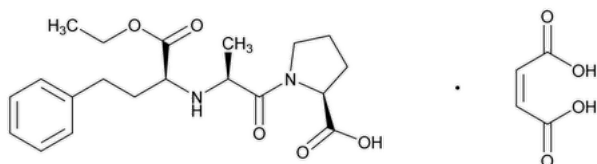


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Enalapril Maleate



$C_{20}H_{28}N_2O_5 \cdot C_4H_4O_4$

492.52

L-Proline, 1-[N-[1-(ethoxycarbonyl)-3-phenylpropyl]-L-alanyl]-, (S)-, (Z)-2-butenedioate (1:1);

1-[N-[(S)-1-Carboxy-3-phenylpropyl]-L-alanyl]-L-proline, 1'-ethyl ester, maleate (1:1) CAS RN®: 76095-16-4; UNII: 9025354EPJ.

DEFINITION

Enalapril Maleate contains NLT 98.0% and NMT 102.0% of enalapril maleate ($C_{20}H_{28}N_2O_5 \cdot C_4H_4O_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: \(197M\)](#), or [\(197A\)](#) ▲ (USP 1-Dec-2019)
- **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

Buffer 1: 2.8 g of [sodium phosphate, monobasic](#) in 900 mL of [water](#) in a 1000-mL volumetric flask. Adjust with a 9 M sodium hydroxide solution to a pH of ▲ (USP 1-Dec-2019) 6.8, and dilute with [water](#) to volume.

Buffer 2: 2.8 g of [sodium phosphate, monobasic](#) in 900 mL of [water](#) in a 1000-mL volumetric flask. Adjust with [phosphoric acid](#) to a pH of ▲ (USP 1-Dec-2019) 2.5, and dilute with [water](#) to volume.

Solution A: [Acetonitrile](#) and *Buffer 1* (5:95)

Solution B: [Acetonitrile](#) and *Buffer 1* (66:34)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	95	5
20	40	60
25	40	60
26	95	5
30	95	5

Diluent: [Acetonitrile](#) and *Buffer 2* (5:95)

Standard solution: 0.3 mg/mL of [USP Enalapril Maleate RS](#) in *Diluent*

▲ (USP 1-Dec-2019)

Sample solution: 0.3 mg/mL of Enalapril Maleate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.1-mm × 15-cm; ▲5-µm▲ (USP 1-Dec-2019) packing [L21](#)

Column temperature: 70°

Flow rate: 1.5 mL/min

Injection volume: 50 µL

System suitability

Sample: *Standard solution* ▲ (USP 1-Dec-2019)

Suitability requirements

▲**Tailing factor:** NMT 2.0▲ (USP 1-Dec-2019)

Relative standard deviation: NMT ▲0.73%▲ (USP 1-Dec-2019)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of enalapril maleate ($C_{20}H_{28}N_2O_5 \cdot C_4H_4O_4$) in the portion of Enalapril Maleate taken:

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

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

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

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

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

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

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

Change to read:

- **ORGANIC IMPURITIES**

▲**Buffer:** 0.14 g/L of [potassium phosphate, monobasic](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.0.

Solution A: [Acetonitrile](#) and *Buffer* (10:90)

Solution B: [Acetonitrile](#) and *Buffer* (80:20)

Mobile phase: See [Table 2](#).

Table 2

Time (min)	Solution A (%)	Solution B (%)
0	100	0
5	100	0
21	80	20
30	15	85
40	100	0
50	100	0

Diluent: [Acetonitrile](#) and *Buffer* (20:80)

System suitability solution: 1 mg/mL of [USP Enalapril Maleate RS](#) and 3 µg/mL of [USP Moexipril Related Compound F RS](#) in *Diluent*. Sonicate to dissolve as needed.

Standard solution: 0.01 mg/mL of [USP Enalapril Maleate RS](#) in *Diluent*

Sensitivity solution: 0.5 µg/mL of [USP Enalapril Maleate RS](#) in *Diluent* from the *Standard solution*

Sample solution: 1 mg/mL of Enalapril Maleate in *Diluent*. Sonicate to dissolve as needed.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 25-cm; 5-µm packing [L7](#)