Detection information				
样品接收日期 Sample received Date	2024.08.22		测试实施日期 Test Date	2024.09.02-2024.09.05
检测地址 Detect the address	广州市黄埔区博华一路 203 号 B1201 室 Room B1201, No. 203, Bohua 1st Road, Huangpu District,Guangzhou			

表 2 检测结果 Table 2 Test results					
样品号 Sample No.	测试项目 Test Item	测试方法 Test Method	测试结果 Result	判定规则 Judgment Rules	测试结论 Conclusion
G240337-1	口腔修护 Oral repair	WI-GZB-726 化妆品体外功效测试-细胞增殖实验操作规程* WI-GZB-726 In vitro efficacy test of cosmetics - operating procedures for cell proliferation experiments*	0.1%浓度样品作用细胞 24h, 细胞增殖率=26.59% 0.1% concentration of samples treated cells for 24 h, cell proliferation rate = 26.59%	见附件 8.结果判定 See Annex 8: Determination of Results	在本次实验条件下, 0.1%浓度样品作用细胞 24h 的测试结果可以支持客户对于“口腔修护”结论的宣称。 In this experiment, the test results of 0.1% concentration of cells for 24 hours can support the customer's claim about "oral repair".

备注: 1.具体测试数据见附件; 2.*测试方法为实验室方法。
Remarks: 1. See the attachment for specific test data;2. *The test method is a laboratory method.

附件 Annex

1. 仪器 Instrument

倒置显微镜 Invert microscope	二氧化碳培养箱 CO ₂ incubator	细胞计数仪 Cell Counter
酶标仪 Microplate reader	离心机 Centrifuge	生物安全柜 Biosafety cabinet

2. 实验材料 Experimental materials

空白对照组 Blank control	0.5%血清培养基 High glucose medium+0.5% serum
阳性对照组 Positive control	15%血清培养基 High glucose medium+15% serum
噻唑蓝 (MTT) 工作液 MTT working solution	用完全培养基稀释 5mg/ml MTT 储备液为 1mg/ml MTT 工作液，现配现用。 Dilute 5mg/ml MTT stock solution with complete culture medium to 1mg/ml MTT working solution, prepare and use immediately.
样品 Sample	将样品用含 0.5%血清的高糖培养基稀释成 0.5%、0.1%、0.01%、0.001%和 0.0001%浓度进行细胞增殖实验。 Dilute the sample with high glucose medium containing 0.5% serum to concentrations of 0.5%, 0.1%, 0.01%, 0.001%, and 0.0001% for cell proliferation experiments.
细胞及代次 Cells and passages	牙龈成纤维细胞 (HGF)细胞来源于北京博瑞康沐生物技术有限公司，细胞增殖测试为 07 代。 Gingival fibroblast (HGF) cells were derived from Beijing Borui Kangmu Biotechnology Co., Ltd., and the cell proliferation test was 07 generation.

3. 原理

牙龈成纤维细胞 (HGF) 是牙龈结缔组织和牙周膜的主要细胞类型在牙周组织的形成与再生、完整性的维持和功能的实施中起重要作用，牙龈成纤维细胞来源丰富，有很强的生长和自我繁殖能力。血清的含量对于细胞的增殖修护有明显的作用，以 15%的血清作为阳性对照，通过测定给药后样品组的细胞增殖率，评价样品对细胞的增殖作用。

Gingival fibroblasts (HGFs) are the main cell types of gingival connective tissue and periodontal ligament, which play an important role in the formation and regeneration of periodontal tissue, the maintenance of integrity and the implementation of function. The

content of serum has a significant effect on the proliferation and repair of cells, and 15% serum was used as a positive control to evaluate the proliferation rate of the sample group after administration by measuring the cell proliferation rate of the sample group after administration.

4. 测试分组

组别 Group	培养条件（24-72h） Culture conditions	重复孔 Repetitive well
空白对照组 Blank control group	含有 0.5%血清培养基 Medium containing 0.5% serum	4
待测样品组 Sample group	含有 0.5%血清+5 个浓度样品培养基 Culture medium containing 2% serum and 5 concentration samples	4
阳性对照组 Positive control group	含有 15%血清培养基 Containing 15% serum medium	4

5. 实验步骤 Experimental steps

5.1. 细胞传代培养 Cell passage Culture

按照 WI-GZB-703 规程进行细胞的复苏、传代培养。

Perform cell recovery and culture according to the WI-GZB-703 cell recovery, passage, and cryopreservation protocol.

5.2. 种板 Seed plate

选择对数生长期的细胞，经胰酶消化后收集细胞，制成细胞悬液，用细胞计数仪进行计数，将细胞悬液接种至 96 孔板中，要求培养 24h 细胞融合度达到 20%-30%，每孔液量为 100μL。接种结束后，于 37℃、5% CO₂ 培养箱内 24±2h。

Select cells in logarithmic growth phase, collect them after trypsin digestion, make cell suspensions, count them with a cell counter, and inoculate the cell suspensions into a 96 well plate. The cell fusion degree should reach 20% -30% after 24 hours of cultivation, with a volume of 100μL per well. After vaccination, incubate in a 37 °C, 5% CO₂ incubator for 24 ± 2 hours.

5.3. 给药 Add sample

弃掉板中的培养基，按照测试分组开展给药操作，每孔 100μL。于 37℃、5% CO₂ 培养箱内培养 24±2h、48±2h。

Discard the culture medium from the plate and perform sample addition according to the test group,

with 100μL per well. Cultivate in a 37 °C, 5% CO₂ incubator for 24 ± 2 hours and 48 ± 2 hours.

5.4. MTT 测试 MTT test

按照 WI-GZB-717 细胞毒性实验操作程序进行 MTT 测试的步骤, 测定每个组别的吸光度。

According to the WI-GZB-717 cytotoxicity assay procedure, perform MTT testing to determine the absorbance of each group.

6. 数据分析 Data analysis

细胞增殖率计算公式 Formula for calculating cell proliferation rate

细胞增殖率 (%) = (测试组 OD 值 - 24h 空白对照组 OD 值平均值) / 24h 空白对照组 OD 值平均值 * 100

Cell proliferation rate (%) = (OD value of the test group - average OD value of the 24h blank control group) / average OD value of the 24h blank control group * 100

7. 试验有效性验证 Determination of experimental effectiveness

7.1. 每批次试验均须设置阳性对照, 要求每批次试验, 至少有一个时间点阳性对照与空白对照组相比细胞增殖率显著提高 (**P* < 0.05)。

A positive control must be set up for each batch of trials, and at least one time point of each batch of trials is required to have a significant increase in cell proliferation rate of the positive control compared with the blank control group (**P* < 0.05).

7.2. 统计酶标仪测得的各组复孔间光密度的标准差 (Standard Deviation, SD), 并计算变异系数 (Coefficient of Variation, C.V), C.V 值 ≤ 20%, 则认为试验平行性有效。

Calculate the standard deviation (SD) of optical density between each group's multiple wells using a statistical microplate reader, and calculate the coefficient of variation (C.V). If the C.V value is ≤ 20%, it is considered that the test parallelism is valid.

8. 结果判定 Results report

评价受试物对 HGF 细胞的增殖能力, 需要受试物与空白对照组 (BC) 的细胞增殖率之间具有显著性差异 (**P* < 0.05)。

To evaluate the proliferation ability of the test substance on HGF cells, it is necessary to significantly increase the cell proliferation rate of the test substance compared to the blank control group (**P* < 0.05).

9. 测试结果 Test result

样品组、阳性对照组和空白对照组 (BC) 的吸光度 OD 值变异系数 C.V 值均小于等于 20%, 且阳性对照细胞增殖率与空白组相比有显著提高, 试验有效。具体测试数据见表 1 图 1

The coefficient of variation (CV) of absorbance OD values for the sample group, positive control group, and blank control group (BC) is less than or equal to 20%, and the proliferation rate of positive control cells is significantly improved compared to the blank group, indicating the effectiveness of the experiment. The specific test data is shown in Table 1 and Figure 1.

表 1 不同组的细胞增殖率 (Mean±SD)

(*表示与空白组对比差异具有统计学意义*P<0.05, **P<0.01)

Table2 Cell proliferation rates of different groups (Mean ± SD)

(* indicates statistically significant difference compared to the blank group * P<0.05, **P<0.01)

实验组 Experimental group	24 小时细胞增殖率 (%) 24H Cell proliferation rates (%)	OD 值 C.V 值 (%) C.V value of OD value (%)	48 小时细胞增殖率 (%) 48H Cell proliferation rates (%)	OD 值 C.V 值 (%) C.V value of OD value (%)
空白组 Blank group	0.00±3.09	3.09	1.18±2.66	2.63
阳性对照 Positive control	34.79±1.83**	1.36	157.55±1.76**	0.69
0.5%-样品	-42.42±0.43	0.75	-46.85±0.25	0.47
0.1%-样品	26.59±2.63**	2.08	-9.82±2.33	2.59
0.01%-样品	14.65±0.96**	0.84	24.19±2.15**	1.73
0.001%-样品	10.40±3.61*	3.27	13.72±3.56*	3.13
0.0001%-样品	20.42±4.47**	3.71	8.79±5.54	5.09

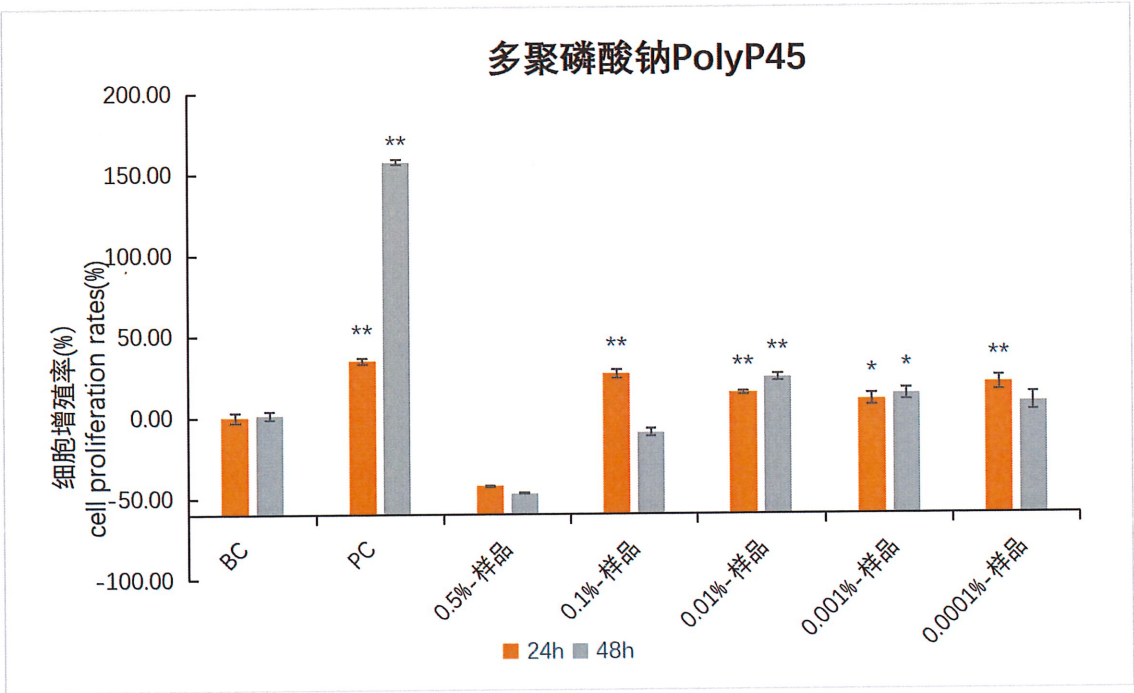


图 1.各实验组 24h 和 48h 细胞增殖率

(*表示与空白组 (BC) 对比差异具有统计学意义*P<0.05, **P<0.01)

Figure 1. Cell proliferation rate at 24h and 48h in each experimental group
(* indicates statistically significant difference compared to the blank group * $P < 0.05$, ** $P < 0.01$)

10. 结论 Conclusion

本次实验条件下, 样品“多聚磷酸钠 (PolyP45)”在 0.1% 浓度下作用细胞 24h, 对 HGF 细胞增殖具有显著的促进作用, 该浓度样品的测试结果可以支持客户对于“口腔修护”结论的宣称。

Under the conditions of this experiment, the sample "sodium polyphosphate (PolyP45)" had a significant effect on the proliferation of HGF cells when it acted on cells at a concentration of 0.1% for 24 hours. The test results of this concentration sample can support the customer's claim about the conclusion of "oral repair".

11. 备注 Remark

- a) 本报告中的测试结果和结论仅适用于该客户提供的该批样品。因此, 该报告中的结果并不代表除该样品以外的样本或类似样品;

The testing results and conclusions in this report are only applicable to the batch of samples provided by the customer. Therefore the results in this report do not represent samples other than this one or similar samples.

- b) 本报告中的数据结果仅供科研、教学、企业内部质量控制、企业内部产品研发等目的用。

The data results in this report are for purposes such as scientific research education internal quality control within a company and internal product development within a company.

报告结束

*** The End of Report ***