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Quinidine Gluconate Extended-Release Tablets

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DEFINITION

Quinidine Gluconate Extended-Release Tablets contain amounts of quinidine gluconate and dihydroquinidine gluconate totaling NLT 90.0% and NMT 110.0% of the labeled amount of quinidine gluconate, calculated as quinidine gluconate ($C_{20}H_{24}N_2O_2 \cdot C_6H_{12}O_7$).

IDENTIFICATION

• A.

Sample solution: Shake an amount, equivalent to 50 mg of quinidine gluconate from powdered Tablets, with 100 mL of dilute sulfuric acid (1 in 350), and filter.

Acceptance criteria: The filtrate so obtained exhibits a vivid blue fluorescence when viewed under long-wavelength UV light. On the addition of hydrochloric acid, the fluorescence disappears.

• B. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

• C. The R_f value of the principal spot of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in *Organic Impurities*.

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 prepare a 100-mL solution.

Mobile phase: [Acetonitrile](#), *Solution A*, *Solution B*, and [water](#) (100:20:20:860). Adjust with *Solution B* to a pH of 2.6, if found to be lower.

System suitability solution: Transfer 10 mg each of quinidine gluconate and dihydroquinidine hydrochloride to a 50-mL volumetric flask. Dissolve in 5 mL of [methanol](#), and dilute with *Mobile phase* to volume.

Standard solution: 0.2 mg/mL of [USP Quinidine Gluconate RS](#) in *Mobile phase*

Sample stock solution: To an amount equivalent to 160 mg of quinidine gluconate from NLT 20 finely powdered Tablets in a 100-mL volumetric flask add 80 mL of a mixture of [methanol](#) and [water](#) (1:1), and sonicate until evenly dispersed. Cool to room temperature, dilute with a mixture of [methanol](#) and [water](#) (1:1) to volume, and filter, discarding the first 20 mL of the filtrate.

Sample solution: 0.19 mg/mL of quinidine gluconate in *Mobile phase* prepared as follows. Transfer 3.0 mL of the *Sample stock solution* to a 25-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 235 nm

Column: 3- to 5-mm × 25- to 30-cm; packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for quinidine and dihydroquinidine are 1 and 1.5, respectively, for the *System suitability solution*.]

Suitability requirements

Resolution: NLT 1.2 between quinidine and dihydroquinidine, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the sum of the percentages of quinidine gluconate and dihydroquinidine gluconate in the Tablets taken;

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

$r_{B,U}$ = 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 Gluconate RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of quinidine gluconate in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 1*.

Medium: Add 6.9 g of [anhydrous sodium acetate](#) and 0.525 mL of [glacial acetic acid](#) to 1 L of [water](#). Adjust with 0.1 N [hydrochloric acid](#) or 0.1 N [sodium hydroxide](#) to a pH of 5.4; 900 mL.

Apparatus 2: 75 rpm

Times: 1, 2, 4, and 8 h

Standard solution: A known concentration of [USP Quinidine Gluconate RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium* if necessary, in comparison with the *Standard solution* concentration.

Instrumental conditions

Mode: UV

Analytical wavelength: 235 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of the labeled amount of quinidine gluconate ($C_{20}H_{24}N_2O_2 \cdot C_6H_{12}O_7$) dissolved from UV absorbances of the *Sample solution* and *Standard solution*.

Tolerances: See [Table 1](#).

Table 1

Time (h)	Amount Dissolved
1	30%–50%
2	45%–65%
4	60%–85%
8	NLT 85%

The percentages of the labeled amount of quinidine gluconate ($C_{20}H_{24}N_2O_2 \cdot C_6H_{12}O_7$) dissolved at the times specified conform to

[Dissolution \(711\)](#), [Acceptance Table 2](#).

Test 4: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 4*.

Medium: 0.1 N [hydrochloric acid](#); 600 mL

Apparatus 2: 75 rpm

Times: Proceed as directed for *Test 1*.

Standard solution: A known concentration of [USP Quinidine Gluconate RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter. Dilute with *Medium* if necessary, in comparison with the *Standard solution* concentration.

Instrumental conditions

Mode: UV