

山东久隆恒信药业有限公司

SHANDONG JIULONG HISINCE PHARMACEUTICAL CO.,LTD

分析报告单

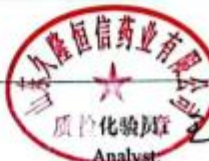
Certificate of Analysis

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|-------------------------------|--|---------------------------|--------------------------|
| 品名 Product Name | 替米考星 Tilmicosin Base | 批号 Batch No. | 202302003 |
| 数量 Quantity | 500KG | 生产日期 MFG. Date | FEB .09, 2023 |
| 检验日期: Date of analysis | FEB .13, 2023 | 有效期 EXP. Date | FEB .08, 2025 |
| 分析项目 Analysis Item | 标准 Standard | 分析结果 Test results | 项目结论 Items Conclusion |
| 外观 Appearance | 白色或类白色粉末 White or off white powder | 类白色粉末 Off white powder | 符合规定 Conforms |
| 鉴别 Identification | 样品的红外光谱与标准图谱一致 IR spectra is consistent with CRS. | 符合规定 Conforms | 符合规定 Conforms |
| | 在含量检测项下, 样品的出峰时间和标准品出峰时间一致 The retention time of the major peak of the assay preparation corresponds to that of the standard preparation, as obtained in the assay. | 符合规定 Conforms | 符合规定 Conforms |
| 水分 Water | ≤5.0% | 1.5% | 符合规定 Conforms |
| 顺式 Cis-Isomer | 82.0%~88.0% | 86.0% | 符合规定 Conforms |
| 反式 Trans-Isomer | 12.0%~18.0% | 14.0% | 符合规定 Conforms |
| 单个杂质 Individual impurities | ≤3.0% | 2.0% | 符合规定 Conforms |
| 总杂质 Total impurities | ≤10.0% | 4.0% | 符合规定 Conforms |
| 灼烧残渣 Residue on Ignition | ≤5.0% | 1.6% | 符合规定 Conforms |
| 重金属 Heavy Metal | ≤30PPM | 符合规定 Conforms | 符合规定 Conforms |
| 含量 Assay | ≥85.0% (Tilmicosin) | 95.1% | 符合规定 Conforms |
| 结论 Conclusion | 本品符合 USP39. Complies with the requirements of USP39. | | |

品质保证部批
Chief of Q.A.D.



复核人: 刘梅
Reinspector:



Address: Huadian Pioneer Park, Huadian Township, Qihe County, Dezhou City, Shandong Province, China