

C_U = concentration of the *Sample solution* (mg/mL)
Acceptance criteria: 98.0%–101.0% on the anhydrous basis

IMPURITIES

- **RESIDUE ON IGNITION** (281): NMT 0.2%
- **ORGANIC IMPURITIES**

Conduct this test without exposure to daylight, and with the minimum necessary exposure to artificial light.

Diluent: Methanol and diethylamine (19:1)

Sample solution: 20.0 mg/mL of Acepromazine Maleate in *Diluent*

Standard solution: 0.1 mg/mL of Acepromazine Maleate in *Diluent* from the *Sample solution*

Chromatographic system

(See *Chromatography* (621), *Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 μ L

Developing solvent system: *n*-Heptane, isobutyl alcohol, and diethylamine (75:17:8)

Analysis

Samples: *Standard solution* and *Sample solution*

Develop the chromatogram in the *Developing solvent system* until the solvent front has moved three-fourths the length of the plate. Remove the plate from the chamber and allow to air dry. Examine the plate under short-wavelength UV light.

Acceptance criteria: 0.5%; no spot, other than the principal acepromazine spot and any at the origin, observed in the chromatogram of the *Sample solution* is more intense than the principal spot observed in the chromatogram of the *Standard solution*.

SPECIFIC TESTS

- **MELTING RANGE OR TEMPERATURE** (741): 136°–139°

- **PH** (791)

Sample solution: 10 mg/mL of Acepromazine Maleate in water

Acceptance criteria: 4.0–5.5

- **WATER DETERMINATION, Method I** (921): NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers, protected from light. Store at room temperature.
- **LABELING:** Label it to indicate that it is for veterinary use only.
- **USP REFERENCE STANDARDS** (11)
USP Acepromazine Maleate RS

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

- **A. INFRARED ABSORPTION** (197K)

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 \times 15-cm; 5- μ m packing L7

Flow rate: 1 mL/min

Injection volume: 10 μ L

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.