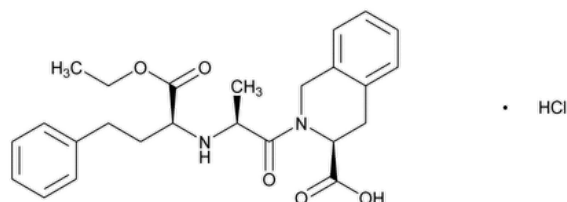


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Quinapril Hydrochloride

Change to read:



$C_{25}H_{30}N_2O_5 \cdot HCl$

474.98

3-Isoquinolinecarboxylic acid, 2-[2-[[1-(ethoxycarbonyl)-3-phenylpropyl]amino]-1-oxopropyl]-1,2,3,4-tetrahydro-, monohydrochloride, [3S-[2[R* (R*)],3R*]];

(S)-2-[(S)-N-[(S)-1-Carboxy-3-phenylpropyl]alanyl]-1,2,3,4-tetrahydro-3-isoquinolinecarboxylic acid, 1-ethyl ester, monohydrochloride;

▲(S)-2-[(S)-1-Ethoxy-1-oxo-4-phenylbutan-2-yl]-L-alanyl]-1,2,3,4-tetrahydroisoquinoline-3-carboxylic acid hydrochloride.▲ (USP 1-May-2021) CAS RN®: 82586-55-8; UNII: 33067B3N2M.

▲Quinapril hydrochloride (acetone solvate):

$C_{25}H_{30}N_2O_5 \cdot HCl \cdot C_3H_6O$

533.06 CAS RN®: 757964-89-9.▲ (USP 1-May-2021)

DEFINITION

Change to read:

Quinapril Hydrochloride contains NLT 98.5% and NMT 101.5% of quinapril hydrochloride ($C_{25}H_{30}N_2O_5 \cdot HCl$), calculated on the anhydrous basis.

▲If labeled as acetone solvate, it contains NLT 98.5% and NMT 101.5% of quinapril hydrochloride ($C_{25}H_{30}N_2O_5 \cdot HCl$) calculated on the anhydrous and acetone-free basis.▲ (USP 1-May-2021)

IDENTIFICATION

Change to read:

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K ▲ or 197A▲ (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

Mobile phase: [Acetonitrile](#), [methanesulfonic acid](#), and [water](#) (28: 0.1: 72)

Diluent: [Acetonitrile](#) and pH 6.5 0.025 M [monobasic ammonium phosphate](#) solution (40:60)

System suitability solution: 2 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*

Standard solution: 2 mg/mL of [USP Quinapril Hydrochloride RS](#) in *Diluent*

Sample solution: 2 mg/mL of Quinapril Hydrochloride in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 214 nm

Columns

Guard: 4.6-mm × 3-cm; 5-μm packing [L10](#)

Analytical: 4.6-mm × 25-cm; 5-μm packing [L10](#)

Flow rate: 1.5 mL/min

Injection volume: 10 µL

▲Run time: NLT 3 times retention time of quinapril▲ (USP 1-May-2021)

System suitability

Samples: *System suitability solution*▲ and *Standard solution*▲ (USP 1-May-2021)

Suitability requirements

Resolution: NLT 1.75 between quinapril and quinapril related compound A; NLT 3.5 between quinapril and quinapril related compound B,

▲*System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*▲ (USP 1-May-2021)

Relative standard deviation: NMT ▲0.55%, *Standard solution*▲ (USP 1-May-2021)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of quinapril hydrochloride ($C_{25}H_{30}N_2O_5 \cdot HCl$) in the portion of Quinapril Hydrochloride taken:

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

r_U = peak response of quinapril ▲ (USP 1-May-2021) from the *Sample solution*

r_S = peak response of quinapril ▲ (USP 1-May-2021) from the *Standard solution*

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

C_U = concentration of Quinapril Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.5%–101.5% on the anhydrous basis ▲ and 98.5%–101.5% on the anhydrous and acetone-free basis if labeled as acetone solvate▲ (USP 1-May-2021)

OTHER COMPONENTS

• CONTENT OF CHLORIDE

Sample: 100 mg of Quinapril Hydrochloride

Titrimetric system

(See [Titrimetry \(541\)](#).)

Mode: Direct titration

Titrant: 0.01 N silver nitrate VS

Analysis: Transfer the *Sample* to a 100-mL beaker. Dissolve in 50 mL of [water](#) and 10 mL of [alcohol](#), and acidify with [nitric acid](#). Titrate with *Titrant* using suitable electrodes. Perform a blank determination, and make any necessary corrections. Each milliliter of 0.01 N silver nitrate is equivalent to 0.3545 mg of chloride.

Acceptance criteria: 7.2%–7.6%

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

Delete the following:

▲• LIMIT OF RESIDUAL SOLVENTS

Standard stock solution: Transfer 50 mL of dimethylformamide to a 200-mL volumetric flask. Add 75 mg each of acetone and acetonitrile and 30 mg each of methylene chloride and toluene, each weighed by difference. Dilute with dimethylformamide to volume.

Standard solution: 4.0 mL of the *Standard stock solution*, diluted with dimethylformamide to 50 mL

System suitability solution 1: Transfer 25 mL of dimethylformamide to a 50-mL volumetric flask. Add 35 µL of dehydrated alcohol and 25 µL of methylene chloride. Dilute with dimethylformamide to volume. Transfer 1.0 mL of this solution to a 50-mL volumetric flask, and dilute with dimethylformamide to volume.

System suitability solution 2: 2.0 mL of the *Standard stock solution*, diluted with dimethylformamide to 50 mL

Sample solution: 60 mg of Quinapril Hydrochloride to a suitable headspace vial, add 5.0 mL of dimethylformamide, seal, and shake to dissolve.

Chromatographic system

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

Mode: GC