

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

QUININE SULFATE

COA No.:	16217	Manufacturing Date:	Dec, 2014
Lot No.:	SWX20150116	Expiry date:	Dec, 2017

<u>Items</u>	<u>Standard</u>	<u>Result</u>
Characteristics	White needle like crystalline powder	Complies
Solubility	Soluble in Dichloromethane:Ethanol 2:1 solution, Slightly soluble in water Dichloromethane, alcohol and ether	Complies
Identification		
1) Fluorescence	Blue Fluorescence	Complies
2) Colour	Bright green	Complies
3) Precipitation	White precipitate	Complies
4) IR Absorption	As per standard	Complies
Loss on drying	5.0% max.	4.21%
Acidity pH	5.7~6.6	6.49
Specific rotation	-237° ~ -244°	-243.23°
Residue on ignition	0.1% max.	0.08%
1) Total Impurities	10.0% max.	5.65%
2) Before Quinine Sulfate	5.0% max.	2.01%
3) Other Impurities	2.5% max.	Nil
Dichloromethane:Ethanol residue	0.1% max.	0.06%
Content Assay	99.0% max.	99.3%

Conclusion:	This product complies to the standard.
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Kalchem International, Inc
224 South Main Street - Lindsay, OK 73052
Toll Free 888-298-9905 | FAX: 405-756-2373

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检测项目	检测标准	检测结果
性状		
1. 外观	本品为白色细微的针状结晶，轻柔，易压缩	符合标准
2. 溶解性	本品在三氯甲烷-无水乙醇(2:1)中易溶，在水、乙醇、三氯甲烷或乙醚中微溶。	符合标准
3. 比旋度	-237°-- -244°	-243.23°
鉴别		
1) 荧光反应	溶液应即显蓝色荧光。	符合标准
2) 颜色反应	溶液应即显翠绿色	符合标准
3) 沉淀反应	溶液应即发生白色沉淀。	符合标准
4) 红外图谱	本品的红外吸收图谱应与对照品图谱(光谱集 488 图)一致。	符合标准
检测		
A. 酸度	5.7-6.6	6.49
B. 三氯甲烷-乙醇中不溶物	≤ 0.1%	0.06%
C. 其他金鸡纳碱	杂质 C ≤ 10.0% 奎宁峰前任何杂质 ≤ 5.0% 其他杂质 ≤ 2.5%	5.65% 2.01% 无
D. 干燥失重	≤ 5.0%	4.21%
E. 炽灼残渣	≤ 0.1%	0.08%
含量(干燥品计)	≥ 99.0%	99.3%
结论		
本品符合中国药典 2010 检测标准。		

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