

NANJING PHARMACEUTICAL FACTORY CO., LTD. CERTIFICATE OF ANALYSIS
PRAZIQUANTEL (CEP Grade)

南京制药厂有限公司吡喹酮原料药(CEP 规格)分析报告

Chemical Name: (11bRS)-2-(Cyclohexylcarbonyl)-1,2,3,6,7,11b-hexahydro-4H-pyrazino[2,1-a]isoquinolin-4-one
 CAS Number: 55268-74-1
 CEP Certificate: R1-CEP 2005-034-Rev 00
 化学名称: 2-环己基甲酰基-1,2,3,6,7,11b-六氢-4H-吡嗪并[2,1-a]异喹啉-4-酮
 CAS 号: 55268-74-1

Batch No. (批号): C-PQ2012029

Batch Size (批量): 100.5kg

Manufacturing Date (生产日期): 2012.12.12

Retest Date (复验日期): 2015.12.11

Tests 检测项目	Specifications 标准	Results 结果
Appearance 外观	White or almost white crystalline powder 白色或类白色结晶性粉末	almost white crystalline powder 类白色结晶性粉末
Solubility 溶解度	Very slightly soluble in water, freely soluble in ethanol (96%) and in methylene chloride 极微溶于水, 易溶于乙醇和二氯甲烷	Conforms 符合规定
Identification 鉴别	IR spectrum in accordance with that of Reference Standard 与标准品的红外图谱一致	Conforms 符合规定
Heavy metals 重金属	≤ 20 ppm	< 20 ppm
Loss on drying 干燥失重	≤ 0.5 %	0.02%
Sulphated ash 硫酸灰分	≤ 0.1 %	0.02%
Related substances 有关物质	A ≤ 0.5 % B ≤ 0.5 % C ≤ 0.5 % (Not more than one is more than or equal 0.2%) 杂质 A、B 和 C ≤ 0.5% 且 ≥ 0.2% 的不超过 1 个 Any other impurity (unknown and unspecified) ≤ 0.2 % 其它任何杂质 (未知杂质和未明确杂质) ≤ 0.2 % Total impurities ≤ 0.5 % 总杂质 ≤ 0.5 %	0.03% 0.03% ND Conforms 符合规定 0.02%
Residual solvents 溶剂残留	Ethanol (乙醇) ≤ 200 ppm Chloroform (氯仿) ≤ 10 ppm	65 ppm 23 ppm
Assay (C ₁₉ H ₂₁ N ₂ O ₂) 含量	97.5%~102.0% (dried substance) 按干燥品计算	100.1%

Conclusion: Meets Ph. Eur 7.0 and in-house Specifications
 结论: 本品符合欧洲药典 7.0 及内控标准。

QC Reporter (报告人): [Signature]

Date (日期): 2013.05.09

QC Supervisor (QC 主管): [Signature]

Date (日期): 2013.05.09

QA Reviewer (QA 审核): [Signature]

Date (日期): 2013.05.09

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FAGRON IBÉRICA, S.A.U
 Corresponde al lote de Fagron:

U13080026

[Signature]

Director Técnico