



## TECHNICAL DATA SHEET

1521-TDS-ENG-2021

QUININA SULFATO (PH.EUR)		
DESCRIPTION DCI: QUININE SULFATE		DESCRIPTION DOE: QUININA SULFATO
CAS Nº: 6119-70-6	EC Nº: 212-359-2	AEMPS CODE: 2255SU
MOL. WEIGHT: 782.95	MOL. FORMULA: C <sub>40</sub> H <sub>50</sub> N <sub>4</sub> O <sub>8</sub> S <sub>2</sub> H <sub>2</sub> O	ARTICLE CODE: 1521

ATTRIBUTES	SHOULD BE
Appearance	White or almost white, crystalline powder or fine, colourless needles
Solubility	Slightly soluble in water, sparingly soluble in boiling water and in ethanol (96 %)
Identification A	Complies
Identification B	Complies
Identification C	Complies
Identification D	Complies
Identification E	Complies
Appearance of solution	Clear and not more intensely coloured than ref. sol. GY6
pH	5.7 - 6.6
Specific optical rotation	-237 / -245
Other cinchona alkaloids	
Impurity C	=< 10 %
Any impurity eluted before quinine	=< 5 %
Any other impurity	=< 2.5 %
Loss on drying	3.0 - 5.0 %
Sulfated ash	=< 0.1 %
Assay	99.0 - 101.0 %

### COMPLIES WITH

European Pharmacopoeia 10.0

### STORAGE

Store in a cool place. Keep the container tightly closed in a dry and well-ventilated place.

### REMARKS

Quinine Sulfate is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

Absence of N-nitrosamines impurities has been ensured after a risk evaluation according to ICH Q9, ICH M7 and in accordance with guidelines EMA/428592/2019 Rev 2 and EMA/189634/2019.

Certificates of residual solvents, allergens, non-GMO and BSE-TSE, among others, are available upon request.

All methods of analysis are validated by official pharmacopoeias or are validated by internal methods of the manufacturer, which can be obtained at specific request.

The above information does not exempt from the obligation to identify the product before use.