



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 220224

Product:	QUININE SULPHATE
Lot:	220224
Expiry date:	09/05/2026
Reference:	Cumple PhEur10.6
Synonyms:	
Formula:	
Molecular weight:	782,95 g/mol

Assay	Result	Specification	
Identification	Conform (A,B,C,D,E)	Test PhEur (A,B,C,D,E)	
Organoleptic properties	Conform	PhEur	
Appearance of the S solution (2%, HCl 0,1M)	Conform		
pH of the 1% aqueous solution	6,6	5,7-6,6	
Other alkaloids of cinchona	Conform	Test PhEur	
Specific rotation (sol. S)	-241°	(-237°)-(-245°)	
Loss on drying (1 g, 105°C)	4,6 %	3,0-5,0%	
Sulphated ashes	0,01 %	<= 0,1%	
Assay	99,9 %	99,0-101,0%	
Impurity C	5 %	<= 10 %	
Any impurity eluted before quinine	2 %	<= 5 %	
Any other impurity	< 0,2 %	<= 2,5 %	
Residual solvent: Toluene	<= 890 ppm	<= 890 ppm	#

Organoleptic characteristics: White or almost white crystalline powder or fine colorless needles. Slightly soluble in water, quite soluble in boiling water and in 96% ethanol. Formula: $(C_{20}H_{24}O_2N_2)_2 \cdot H_2SO_4 \cdot 2H_2O$
Conservation: In tightly closed containers. Protect from light.

Date of analysis: 11/03/2022

Judgement:
APPROVED

Responsible: C. Codina

Technical director: Montserrat Enrique

Manufacturer: F00105 BUCHLER GmbH

Manufacturer batch: 9989

Product	Name	Capacity	Batch
1174503	QUININA SULFATO	25 g	220224-G-1
1174503	QUININA SULFATO	25 g	220224-G-2
1174503	QUININA SULFATO	25 g	220224-G-3
1174503	QUININA SULFATO	25 g	220224-G-4

1174505	QUININA SULFATO	100 g	220224-J-1
1174505	QUININA SULFATO	100 g	220224-J-2
1174505	QUININA SULFATO	100 g	220224-J-3
1174505	QUININA SULFATO	100 g	220224-J-4
1174505	QUININA SULFATO	100 g	220224-J-5

This certificate is not initialled as it is computer processed, it is validated with the originals available at Acofarma.

Original manufacturer's certificate available on request.

(#) Parameter controlled by the manufacturer

(=) UE certificate

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