

DIHYDROQUINIDINE HYDROCHLORIDE

Ph. Franc X

APPEARANCE

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

PARAMETER

LIMIT

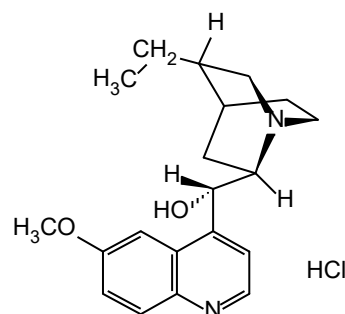
Identification A. Retention time - HPLC / B. Chloride test / C. Fluorescence	passes
Appearance of solution	clear and \leq GY ₅
pH	6.0 – 7.0
Loss on drying	\leq 1.0 %
Specific optical rotation (on dry basis, c = 1.0 in H ₂ O, $[\alpha]^{20}_D$)	+ 185 ° to + 191 °
Other Cinchona alkaloids (HPLC) Σ Other cinchona alkaloids each other cinchona alkaloid	\leq 2.0 % \leq 1.0 %
Nickel	\leq 2 ppm
Chlorides	\leq 300 ppm
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 C₂₀H₂₆N₂O₂·HCl
CAS Number 1476-98-8



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