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Amprolium Soluble Powder

DEFINITION

Amprolium Soluble Powder contains NLT 95.0% and NMT 105.0% of the labeled amount of amprolium ($C_{14}H_{19}ClN_4 \cdot HCl$).

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U ▲](#) (CN 1-MAY-2020)

Sample solution: 10 µg/mL (filtered) in 0.1 N hydrochloric acid

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Diluent: Methanol, acetonitrile, and water (45:5:50)

Mobile phase: 6 g of sodium 1-heptanesulfonate in 500 mL of water. Add 12 mL of glacial acetic acid, 2.0 mL of triethylamine, 450 mL of methanol, and 50 mL of acetonitrile. Pass through a suitable filter of 0.5-µm or finer pore size.

System suitability solution: 0.5 mg/mL of [USP Amprolium RS](#) and 0.2 mg/mL of 2-picoline in *Diluent*

Standard solution: 0.5 mg/mL of [USP Amprolium RS](#) in *Diluent*

Sample solution: Nominally 0.5 mg/mL of amprolium in *Diluent*, prepared as follows. Transfer a portion of Soluble Powder, equivalent to 50 mg of amprolium, to a 100-mL volumetric flask, add 75 mL of *Diluent*, and sonicate for 10 min. Allow to cool to room temperature, and dilute with *Diluent* to volume. Pass through a suitable filter of 0.5-µm or finer pore size, and use the clear filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L13

Flow rate: 0.6 mL/min

Injection volume: 10 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 7 between amprolium and 2-picoline

Column efficiency: NLT 6500 theoretical plates from the amprolium peak

Tailing factor: NMT 2.3 for the amprolium peak

Relative standard deviation: NMT 1.0% for amprolium

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of amprolium ($C_{14}H_{19}ClN_4 \cdot HCl$) in the portion of Soluble Powder taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 95.0%–105.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **LABELING:** Label it to indicate that it is for veterinary use only.

- [USP REFERENCE STANDARDS \(11\)](#).
[USP Amprolium RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
AMPROLIUM SOLUBLE POWDER	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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