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QUININE HYDROCHLORIDE DIHYDRATE

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APPEARANCE

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

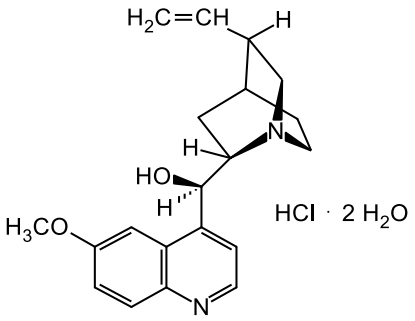
PARAMETER	LIMIT
Identification A. TLC / B. Bromine water-ammonia test / C. Fluorescence / D. Chloride test / E. pH	passes
Appearance of solution	clear and ≤ Y_6
pH	6.0 to 6.8
Specific optical rotation (on dry basis, c = 2.0 in 0.1 M HCl, $[\alpha]^{20}_D$)	- 245 ° to - 258 °
Other Cinchona alkaloids (HPLC)	
Dihydroquinine Hydrochloride	≤ 10.0 %
Any other impurity eluted before Quinine	≤ 5.0 %
Any other impurity	≤ 2.5 %
Sulfates	≤ 500 ppm
Loss on drying	6.0 to 10.0 %
Sulfated ash	≤ 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

04 / 28.02.2024