

合格证书
Certificate of Conformity

产品名称: 4层细胞工厂双大口标准装, 一箱6个
Product Name: Cell Factory Systems, 4 Trays,6EA/CS
货号: 166003
Item number
批号: 23103102
Lot number
生产日期: 10/31//2023
Date of manufacture
有效期: 月/年(生产日期起+3年)
Date of expiry Month/Year (manufacturing plus 3 years)



苏州欧尼思特智造科技确认所供应的产品已按照相关规范进行检验和测试

Suzhou Honest Intelligent manufacturing confirms that the product supplied has been inspected and tested in accordance to relevant specifications

| 测试项目 Test Item | 测试要求 Test Requirements | 测试结果 Test Result |
|---|---|---------------------|
| 外观检测 Visual | 根据检验规范 According to specification | 符合 Complies |
| 功能检测 Test of function | 根据检验规范 According to specification | 符合 Complies |
| 克隆效率 Cloning efficiency with V-79 cell line | 根据检验规范 According to specification | 符合 Complies |
| 细菌内毒素 USP <85> Bacterial Endotoxins test | <0.5内毒素单位/ml <0.5 Endotoxins unit/ml | 符合 Complies |
| 细胞培养测试 Cell Culture Test | 根据检验规范 According to specification | 符合 Complies |
| 理化测试 Physical Chemistry Test | USP当前版本 USP current edition | 符合 Complies |
| 生物活性测试 USP <87> Biological Reactivity Tests | USP当前版本 USP current edition | 符合 Complies |
| 医疗器械生物学评价 ANSI/AAMI/ISO 10993 Biological evaluation of medical devices | ISO当前版本 ISO current edition | 符合 Complies |

无菌: 根据ISO11137医疗保健产品灭菌-辐射灭菌, 无菌保证水平SAL=10⁻⁶.

Sterility: According to ISO 11137 "Sterilization of health care products - Radiation", with SAL= 10⁻⁶.

产品质量保证按照ISO 13485:2016“医疗器械-质量管理体系-监管目的的体系要求”的要求执行

The product Quality assurance is performed in accordance with the requirements of ISO 13485:2016 "Medical devices - Quality management systems - System requirements for regulatory purposes".