

QUINIDINE GLUCONATE

USP-NF 2022

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 pharmaco- poeial requirements

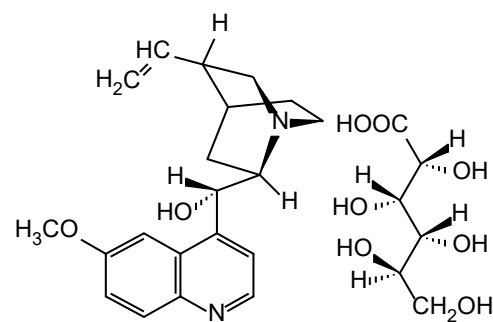
ORIGIN

Product is made in Germany.

CHEMICAL DATA

Formula C₂₀H₂₄N₂O₂·C₆H₁₂O₇

CASNumber 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

Store in the original packaging to protect from light. No specific temperature requirements.

VERSION / VALID FROM

02 / 01.05.2022