

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2021
 Document Type: USP Monographs
 DocId: GUID-BD1B162C-69A7-4E95-A605-8D6E17C3B2AC_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M72488_02_01
 DOI Ref: tuj50

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Quinapril Tablets

DEFINITION

Quinapril Tablets contain quinapril hydrochloride ($C_{25}H_{30}N_2O_5 \cdot HCl$) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of quinapril ($C_{25}H_{30}N_2O_5$).

IDENTIFICATION

Change to read:

- **A.** ▲ The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲ (USP 1-May-2021)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

Change to read:

• PROCEDURE

Diluent: [Acetonitrile](#) and [water](#) (35:65)

▲ (USP 1-May-2021)

Mobile phase: [Acetonitrile](#), [methanesulfonic acid](#), and [water](#) (35:0.2:65)

▲ (USP 1-May-2021)

Standard solution: 0.108 mg/mL of [USP Quinapril Hydrochloride RS](#), equivalent to 0.1 mg/mL of quinapril, ▲ in *Diluent* ▲ (USP 1-May-2021)

Sample solution: Nominally 0.1 mg/mL of quinapril in *Diluent* prepared as follows. Transfer ▲ a suitable amount of Tablets to a suitable volumetric flask. ▲ (USP 1-May-2021) Add about 60% of the flask volume of *Diluent*, and sonicate until the Tablets have disintegrated. Shake by mechanical means for about 15 min and dilute with *Diluent* to volume. Pass through a suitable filter, discarding the first portion of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 214 nm. ▲ For *Identification A*, use a diode array detector in the range of 190–400 nm. ▲ (USP 1-May-2021)

Column: 6.0-mm × 4-cm; 3-μm packing [L10](#)

Flow rate: 1.2 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

▲ (USP 1-May-2021)

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of quinapril ($C_{25}H_{30}N_2O_5$) in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_r/M_{r2}) \times 100$$

r_U = peak response of quinapril from the *Sample solution*

r_s = peak response of quinapril from the *Standard solution*

C_s = concentration of [USP Quinapril Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of quinapril in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of quinapril, 438.52

M_{r2} = molecular weight of quinapril hydrochloride, 474.98

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#)

Medium: [Water](#); 900 mL

Apparatus 1: 100 rpm

Time: 30 min

Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay.

Standard solution: Δ (L/900) mg/mL of quinapril, where L is the label claim in mg/Tablet, prepared as follows. Δ (USP 1-May-2021) Dissolve a suitable amount of [USP Quinapril Hydrochloride RS](#) in [methanol](#). Make any necessary volumetric adjustments with [water](#).

Sample solution: Pass a portion of the solution under test through a suitable filter.

Δ Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of quinapril ($C_{25}H_{30}N_2O_5$) dissolved:

$$\text{Result} = (r_u/r_s) \times (C_s/L) \times V \times (M_{r1}/M_{r2}) \times 100$$

r_u = peak response of quinapril from the *Sample solution*

r_s = peak response of quinapril from the *Standard solution*

C_s = concentration of [USP Quinapril Hydrochloride RS](#) in the *Standard solution* (mg/mL)

L = label claim (mg/Tablet)

V = volume of *Medium*, 900 mL

M_{r1} = molecular weight of quinapril, 438.52

M_{r2} = molecular weight of quinapril hydrochloride, 474.98 Δ (USP 1-May-2021)

Tolerances: NLT 80% (Q) of the labeled amount of quinapril ($C_{25}H_{30}N_2O_5$) is dissolved.

Change to read:

- [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

Δ Δ (USP 1-May-2021)

IMPURITIES

Change to read:

- **ORGANIC IMPURITIES**

Diluent, Δ Δ (USP 1-May-2021) **Mobile phase, Sample solution, and Chromatographic system:** Proceed as directed in the Assay.

System suitability solution: 0.1 mg/mL of [USP Quinapril Hydrochloride RS](#) and 0.005 mg/mL each of [USP Quinapril Related Compound A RS](#) and [USP Quinapril Related Compound B RS](#) in *Diluent*

Δ Sensitivity solution: 0.1 μ g/mL of [USP Quinapril Hydrochloride RS](#) in *Diluent* Δ (USP 1-May-2021)

Standard solution: 0.5 μ g/mL each of [USP Quinapril Hydrochloride RS](#), [USP Quinapril Related Compound A RS](#), and [USP Quinapril Related Compound B RS](#) in *Diluent*

System suitability

Samples: *System suitability solution*, Δ *Sensitivity solution*, Δ (USP 1-May-2021) and *Standard solution*