



## ANALYSIS CERTIFICATE

**Lot/Analysis/Analysis N°: 250967**

|                   |                                                                                               |
|-------------------|-----------------------------------------------------------------------------------------------|
| Product:          | QUININE SULPHATE                                                                              |
| Lot:              | 250967                                                                                        |
| Expiry date:      | 11/03/2029                                                                                    |
| Reference:        | Cumple PhEur11.7                                                                              |
| Synonyms:         |                                                                                               |
| 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 |
| Molecular weight: | 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: (C<sub>20</sub>H<sub>24</sub>O<sub>2</sub>N<sub>2</sub>)<sub>2</sub> H<sub>2</sub>SO<sub>4</sub> 2H<sub>2</sub>O  
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

| Product | Name            | Capacity | Batch      |
|---------|-----------------|----------|------------|
| 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

ACOFARMA DISTRIBUCIÓN, S.A.

C/ Llobregat, 20 - 08223 Terrassa (Barcelona)

Tel./ 93-736.00.88

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