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Benazepril Hydrochloride Compounded Oral Suspension, Veterinary

DEFINITION

Benazepril Hydrochloride Compounded Oral Suspension, Veterinary contains NLT 90.0% and NMT 110.0% of the labeled amount of benazepril hydrochloride ($C_{24}H_{28}N_2O_5 \cdot HCl$).

Prepare Benazepril Hydrochloride Compounded Oral Suspension, Veterinary, 5 mg/mL, as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Benazepril Hydrochloride powder	500 mg
Vehicle: a 1:1 mixture of Ora-Plus[a] and Ora-Sweet[a], a sufficient quantity to make	100 mL

[a] Perrigo Pharmaceuticals, Allegan, MI.

Pour the *Benazepril Hydrochloride powder* into a suitable container. Wet the powder with a small amount of *Vehicle*, and triturate to make a smooth paste. Add the *Vehicle* to make the contents pourable. Transfer the contents, stepwise and quantitatively, to a calibrated container using the remainder of the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

ASSAY

• **Procedure**

Solution A: 25 mM sodium phosphate adjusted with phosphoric acid to a pH of 3.0. Pass through a nylon filter of 0.45-µm pore size.

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

Diluent: Water adjusted with phosphoric acid to a pH of 3.0

Standard stock solution: 5 mg/mL of USP Benazepril Hydrochloride RS in *Diluent*. Sonicate for 3 min. Mix well, and store at 2°–8°.

Standard solution: 0.01 mg/mL of benazepril hydrochloride prepared with *Standard stock solution* and *Diluent*. Centrifuge for 5 min at 14,000 rpm, and use the supernatant. Protect from light, and store at 2°–8°.

Sample solution: Shake thoroughly each bottle of Oral Suspension, Veterinary. Transfer 2.0 mL of the Oral Suspension, Veterinary into a 1-L volumetric flask, and dilute with *Diluent* to volume. Mix well. Centrifuge for 5 min at 14,000 rpm, and use the supernatant. Protect from light, and store at 2°–8°.

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

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

Temperatures

Column: 30°

Autosampler: 5°

Flow rate: 1.2 mL/min

Injection volume: 25 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for benazepril hydrochloride is about 6.5 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 benazepril hydrochloride ($C_{24}H_{28}N_2O_5 \cdot HCl$) in the portion of Oral Suspension, Veterinary taken:

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

r_U = peak response of benazepril hydrochloride from the *Sample solution*

r_S = peak response of benazepril hydrochloride from the *Standard solution*

C_S = concentration of benazepril hydrochloride in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.8–4.8

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 well-shaken 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° or at controlled room temperature

• **USP Reference Standards** ⟨11⟩

USP Benazepril Hydrochloride RS

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

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

Chromatographic Database Information: Chromatographic Database

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