

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 <sub>6</sub>	浅于对照液, <Y <sub>6</sub>
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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复核者/日期

Review By/Date 李芳芳 2021-06-25

批准人/日期

QC Approver/Date 李芳芳 2021-06-25