

Kalchem International

Chemicals & Compounding Supplies

CERTIFICATE OF ANALYSIS

PRODUCT NAME: QUININE SULPHATE

CAS NO: 6119-70-6

MF: $2(C_{20}H_{24}N_2O_2) \cdot H_2SO_4 \cdot 2(H_2O)$

LOT NO: SWX20160418

MANUFACTURE DATE: 20160410

EXPIRY DATE: 20190409

ANALYSIS DATE: 20160418

QUANTITY: 500.00kg

Items	Specifications	Results
Appearance	White or almost white, crystalline powder or fine, colourless needles.	Complies
Solubility	Slightly soluble in water, sparingly soluble in boiling water and in ethanol(96 per cent)	Complies
Identification		
A) TLC	The principal spot in the chromatogram obtained with the test solution is similar in position, colour and size to the principal spot in the chromatogram obtained with the reference solution	Complies
B) bromine and ammonia	A green colour develops when treated with bromine water and dilute ammonia	Complies
C) Fluorescence	When examined in ultraviolet light at 366 nm, an intense blue fluorescence appears which disappears almost completely on the addition of 1 ml of HCL	Complies
D) Characteristic of sulphates	The solution gives reaction of sulphates	Complies
E) Test for pH	Should comply	Complies
Tests		
1) Appearance of solution	Solution S is clear and not more intensely coloured than reference solution GY ₆	Complies
2) pH	5.7-6.6	6.06
3) Specific optical rotation	-237° - -245°	-241.1°
4) Other cinchona alkaloids	Impurity C :NMT 10.0% Any impurity eluted before quinine: NMT 5.0% Any other impurity :NMT 2.5%	6.09% 2.28% N.A
5) Loss on drying	3%-5%	4.32%
6) Sulphated ash	NMT 0.1%	0.08%
Assay	99.0 %-101.0 % on dried substance	99.1%
Additional test		
Residual solvent(toluene)	NMT 890ppm	356ppm
Conclusion: the product conforms to BP2010/USP34		

Analyzed By:

Checked By:

Approved By:

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