Status: Currently Official on 15-Feb-2025
Official Date: Official as of 01-Dec-2016
Document Type: USP Monographs
DocId: GUID-FBDF22F8-4A09-43B3-A205-68E269D07399_1_en-US
DOI: https://doi.org/10.31003/USPNF_M1785_01_01
DOI Ref: i7fqr

Lisinopril Compounded Oral Suspension

DEFINITION

Lisinopril Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of lisinopril ($C_{21}H_{31}N_3O_5$).

Prepare Lisinopril Compounded Oral Suspension 1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Lisinopril tablets[a] equivalent to	100 mg of lisinopril
Vehicle: a 1:1 mixture of Ora-Sweet[b] and Ora-Plus,[b] a sufficient quantity to make	100 mL

[a] Prinivil 10-mg tablets, Merck & Co., West Point, PA.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Lisinopril tablets* in a suitable mortar, and comminute to a fine powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a lisinopril liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Solution A: 4.1 g/L of monobasic potassium phosphate. Adjust with phosphoric acid to a pH of 2.0.

Mobile phase: 1.0 g/L of sodium 1-hexanesulfonate in acetonitrile and *Solution A* (18:82). Filter and degas.

Diluent: Methanol and water (20:80)

Standard solution: 0.2 mg/mL of USP Lisinopril RS in *Diluent*

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Mix 1.0 mL of Oral Suspension with 4.0 mL of *Diluent* to obtain a solution having a nominal concentration of 0.2 mg/mL of lisinopril.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 215 nm

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

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for lisinopril is about 12.9 min.]

Suitability requirements

Column efficiency: NLT 1800 theoretical plates

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of lisinopril ($C_{21}H_{31}N_3O_5$) in the portion of Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.3–5.3

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Lisinopril RS

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

Topic/Question	Contact	Expert Committee
LISINOPRIL COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 40(6)

Current DocID: GUID-FBDF22F8-4A09-43B3-A205-68E269D07399_1_en-US

DOI: https://doi.org/10.31003/USPNF_M1785_01_01

DOI ref: i7fqr