

# QUININE SULFATE

**BP 2025 / Ph.Eur. 11<sup>th</sup> Edt.**

## APPEARANCE

White or almost white or colourless, fine, silky needles, often in clusters

## PARAMETER

## LIMIT

|                                                                                                         |                                       |
|---------------------------------------------------------------------------------------------------------|---------------------------------------|
| Identification<br>A. TLC / B. Bromine water-ammonia test /<br>C. Fluorescence / D. Sulfate test / E. pH | passes                                |
| Appearance of solution                                                                                  | clear and $\leq$ GY <sub>6</sub>      |
| pH                                                                                                      | 5.7 – 6.6                             |
| Loss on drying                                                                                          | 3.0 to 5.0 %                          |
| Specific optical rotation<br>(on dry basis, c = 2.0 in 0.1 M HCl, $[\alpha]^{20}_D$ )                   | - 237° to - 245°                      |
| Other Cinchona alkaloids (HPLC)                                                                         |                                       |
| Dihydroquinine Sulfate                                                                                  | $\leq$ 10.0 %                         |
| Any other impurity eluted before Quinine                                                                | $\leq$ 5.0 %                          |
| Any other impurity                                                                                      | $\leq$ 2.5 %                          |
| Sulfated ash                                                                                            | $\leq$ 0.1 %                          |
| Assay (on dry basis)                                                                                    | 99.0 to 101.0 %                       |
| Residual solvents                                                                                       | meets the pharmacopoeial requirements |

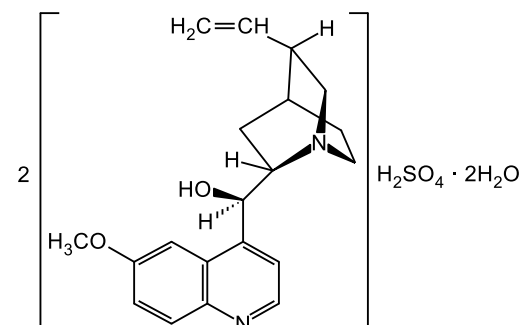
## ORIGIN

Product is made in Germany.

## CHEMICAL DATA

Formula  $C_{40}H_{48}N_4O_4 \cdot H_2SO_4 \cdot 2H_2O$

CAS Number 6119-70-6



## STANDARD PACKAGING

25 kg Unit

|                 |            |
|-----------------|------------|
| Outer container | Fiber drum |
| Outer liner     | LDPE       |
| Inner liner     | LDPE       |

## STABILITY

Product is stable for 5 years from date of production if stored under recommended conditions in original packaging.

## STORAGE

Store in the original packaging to protect from light. No specific temperature requirements.

## VERSION / VALID FROM

04 / 25.04.2025