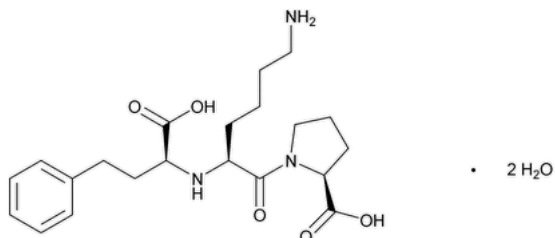


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Lisinopril



$C_{21}H_{31}N_3O_5 \cdot 2H_2O$ 441.52

L-Proline, 1-[N²-(1-carboxy-3-phenylpropyl)-L-lysyl]-, dihydrate, (S)-;

1-[N²-[(S)-1-Carboxy-3-phenylpropyl]-L-lysyl]-L-proline dihydrate CAS RN®: 83915-83-7; UNII: E7199S1YWR.

DEFINITION

Lisinopril contains NLT 98.0% and NMT 102.0% of lisinopril ($C_{21}H_{31}N_3O_5$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M ▲](#) (CN 1-May-2020)
- **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

PROCEDURE

Solution A: 2.76 g/L of monobasic sodium phosphate in water prepared as follows. Dissolve 2.76 g of monobasic sodium phosphate in about 900 mL of water in a 1000-mL volumetric flask. Adjust with 1 N sodium hydroxide to a pH of 5.0 and dilute with water to volume.

Mobile phase: Acetonitrile and *Solution A* (4:96)

Standard solution: 0.3 mg/mL of [USP Lisinopril RS](#) in water

Sample solution: 0.3 mg/mL of Lisinopril in water

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-μm packing L7

Column temperature: 50°

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.7

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of lisinopril ($C_{21}H_{31}N_3O_5$) in the portion of Lisinopril taken:

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

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

r_S = peak response of lisinopril from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• **RESIDUE ON IGNITION (281):** NMT 0.1%

• ORGANIC IMPURITIES

Buffer: 3.53 g/L of monobasic sodium phosphate dihydrate in water adjusted with phosphoric acid to a pH of 4.1

Solution A: Acetonitrile and *Buffer* (7:193)

Solution B: Acetonitrile and *Buffer* (20:80)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
35	60	40
55	60	40
60	100	0

Standard solution: 0.006 mg/mL of [USP Lisinopril RS](#) in *Solution A*

Sensitivity solution: 1.0 µg/mL of [USP Lisinopril RS](#) in *Solution A* from *Standard solution*

Sample solution: 2 mg/mL of Lisinopril in *Solution A*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 25-cm; 5-µm packing L7

Column temperature: 45°

Flow rate: 1.8 mL/min

Injection volume: 20 µL

System suitability

Samples: *Standard solution* and *Sensitivity solution*

Suitability requirements

Relative standard deviation: NMT 10.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Lisinopril taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of lisinopril from the *Standard solution*

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

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

F = relative response factor (see [Table 2](#))

Acceptance criteria: See [Table 2](#). Disregard any peak less than 0.05%.

Table 2