

检验报告书 / Certificate of Analysis

| | | | |
|-----------------------|--|-----------------------------|------------------------------------|
| 产品名称 Product Name | PDE RecTrypsin-LQ02(1×) | 检验编号 Analysis ID | 230620PDELQ02002B |
| 产品编号 Catalog No. | PDE-LQ02 | 报告日期 Report Date | 2023.07.04 |
| 生产批号 Lot Number | PDE-LQ02230620002.B | 贮存条件 Storage Requirement | 2 ~ 8°C 避光 Protected from light |
| 生产日期 MFG Date | 2023.06.20 | 有效日期 Expiration Date | 2024.06.19 |
| 检验依据 Test Standard | 检验方法标准操作规程 Sop for inspection methods | | |

| 检验项目 Test Categories | 标准要求 Test Specifications | 检验结果 Test Results |
|------------------------------|--|--|
| 外观 Physical Appearance | 无色澄清液体 Colorless transparent liquid | 无色澄清液体 Colorless transparent liquid |
| 澄清度 Clarity | 澄清 Clear | 澄清 Clear |
| pH 值 pH Value | 7.0 ~ 7.4 | 合格 PASS |
| 渗透压 Osmolality | 280 ~ 300 (mOsmol/Kg) | 合格 PASS |
| 酶活力 Activity Assay (BAEE) | ≥160U/mL | 259.7 U/mL |
| 体外生物活性 In-Vitro Bioassay | 符合 Acceptable | 合格 PASS |
| 细菌内毒素 Endotoxin | <1.0 EU/mL | 合格 PASS |
| 无菌检查 Sterility check | 阴性 Negative | 合格 PASS |

结论: 本品按成品检验操作规程检测, 结果均已记录。

Conclusion: This product has been tested according to the finished product inspection operating procedures and the results have been recorded.

QC 复核人: 陈义梅
Quality Control:

QA 复核人: 付紫嫣
Quality Assurance:

