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Acepromazine Maleate Tablets

DEFINITION

Acepromazine Maleate Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$).

Throughout the following procedures, protect samples, the USP Reference Standard, and solutions containing them, by conducting the procedures without delay, under subdued light, or using low-actinic glassware.

IDENTIFICATION

Change to read:

• **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**▲ (CN 1-May-2020)

Sample: To a quantity of powdered Tablets, equivalent to 20 mg of acepromazine maleate, add 2 mL of water and 3 mL of 2 N sodium hydroxide, and extract with two 5-mL portions of cyclohexane. Combine the cyclohexane extracts, and evaporate to dryness under vacuum, using gentle heat if necessary.

Acceptance criteria: Meet the requirements

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer: Add 6 mL of triethylamine to 700 mL of water, and adjust with phosphoric acid to a pH of 2.5.

Mobile phase: Acetonitrile and *Buffer* (300:700)

Standard stock solution: 1 mg/mL of USP Acepromazine Maleate RS in 0.05 N hydrochloric acid

Standard solution: 0.1 mg/mL of USP Acepromazine Maleate RS in water from *Standard stock solution*

Sample stock solution: Transfer NLT 10 Tablets to a 200-mL volumetric flask, add 100 mL of 0.05 N hydrochloric acid, and sonicate for 10 min. Shake by mechanical means for 30 min, and dilute with 0.05 N hydrochloric acid to volume.

Sample solution: Nominally 0.1 mg/mL of Acepromazine Maleate in water from *Sample stock solution*. Pass a portion of this solution through a filter of 0.5-µm or finer pore size.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4-mm × 15-cm; 5-µm packing L7

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1500 theoretical plates

Tailing factor: NMT 2.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$) in the portion of Tablets taken:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of USP Acepromazine Maleate RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers, and store at controlled room temperature.
- **Labeling:** Label the Tablets to indicate that they are for veterinary use only.
- **USP Reference Standards** ⟨11⟩
  USP Acepromazine Maleate RS

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

Topic/Question	Contact	Expert Committee
ACEPROMAZINE MALEATE TABLETS	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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