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| 山东力诺医药包装股份有限公司<br>Shandong Linuo Pharmaceutical Packaging Co., Ltd.        | 文件编号: SOP/ZG 224-02<br>File Number: SOP/ZG 224-02 |
| 无菌卡式瓶系统检验报告<br>Ready To Use Cartridges System<br>Product Inspection Report | 版本号: A<br>version Number: A                       |

Report NO. 报告编号: RTU202607-0006

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| 产品名称<br>Product name    | 无菌卡式瓶系统<br>Ready To Use Cartridges System                          |                                                                                                                                                                                                                                                                                                                                     | 规格<br>Specification                | 3ml                                                                                                                           |                           |
| 批号<br>Batch number      | 2607403                                                            |                                                                                                                                                                                                                                                                                                                                     | 灭菌批号<br>Sterilization Batch Number | 20260712031                                                                                                                   |                           |
| 产品数量<br>Quantity        | 14750 PCS                                                          |                                                                                                                                                                                                                                                                                                                                     | 包装规格<br>Packing specification      | 1 支/袋<br>1 PCS / BAG                                                                                                          |                           |
| 取样数量<br>Sampling amount | 250 PCS                                                            | 请检日期<br>Date of application                                                                                                                                                                                                                                                                                                         | 2026.07.14                         | 报告日期<br>Report date                                                                                                           | 2026.07.29                |
| 检验依据<br>Test reference  | 《无菌卡式瓶系统》Q/LN057-2025<br><Aseptic Card Bottle System> Q/LN057-2025 |                                                                                                                                                                                                                                                                                                                                     |                                    |                                                                                                                               |                           |
| 序号<br>Order NO.         | 检验项目<br>Test item                                                  | 技术要求<br>Specification                                                                                                                                                                                                                                                                                                               |                                    | 检验结果<br>Result                                                                                                                | 单项判定<br>Single conclusion |
| 1                       | 外观<br>Appearance                                                   | 关键缺陷应符合要求<br>Critical flaw should meet the requirements                                                                                                                                                                                                                                                                             |                                    | 符合规定<br>Meet requirement                                                                                                      | 合格<br>Qualified           |
|                         |                                                                    | 主要缺陷应符合要求<br>Main defect should meet the requirements                                                                                                                                                                                                                                                                               |                                    | 符合规定<br>Meet requirement                                                                                                      | 合格<br>Qualified           |
|                         |                                                                    | 次要缺陷应符合要求<br>Minor defect should meet the requirements                                                                                                                                                                                                                                                                              |                                    | 符合规定<br>Meet requirement                                                                                                      | 合格<br>Qualified           |
| 2                       | 配合性<br>Compatibility                                               | The aluminum cover should fit snugly with the glass sleeve and there should be no looseness or detachment.<br>铝盖与玻璃套筒配合适宜, 应无松动或脱落现象。                                                                                                                                                                                               |                                    | 符合规定<br>Meet requirement                                                                                                      | 合格<br>Qualified           |
| 3                       | 密合性<br>Tightness                                                   | 铝盖或活塞部位无泄漏。<br>There should be no leakage observed in the aluminum cover or piston area.                                                                                                                                                                                                                                            |                                    | 符合规定<br>Meet requirement                                                                                                      | 合格<br>Qualified           |
| 4                       | 滑动性能<br>Sliding performance                                        | 启动力应不超过 30N; 持续推动力应不超过 15N; 重新启动力应不超过 30N; 并检查在连续运动期间不得有“颤动”(指活塞的不规则运动)现象。<br>The starting force should not exceed 30N; The sustained driving force should not exceed 15N; The restart force should not exceed 30N; And check that there is no "vibration" (referring to irregular movement of the piston) during continuous motion |                                    | 启动力: 2.40N<br>Starting force: 2.40N<br>持续推动力: 1.65N<br>Sustained driving force: 1.65N<br>重新启动力: 1.71N<br>Restart force: 1.71N | 合格<br>Qualified           |

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|-----------------|-----------------------------------|-----------------------------------|--------------------------|---------------------------|
| 5               | 硅油量<br>Silicone amount            | $\leq 1.0\text{mg}$               | 0.16mg                   | 合格<br>Qualified           |
| 6               | 不溶性微粒<br>No soluble particles     | $\geq 10\mu\text{m}$ 的微粒数不得过 60 粒 | 10                       | 合格<br>Qualified           |
|                 |                                   | $\geq 25\mu\text{m}$ 的微粒数不得过 6 粒  | 1                        | 合格<br>Qualified           |
| 7               | 环氧乙烷残留量<br>Ethylene oxide residue | $\leq 1 \mu\text{g/ml}$           | 未检出<br>Not detected      | 合格<br>Qualified           |
| 8               | 细菌内毒素<br>Bacterial endotoxin      | $< 0.25\text{EU/ml}$              | $< 0.25\text{EU/ml}$     | 合格<br>Qualified           |
| 9               | 无菌<br>Sterility test              | 应无菌<br>Should be no bacteria      | 符合规定<br>Meet requirement | 合格<br>Qualified           |

汇总人/日期: 杨程程

Collector/Date:

复核人/日期: 张海洋

Reviewer/Date:

批准人/日期: 张海洋

Approver/Date:

