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Acepromazine Maleate Injection

DEFINITION

Acepromazine Maleate Injection is a sterile solution of Acepromazine Maleate in Water for Injection. It contains 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 volume of Injection, 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: Meets 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: 1 mg/mL of Acepromazine Maleate in 0.05 N hydrochloric acid from an appropriately diluted volume of Injection

Sample solution: Nominally 0.1 mg/mL of Acepromazine Maleate in water from *Sample stock solution*

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 Injection 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%

SPECIFIC TESTS

- **pH** (791): 4.5–5.8
- **BACTERIAL ENDOTOXINS TEST** (85): NMT 4.5 USP Endotoxin Units/mg of acepromazine maleate
- **STERILITY TESTS** (71): It meets the requirements when tested as directed for *Test for Sterility of the Product to Be Examined, Membrane Filtration*.
- **OTHER REQUIREMENTS**: It meets the requirements in [Injections and Implanted Drug Products \(1\)](#).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE**: Preserve in tight, light-resistant, single-dose or multiple-dose containers as described in [Packaging and Storage Requirements \(659\)](#), [Injection Packaging](#). Store at controlled room temperature.
- **LABELING**: Label it to indicate that it is 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 INJECTION	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:

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