

# QUININE HYDROCHLORIDE DIHYDRATE

**BP 2022 / Ph.Eur. 10<sup>th</sup> Edt.**

## APPEARANCE

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

## PARAMETER

## LIMIT

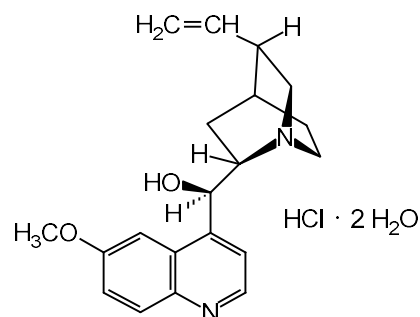
|                                                                                                          |                                       |
|----------------------------------------------------------------------------------------------------------|---------------------------------------|
| Identification<br>A. TLC / B. Bromine water-ammonia test /<br>C. Fluorescence / D. Chloride test / E. pH | passes                                |
| Appearance of solution                                                                                   | clear and $\leq Y_6$                  |
| pH                                                                                                       | 6.0 to 6.8                            |
| Specific optical rotation<br>(on dry basis, $c = 2.0$ in 0.1 M HCl, $[\alpha]^{20}_D$ )                  | - 245 ° to - 258 °                    |
| Other Cinchona alkaloids (HPLC)                                                                          |                                       |
| Dihydroquinine Hydrochloride                                                                             | $\leq 10.0 \%$                        |
| Any other impurity eluted before Quinine                                                                 | $\leq 5.0 \%$                         |
| Any other impurity                                                                                       | $\leq 2.5 \%$                         |
| Sulfates                                                                                                 | $\leq 500$ ppm                        |
| Barium                                                                                                   | no turbidity produced                 |
| Loss on drying                                                                                           | 6.0 to 10.0 %                         |
| 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  $C_{20}H_{24}N_2O_2 \cdot HCl \cdot 2H_2O$   
CAS Number 6119-47-7



## 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

01 / 07.04.2022