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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:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

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)

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: ▲(*L*/900) mg/mL of quinapril, where *L* is the label claim in mg/Tablet, prepared as follows.▲ (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.

▲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▲ (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

▲▲ (USP 1-May-2021)

IMPURITIES

Change to read:

• **Organic Impurities**

Diluent, ▲▲ (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*

▲Sensitivity solution: 0.1 µg/mL of USP Quinapril Hydrochloride RS in *Diluent*▲ *(USP 1-May-2021)*

Standard solution: 0.5 µg/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*, ▲*Sensitivity solution,*▲ (USP 1-May-2021) and *Standard solution*

Suitability requirements

Resolution: NLT 2.0 between quinapril and quinapril related compound A; NLT 2.0 between quinapril and quinapril related compound B, *System suitability solution*

▲▲ (USP 1-May-2021)

Tailing factor: NMT 1.5 for the quinapril and quinapril related compound A peaks; NMT 2.0 for the quinapril related compound B peak, *Standard solution*

Relative standard deviation: NMT 2.0% for quinapril; NMT 3.0% for each quinapril related compound, *Standard solution*

▲**Signal-to-noise ratio:** NLT 10, *Sensitivity solution*▲ *(USP 1-May-2021)*

Analysis

Samples: *Sample solution* and *Standard solution*

Calculate the percentage of quinapril related compound A or quinapril related compound B in the portion of Tablets taken:

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

r_U = peak response of quinapril related compound A or quinapril related compound B from the *Sample solution*

r_S = peak response of quinapril related compound A or quinapril related compound B from the *Standard solution*

C_S = concentration of USP Quinapril Related Compound A RS or USP Quinapril Related Compound B RS in the *Standard solution* (mg/mL)

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

▲Calculate the percentage of any unspecified degradation product in the portion of Tablets taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of any unspecified degradation product 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▲ (USP 1-May-2021)

Acceptance criteria: See *Table 1*. ▲The reporting threshold is 0.1%.▲ (USP 1-May-2021)

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Quinapril related compound B	0.6	3.0
Quinapril	1.0	—
Quinapril related compound A	2.0	1.0
▲Any unspecified degradation product	—	0.2▲ (USP 1-May-2021)
Total degradation products	—	3.6

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at controlled room temperature.

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Quinapril Hydrochloride RS

USP Quinapril Related Compound A RS

▲Ethyl (*S*)-2-((3*S*,11a*S*)-3-methyl-1,4-dioxo-1,3,4,6,11,11a-hexahydro-2*H*-pyrazino[1,2-*b*]isoquinolin-2-yl)-4-phenylbutanoate.
$C_{25}H_{28}N_2O_4$ 420.51▲ (USP 1-May-2021)

USP Quinapril Related Compound B RS

▲(*S*)-2-{[(*S*)-1-Carboxy-3-phenylpropyl]-L-alanyl}-1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid.▲ (USP 1-May-2021)
$C_{23}H_{26}N_2O_5$ 410.47

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

Topic/Question	Contact	Expert Committee
QUINAPRIL TABLETS	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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