

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-1D5879D0-FBF2-4C6F-B8F6-01FF1DA0C880_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M2993_02_01
 DOI Ref: i0bnd

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Ramipril Tablets

DEFINITION

Ramipril Tablets contain NLT 90.0% and NMT 105.0% of the labeled amount of ramipril ($C_{23}H_{32}N_2O_5$).

IDENTIFICATION

Change to read:

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

Sample: Finely powder a suitable number of Tablets and transfer a portion of the powder, equivalent to 100 mg of ramipril, to a suitable beaker. Add 25 mL of methanol, shake to dissolve, and pass through the filter. Evaporate the solution in air and heat to complete dryness at 105° for 1 h.

Acceptance criteria: Meet the requirements

- **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 g of [sodium perchlorate](#) in a mixture of 0.5 mL of [triethylamine](#) and 800 mL of [water](#). Adjust with [phosphoric acid](#) to a pH of 3.6, and add 200 mL of acetonitrile.

Solution B: 2 g of [sodium perchlorate](#) in a mixture of 0.5 mL of [triethylamine](#) and 300 mL of [water](#). Adjust with [phosphoric acid](#) to a pH of 2.6, and add 700 mL of acetonitrile.

Mobile phase: *Solution A* and *Solution B* (60:40)

Diluent: 6.8 g of [monobasic sodium phosphate](#) in 500 mL of [water](#). Add 1000 mL each of methanol and acetonitrile. Adjust with [phosphoric acid](#) to a pH of 5.5.

Standard solution: 0.1 mg/mL of [USP Ramipril RS](#) in *Diluent*

Sample stock solution: Nominally 0.25 mg/mL of ramipril from NLT 10 Tablets prepared as follows. Add 50% of the final volume of *Diluent* to the flask and sonicate to disperse the Tablets. Sonicate for an additional 30 min and dilute with *Diluent* to volume.

Sample solution: Nominally 0.1 mg/mL of ramipril from the *Sample stock solution* in *Diluent*. Pass through a suitable filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Column temperature: 50°

Flow rate: 1 mL/min

Injection volume: 10 µL

Run time: 15 min

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ramipril ($C_{23}H_{32}N_2O_5$) in the portion of Tablets taken:

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

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

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

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

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

Acceptance criteria: 90.0%–105.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N [hydrochloric acid](#); 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard stock solution: 0.25 mg/mL of [USP Ramipril RS](#) in methanol

Standard solution: $(L/500)$ mg/mL of [USP Ramipril RS](#) in *Medium* from the *Standard stock solution* where L is the label claim of ramipril in mg/Tablet

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size.

Solution A, Solution B, Mobile phase, Chromatographic system, and System suitability: Proceed as directed in the Assay except for the *Injection volume*.

Injection volume: 100 μ L

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ramipril ($C_{23}H_{32}N_2O_5$) dissolved:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

V = volume of *Medium*, 500 mL

L = label claim for ramipril (mg/Tablet)

Tolerances: NLT 80% (Q) of the labeled amount of ramipril ($C_{23}H_{32}N_2O_5$) is dissolved.

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): Meet the requirements

IMPURITIES

• ORGANIC IMPURITIES

Solution A and Solution B: Prepare as directed in the Assay.

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
6	70	30
30	30	70
40	30	70
45	70	30



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