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Captopril Compounded Oral Solution

DEFINITION

Captopril Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of captopril (C₉H₁₅NO₃S).

Prepare Captopril Compounded Oral Solution 0.75 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Captopril powder	75 mg
Vehicle for Oral Solution (regular or sugar-free), <i>NF</i> , a sufficient quantity to make	100 mL

Add *Captopril powder* and 10 mL of *Vehicle* to a mortar, and mix. Add the *Vehicle* in small portions almost to volume, and mix thoroughly after each addition. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough *Vehicle* to bring to final volume, and mix well.

ASSAY

• **PROCEDURE**

Mobile phase: Methanol and water (55:45) containing 0.5 mL/L of phosphoric acid. Filter, and degas.

Standard solution: 7.5 µg/mL of [USP Captopril RS](#)

Sample solution: Agitate the container of Oral Solution for 30 min on a rotating mixer, remove a 5-mL sample, and store in a clear glass vial at –70° until analyzed. At the time of analysis, remove the sample from the freezer, allow it to reach room temperature, and mix with a vortex mixer for 30 s. Pipet 1.0 mL of the sample into a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for captopril is about 5.0 min.]

Suitability requirements

Relative standard deviation: NMT 0.9% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of captopril (C₉H₁₅NO₃S) in the portion of Oral Solution taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

C_U = nominal concentration of captopril in the *Sample solution* (µg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH (791):** 3.8–4.3

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator.

- **BEYOND-USE DATE:** NMT 7 days after the date on which it was compounded when stored in a refrigerator
- **LABELING:** Label it to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS (11),**
[USP Captopril RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
CAPTOPRIL COMPOUNDED ORAL SOLUTION	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](#)

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