

QUININE HYDROCHLORIDE DIHYDRATE

BP 2023 / Ph.Eur. 11th Edt.

APPEARANCE

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

PARAMETER

LIMIT

Identification A. TLC / B. Bromine water-ammonia test / 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 (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	≤ 500 ppm
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

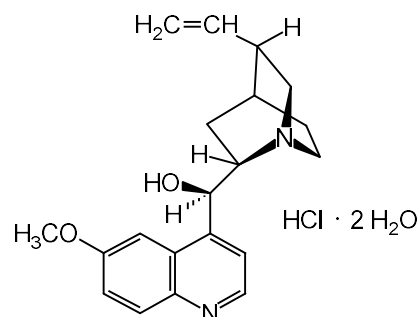
ORIGIN

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

03 / 01.04.2023