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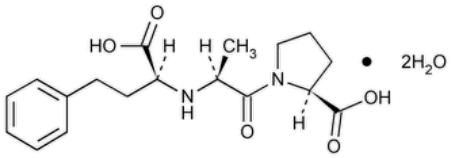
Enalaprilat



$C_{18}H_{24}N_2O_5 \cdot 2H_2O$ 384.42

L-Proline, 1-[*N*-(1-carboxy-3-phenylpropyl)-L-alanyl]-, dihydrate, (*S*)-.

1-[*N*-[(*S*)-1-Carboxy-3-phenylpropyl]-L-alanyl]-L-proline dihydrate CAS RN®: 84680-54-6; UNII: GV0O7ES0R3.

» Enalaprilat contains not less than 98.0 percent and not more than 101.0 percent of $C_{18}H_{24}N_2O_5$, calculated on the anhydrous basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩—

USP Enalaprilat RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197M*▲ (CN 1-May-2020) — [Note—If the spectrum is not comparable to that of the Reference Standard, expose the specimen and Reference Standard to an environment of 98% relative humidity (use a chamber conditioned with a saturated solution of calcium sulfate) for 1 to 3 days to equilibrate them. Prepare dispersions from the equilibrated specimen and Reference Standard, and record the spectra.]

B: The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that of the *Standard preparation* as obtained in the *Assay*.

Specific rotation ⟨781S⟩: between −53.0° and −56.0°.

Test solution: 10 mg per mL, in methanol.

Water Determination, *Method I* ⟨921⟩: between 7.0% and 11.0%.

Residue on ignition ⟨281⟩: not more than 0.2%.

Assay—

pH 3 buffer—Dissolve 1.36 g of monobasic potassium phosphate in 950 mL of water, adjust with phosphoric acid to a pH of 3.0 ± 0.1, dilute with water to 1000 mL, and mix.

Solvent mixture—Prepare a mixture of acetonitrile, methanol, and *pH 3 buffer* (2:2:1). Adjust with phosphoric acid to a pH of 3.0 ± 0.1, and mix.

Diluent—Prepare a mixture of *pH 3 buffer* and *Solvent mixture* (92:8), and filter.

Mobile phase—Prepare a filtered and degassed mixture of *pH 3 buffer* and *Solvent mixture* (85:15). Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Standard preparation—Dissolve an accurately weighed quantity of USP Enalaprilat RS in *Diluent* to obtain a solution having a known concentration of about 0.3 mg per mL. [Note—Use this solution within 24 hours.]

Assay preparation—Transfer about 30 mg of Enalaprilat, accurately weighed, to a 100-mL volumetric flask, dissolve in *Diluent*, dilute with *Diluent* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 210-nm detector and a 4.6-mm × 15-cm column that contains 4-µm packing L1 and is maintained at 70°. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the column efficiency determined from the analyte peak is not less than 500 theoretical plates; the tailing factor for the analyte peak is not more than 1.7; and the relative standard deviation for replicate injections is not more than 1.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. Calculate the quantity, in mg, of $C_{18}H_{24}N_2O_5$ in the portion of Enalaprilat taken by the formula:

$$100C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Enalaprilat RS in the *Standard preparation;* and r_U and r_S are the enalaprilat peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
ENALAPRILAT	Documentary Standards Support	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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