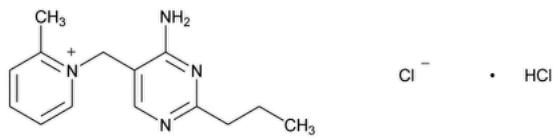


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Amprolium



$C_{14}H_{19}ClN_4 \cdot HCl$ 315.24
1-[(4-Amino-2-propyl-5-pyrimidinyl)methyl]-2-methylpyridinium chloride monohydrochloride;
1-[(4-Amino-2-propyl-5-pyrimidinyl)methyl]-2-picolinium chloride monohydrochloride CAS RN®: 137-88-2; UNII: 95CO6N199Q.

DEFINITION
Amprolium contains NLT 97.0% and NMT 101.0% of amprolium ($C_{14}H_{19}ClN_4 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- A. [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)

Sample: Previously dried

Acceptance criteria: Meets the requirements

Change to read:

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

Analytical wavelength: 246 nm

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

Acceptance criteria: Absorptivities, calculated on the dried basis, do not differ by more than 3.0%.

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: 0.5 mg/mL of Amprolium in *Diluent*

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 amprolium ($C_{14}H_{19}ClN_4 \cdot HCl$) in the portion of Amprolium 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 = concentration of Amprolium in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–101.0% on the dried basis

SPECIFIC TESTS

- [Loss on Drying \(731\)](#)
- Analysis:** Dry a sample at a pressure not exceeding 5 mm of mercury at 100° for 3 h.
- Acceptance criteria:** NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed 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	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:
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