

QUINIDINE GLUCONATE

USP-NF 2026

APPEARANCE

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

PARAMETER

LIMIT

Identification A. Fluorescence / B. TLC / C. Optical rotation / D. Gluconate test	passes
Loss on drying	≤ 0.5 %
Chromatographic purity (TLC) Cinchonine Quininone Any other impurity	≤ 2.0 % ≤ 1.0 % ≤ 1.0 %
Chromatographic purity (HPLC) Dihydroquinidine Gluconate	≤ 20.0 %
Residue on ignition	≤ 0.15 %
Assay (on dry basis)	99.0 to 100.5 %
Residual solvents	meets the pharma- copoeial requirements

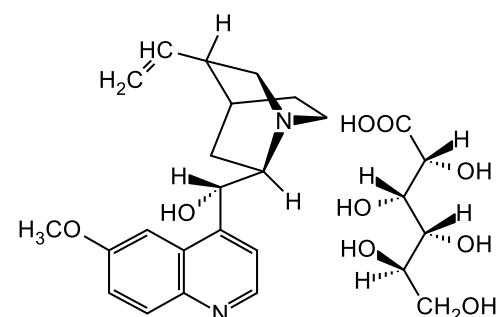
ORIGIN

Product is made in Germany.

CHEMICAL DATA

Formula $C_{20}H_{24}N_2O_2 \cdot C_6H_{12}O_7$

CAS Number 7054-25-3



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

Preserve in well-closed, light resistant containers. Store at a temperature of 25° Celsius. Excursions permitted between 15° Celsius and 30° Celsius.

VERSION / VALID FROM

06 / 03.08.2026