

QUININE GLUCONATE

Buchler specification (Pharma)

APPEARANCE

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

PARAMETER

LIMIT

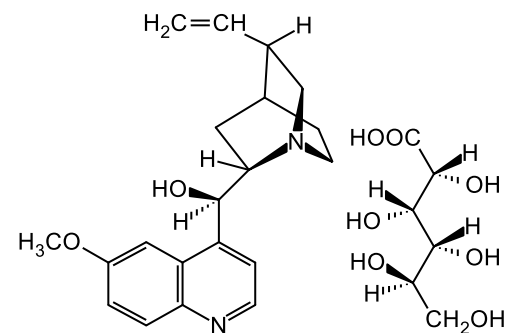
Identification A. TLC / B. Fluorescence / C. Bromine water-ammonia test / D. Gluconate test	passes
Appearance of solution	clear and $\leq Y_6$
pH	6.0 – 6.8
Water	$\leq 3.0 \%$
Specific optical rotation (on dry basis, $c = 2.0$ in H_2O , $[\alpha]^{20}_D$)	- 102 ° to - 110 °
Other Cinchona alkaloids (HPLC)	
Dihydroquinine	$\leq 10.0 \%$
Any other impurity eluted before Quinine	$\leq 5.0 \%$
Any other impurity	$\leq 2.5 \%$
Sulfates	≤ 500 ppm
Barium	no turbidity produced
Loss on drying	6.0 to 10.0 %
Sulfated ash	$\leq 0.1 \%$
Assay (on dry basis)	98.5 to 101.0 %
Residual solvents	meets the pharmacopoeial requirements

ORIGIN

Product is made in Germany.

CHEMICAL DATA

Formula $C_{20}H_{24}N_2O_2 \cdot C_6H_{12}O_7$
CAS Number 4325-25-1



STANDARD PACKAGING

25 kg Unit
Outer container Fiber drum
Outer liner PET/ALU/PE
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