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Amprolium Oral Solution

» Amprolium Oral Solution contains not less than 93.0 percent and not more than 107.0 percent of the labeled amount of amprolium ($C_{14}H_{19}ClN_4 \cdot HCl$).

Packaging and storage—Preserve in tight containers, protected from light. Store at a temperature between 5° and 30°, in a dry place.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—
USP Amprolium RS

Change to read:

Identification, ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020) —

Solution: 10 µg per mL, filtered.

Medium: 0.1 N hydrochloric acid.

pH ⟨791⟩: between 2.5 and 3.0.

Assay—

Mobile phase—To 4.5 g of sodium 1-hexanesulfonate add 1500 mL of water, 400 mL of methanol, and 100 mL of acetonitrile, mix, and allow to cool to room temperature. Adjust with phosphoric acid to a pH of 5.1, and pass through a filter having a 0.5-µm or finer porosity. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Quantitatively dissolve an accurately weighed quantity of USP Amprolium RS in water to obtain a solution having a known concentration of about 0.5 mg per mL.

Assay preparation—Transfer an accurately measured volume of Oral Solution, equivalent to about 960 mg of amprolium, to a 100-mL volumetric flask, dilute with water to volume, and mix. Transfer 5.0 mL of this stock solution to a second 100-mL volumetric flask, dilute with water to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 268-nm detector and a 3.9-mm × 30-cm column that contains packing L11. The column is maintained at a constant temperature of about 45°. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the tailing factor is not more than 1.5; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the peak areas for amprolium. Calculate the quantity, in mg, of amprolium ($C_{14}H_{19}ClN_4 \cdot HCl$) in each mL of the Oral Solution taken by the formula:

$$(2000C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Amprolium RS in the *Standard preparation; V* is the volume, in mL, of Oral Solution taken to prepare the *Assay preparation;* and r_U and r_S are the amprolium peak areas 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
AMPROLIUM ORAL SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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