

QUINIDINE SULFATE

BP 2026 / Ph.Eur. 12th 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 $\leq \text{GY}_6$
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, $[\alpha]^{20}_{\text{D}}$)	+ 275 ° to + 290 °
Other Cinchona alkaloids (HPLC)	
Dihydroquinidine	$\leq 15.0 \%$
Any other impurity eluted before Quinidine	$\leq 5.0 \%$
Any other impurity	$\leq 2.5 \%$
Unknown impurities	$\leq 0.1 \%$
Boron	$\leq 5 \text{ ppm}$
Sulfated ash	$\leq 0.1 \%$
Assay (on dry basis)	99.0 to 101.0 %
Residual solvents	meets the pharmacopoeial requirements

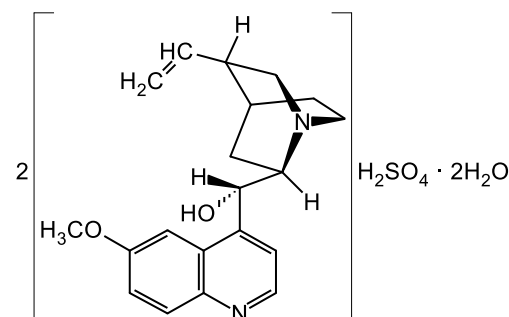
ORIGIN

Product is made in Germany.

CHEMICAL DATA

Formula $\text{C}_{40}\text{H}_{48}\text{N}_4\text{O}_4 \cdot \text{H}_2\text{SO}_4 \cdot 2\text{H}_2\text{O}$

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

04 / 05.01.2026