Status: Currently Official on 18-Feb-2025
Official Date: Official as of 01-Dec-2016
Document Type: USP Monographs
DocId: GUID-060C8C02-AAD2-4571-9972-C9AFC22BC527_1_en-US
DOI: https://doi.org/10.31003/USPNF_M1401_01_01
DOI Ref: d4v3e

Quinidine Sulfate Compounded Oral Suspension

DEFINITION

Quinidine Sulfate Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of quinidine sulfate $[(C_{20}H_{24}N_2O_2)_2 \cdot H_2SO_4 \cdot 2H_2O]$. Prepare Quinidine Sulfate Compounded Oral Suspension 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Quinidine Sulfate	1 g
Vehicle: a 1:1 mixture of Vehicle for Oral Solution (regular or sugar-free), *NF*, and Vehicle for Oral Suspension, *NF*, a sufficient quantity to make	100 mL

If using *Quinidine Sulfate* tablets, place in a suitable mortar, and comminute into a fine powder, or add *Quinidine Sulfate* powder to the mortar. Add 15 mL of the *Vehicle*, and mix to a uniform paste. Add the *Vehicle* in small portions almost to volume, and mix thoroughly after each addition. Transfer the contents of the mortar to the calibrated bottle. Add sufficient *Vehicle* to volume, and mix well.

ASSAY

• **Procedure**

Solution A: Add 35.0 mL of methanesulfonic acid to 20.0 mL of glacial acetic acid, and dilute with water to 500 mL.

Solution B: Dissolve 10.0 mL of diethylamine in water to obtain 100 mL of solution.

Mobile phase: Acetonitrile, *Solution A, Solution B*, and water (10:1:1:40)

Standard solution: 100 µg/mL of USP Quinidine Sulfate RS in *Mobile phase*

Sample solution: Agitate the container of Oral Suspension for 30 min on a rotating mixer, remove a 5-mL sample, and store in a clear glass vial at −70° until analyzed. At the time of analysis, remove the sample from the freezer, allow it to reach room temperature, and mix on a vortex mixer for 30 s. Pipet 1.0 mL of the *Sample solution* into a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV 235 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for quinidine sulfate is about 8.5 min.]

Suitability requirements

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of quinidine sulfate $[(C_{20}H_{24}N_2O_2)_2 \cdot H_2SO_4 \cdot 2H_2O]$ in the portion of Oral Suspension taken:

$$\text{Result} = [(r_{B,U} + r_{D,U})/(r_{B,S} + r_{D,S})] \times (C_S/V) \times 100$$

$r_{B,U}$ = peak response of quinidine from the *Sample solution*

$r_{D,U}$ = peak response of dihydroquinidine from the *Sample solution*

$r_{B,S}$ = peak response of quinidine from the *Standard solution*

$r_{D,S}$ = peak response of dihydroquinidine from the *Standard solution*

C_S = concentration of USP Quinidine Sulfate RS in the *Standard solution* (mg/mL)

V = volume of Oral Suspension taken (mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.4–4.4

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store at room temperature, or in a refrigerator.

• **Beyond-Use Date:** NMT 60 days after the date on which it was compounded when stored at room temperature, or in a refrigerator

• **Labeling:** Label it to state that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Quinidine Sulfate RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
QUINIDINE SULFATE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 50(6)

Current DocID: GUID-060C8C02-AAD2-4571-9972-C9AFC22BC527_1_en-US

DOI: https://doi.org/10.31003/USPNF_M1401_01_01

DOI ref: d4v3e