

山东久隆信和药业有限公司

Shandong Jiulong SINHERO Pharmaceutical Co., Ltd

分析报告单 Certificate of Analysis

品名 Product Name	硫酸头孢喹肟 Cefquinome sulfate	检验日期 Analysis Date	JAN.18, 2024	
数量 Quantity	100kg	生产日期 MFG. Date	JAN.15, 2024	
批号 Batch No.	05124011501	有效期 EXP. Date	JAN.14, 2026	
分析项目 Analysis Item	标准 Standard	分析结果 Test results	项目结论 Items Conclusion	
外观 Appearance	类白色至微黄色结晶性粉末 Off-white to slightly yellow crystalline powder	微黄色结晶性粉末 Slightly yellow crystalline powder	符合规定 Conforms	
鉴别 Identification	供试品溶液主峰的保留时间应与对照品溶液主峰的保留时间一致 The retention time for the major peak of sample should correspond to that of reference standard	符合规定 Conforms	符合规定 Conforms	
	本品的红外光吸收图谱应与对照品的红外图谱一致 The infrared absorption spectrum of sample corresponds to that of reference standard	符合规定 Conforms	符合规定 Conforms	
	本品的水溶液显硫酸盐的鉴别反应 The aqueous solution of this product shows sulfate identification reaction	符合规定 Conforms	符合规定 Conforms	
PH	1.6-2.6	2.1	符合规定 Conforms	
澄清度 Clarity	≤1#	澄清 Clarify	符合规定 Conforms	
颜色 Colour	≤Y7	<Y7	符合规定 Conforms	
碘化物 Iodide	≤0.01%	<0.01%	符合规定 Conforms	
有关物质 Related Substances	与5,6,7,8-四氢喹啉对照品溶液主峰保留时间一致的色谱峰,其峰面积不得大于对照溶液主峰面积的2倍(2.0%)。 The chromatographic peak with the same retention time as the main peak of 5,6,7,8 - tetrahydroquinoline reference solution shall not have a peak area greater than 2 times (2.0%) of the main peak area of the reference solution.	符合规定 Conforms	符合规定 Conforms	
有关物质 Related Substances	其他单个杂质峰面积不得大于对照溶液主峰面积(1.0%)。 The peak area of other single impurities shall not be greater than the main peak area of the control solution (1.0%).	符合规定 Conforms	符合规定 Conforms	

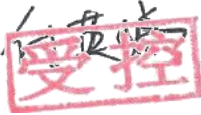
Address: Shanghe County Economic Development Zone, Jinan City, Shandong Province, China

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有关物质 Related Substances	各杂质峰面积的和不得大于对照溶液主峰面积的3.0倍(3.0%)。 The sum of the peak areas of each impurity shall not be greater than 3.0 times (3.0%) of the main peak area of the control solution	符合规定 Conforms	符合规定 Conforms
水分 Water	≤5.0%	3.1%	符合规定 Conforms
炽灼残渣 Residue on Ignition	≤0.3%	0.15%	符合规定 Conforms
重金属 Heavy Metals	≤百万分之二十 ≤20 parts per million	符合规定 Conforms	符合规定 Conforms
细菌内毒素 Bacterial Endotoxins	≤0.1EU/mg	<0.1EU/mg	符合规定 Conforms
无菌 Sterility	符合规定 Conforms	符合规定 Conforms	符合规定 Conforms
含量 Assay (HPLC) (以无水物计 calculated on the anhydrous basis)	≥80.0%	85.1%	符合规定 Conforms
结论 Conclusion	本品符合 CVP2020。 Conclusion: Complies with the requirements of CVP2020.		

化验员:
Analyst:



复核人:
Reviewed:

袁本月

质保部批准
Approved by QA:

