

CINCHONIDINE HYDROCHLORIDE

Buchler specification (Pharma)

APPEARANCE

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

PARAMETER

LIMIT

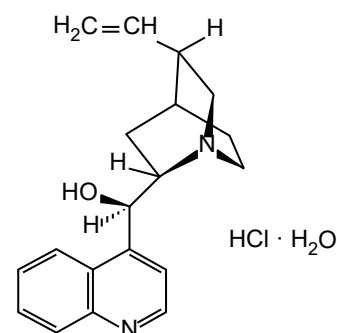
Identification	passes
A. Retention time – HPLC / B. Chloride test	
Appearance of solution	clear and $\leq Y_6$
pH	6.0 to 6.8
Loss on drying	3.5 to 6.0 %
Specific optical rotation (on dry basis, $c = 2.0$ in 0.1 M HCl, $[\alpha]^{20}_D$)	- 150 ° to - 165 °
Other Cinchona alkaloids (HPLC)	
Dihydrocinchonidine	≤ 10.0 %
Σ Quinine + Dihydroquinine	≤ 5.0 %
Any other impurities	≤ 2.5 %
Sulfates	≤ 500 ppm
Barium	no turbidity produced
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 $C_{19}H_{22}N_2O \cdot HCl \cdot H_2O$
CAS Number 524-57-2



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