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Enalapril Maleate Compounded Oral Suspension, Veterinary

DEFINITION

Enalapril Maleate Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled content of enalapril maleate ($C_{20}H_{28}N_2O_5 \cdot C_4H_4O_4$).

Prepare Enalapril Maleate Compounded Oral Suspension, Veterinary 10 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Enalapril maleate	1 g
Ora-Blend[a], a sufficient quantity to make	100 mL

[a] Perrigo, Minneapolis, MN.

Pour the *Enalapril maleate* powder into a suitable container. Wet the powder with a small amount of *Ora-Blend*, and triturate to make a smooth paste. Add the *Ora-Blend* to make the mortar contents pourable. Transfer the contents of the mortar stepwise and quantitatively to a calibrated container using the *Ora-Blend*. Add sufficient *Ora-Blend* to bring the preparation to final volume. Shake to mix well.

ASSAY

• **Procedure**

Solution A: Dissolve 2.8 g of monobasic sodium phosphate in 1000 mL of water. Adjust with 1 N sodium hydroxide to a pH of 6.8.

Solution B: Acetonitrile and *Solution A* (5:95)

Solution C: Acetonitrile and *Solution A* (66:34)

Solution D: Dissolve 2.8 g of monobasic sodium phosphate in 1000 mL of water. Adjust with phosphoric acid to a pH of 2.5.

Diluent: Acetonitrile and *Solution D* (5:95)

Mobile phase: See *Table 1*.

Table 1

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

Standard solution: 1 mg/mL of USP Enalapril Maleate RS in *Diluent*

Sample solution: Shake thoroughly each bottle of Oral Suspension. Transfer 1.0 mL of the Oral Suspension into a 10-mL volumetric flask, dilute with *Diluent* to volume, and mix well to dissolve. Pass through a PVDF filter of 0.45-µm pore size, discarding the first 3 mL to waste.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

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Column: 4.6-mm × 25-cm; 5-µm packing L21

Column temperature: 60°

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for enalapril maleate is about 14.2 min.]

Suitability requirements

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 enalapril maleate ($C_{20}H_{28}N_2O_5 \cdot C_4H_4O_4$) in the portion of Oral Suspension taken:

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

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

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

C_S = concentration of enalapril maleate in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 2.6–3.6

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store at 2°–8° or at controlled room temperature.

• **LABELING:** Label it to indicate that it is to be shaken vigorously immediately before use, and to state the *Beyond-Use Date*. Label it to state that it is for veterinary use only.

• **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored at 2°–8°; NMT 60 days when stored at controlled room temperature

• **USP REFERENCE STANDARDS** ⟨11⟩

USP Enalapril Maleate RS

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

Topic/Question	Contact	Expert Committee
ENALAPRIL MALEATE COMPOUNDED ORAL SUSPENSION, VETERINARY	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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