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QUINIDINE SULFATE

Ph.Eur. 10th Edt.

APPEARANCE

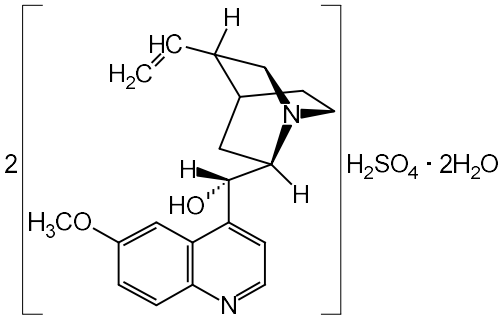
White or almost white or colourless, fine, silky needles, often in clusters

PARAMETER	LIMIT
Identification A. TLC / B. Bromine water-ammonia test / C. Fluorescence / D. Sulfate test (silver nitrate) / E. Sulfate test / F. pH	passes
Appearance of solution	clear and ≤ GY_6
pH	6.0 to 6.8
Loss on drying	3.0 to 5.0 %
Specific optical rotation (on dry basis, c = 2.0 in 0.1 M HCl, $[\alpha]^{20}_D$)	+ 275 ° to + 290 °
Other Cinchona alkaloids (HPLC)	
Dihydroquinidine	≤ 15.0 %
Any other impurity eluted before Quinidine	≤ 5.0 %
Any other impurity	≤ 2.5 %
Unknown impurities	≤ 0.1 %
Boron	≤ 5 ppm
Sulfated ash	≤ 0.1 %
Assay (on dry basis)	99.0 to 101.0 %
Residual solvents	meets the pharmacopoeial requirements

ORIGIN

CHEMICAL DATA

Formula $C_{40}H_{48}N_4O_4 \cdot H_2SO_4 \cdot 2H_2O$
CAS Number 6591-63-5



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