

检验报告单

CERTIFICATE OF ANALYSIS

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| | | | |
|--------------------------|-------------------|-----------------|---|
| 产品名称 Product Name | 酮洛芬 KETOPROFEN | 规格 Grade | API |
| 质量标准 Standard | BP2019 | 代号 Code No. | 2014-0002 |
| 生产日期 Manufacture Date | 2021-02 | 批号 Batch No. | CN3210617 |
| 复验日期 Retest Date | 2026-01 | 数量 Quantity | 551.30kg |
| 报告日期 Report Date | 2021-06-25 | 包装 Package | 20.00 kg/件Package×27 11.30 kg/件Package×1 |
| 检验依据 Reference | LHQS-2014-06.07 | | |

| 检验项目 Test Items | | 检验标准 Specifications | 结果 Results |
|--|------------------------------|---|---|
| 外观 Appearance | | 白色或类白色结晶性粉末 White or Almost White Crystalline Powder | 白色结晶性粉末 White Crystalline Powder |
| 鉴别/红外吸收光谱 Identification/IR | | 与对照品图谱一致 Corresponding to Reference Spectrum | 与对照品图谱一致 Corresponding to Reference Spectrum |
| 溶液外观 Appearance of Solution | 澄清晰度 Clarity | 澄清 (≤Ref. Susp. I), Clear | 澄清 (<Ref. Susp. I), Clear |
| | 颜色 Color | 不深于对照液, ≤Y ₆ | 浅于对照液, <Y ₆ |
| 有关物质 /HPLC Related Substances | 杂质 Impurity C | ≤0.2% | ND |
| | 杂质 Impurity E | ≤0.2% | ND |
| | 杂质 Impurity B | ≤0.2% | <0.05% |
| | 杂质 Impurity D | ≤0.2% | <0.05% |
| | 杂质 Impurity A | ≤0.2% | ND |
| | 杂质 Impurity F | ≤0.2% | ND |
| | 其它单个杂质 Any Other Impurity | ≤0.10% | <0.05% |
| 除杂质A和C外, 其它杂质总和 Apart from A and C, Other Total | | ≤0.4% | <0.05% |
| 干燥失重 Loss on Drying | | ≤0.5% | 0.1% |
| 硫酸化灰分 Sulphated Ash | | ≤0.1% | 0.02% |
| 含量 (折干) Assay (on Dried Basis) | | 99.0~100.5% | 99.8% |
| 结论 Conclusion | | 本品符合BP2019标准规定 CONFORM WITH BP2019 STANDARD | |

制作者/日期

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