

QUINIDINE HYDROCHLORIDE

Buchler specification (Pharma)

APPEARANCE

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

PARAMETER

LIMIT

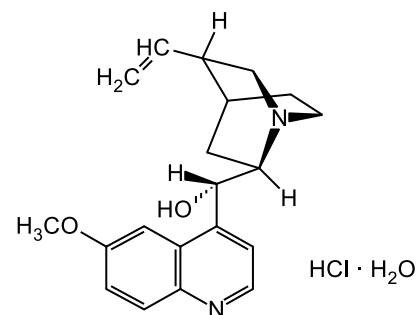
Identification A. TLC / B. Bromine water-ammonia test / C. Fluorescence / D. Chloride test	passes
Appearance of solution	clear and $\leq Y_6$
Chloroform-alcohol-insoluble substances	$\leq 0.1 \%$
pH	6.0 – 6.8
Water	3.0 to 5.0 %
Specific optical rotation (on dry basis, $c = 2.0$ in 0.1 M HCl, $[\alpha]^{20}_D$)	+ 285 ° to + 300 °
Other Cinchona alkaloids (HPLC)	
Dihydroquinidine	$\leq 15.0 \%$
Any other impurity eluted before Quinidine	$\leq 5.0 \%$
Any other impurity	$\leq 2.5 \%$
Sulfates	≤ 500 ppm
Barium	no turbidity produced
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 $C_{20}H_{24}N_2O_2 \cdot HCl \cdot H_2O$
CAS Number 1668-99-1



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