



ANALYSIS CERTIFICATE

Lot/Analysis/Analysis N°: 250967

Product:	QUININE SULPHATE
Lot:	250967
Expiry date:	11/03/2029
Reference:	Cumple PhEur11.7
Synonyms:	
Formule:	C ₄₀ H ₅₀ N ₄ O ₈ S ₂ H ₂ O
Poids moléculaire:	783 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 solution	Conform		
pH	6,4	5,7 - 6,6	
Other alkaloids of cinchona	Conform	Test PhEur	
Specific rotation	(-238°)	(-237°) - (-245°)	
Loss on drying	4,3	3,0 - 5,0 %	
Sulphated ashes	0,01 %	<= 0,1%	
Assay	99,0 %	99,0-101,0%	
Impurity C	6 %	<= 10 %	
Any impurity eluted before quinine	1 %	<= 5 %	
Any other impurity	< 0,2 %	<= 2,5 %	
Residual solvents	Conform		#
Elemental impurities	Conform		#
Nitrosamine impurities	Conform		#

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: (C₂₀H₂₄O₂N₂)₂ H₂SO₄ 2H₂O
Conservation: In tightly closed containers. Protect from light.

Date of analysis: 13/06/2025

Judgement:
APPROVED

Responsible: B.Chia

Technical director: Montserrat Enrique

Manufacturer: F00105 BUCHLER GmbH

Manufacturer batch: 10445

Produit	Nom	Capacité	Lot
1174503	QUININA SULFATO	25 g	250967-G-1
1174505	QUININA SULFATO	100 g	250967-J-1

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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