

Status: Currently Official on 17-Feb-2025

Official Date: Official as of 01-May-2020

Document Type: USP Monographs

DocId: GUID-4931EEC7-CE84-4DA3-AB2E-0D16ED840FBF_4_en-US

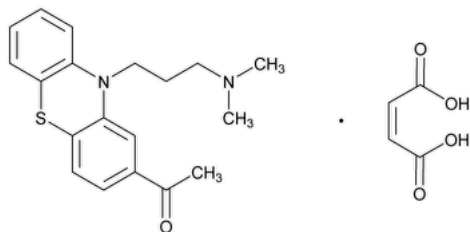
DOI: https://doi.org/10.31003/USPNF_M134_04_01

DOI Ref: gn6t6

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Acepromazine Maleate

 $C_{19}H_{22}N_2OS \cdot C_4H_4O_4$

442.53

Ethanone, 1-[10-[3-(dimethylamino)propyl]-10H-phenothiazin-2-yl]-, (Z)-2-butenedioate (1:1);

10-[3-(Dimethylamino)propyl]phenothiazin-2-yl methyl ketone maleate (1:1) CAS RN[®]: 3598-37-6; UNII: 37862HP2OM.

DEFINITION

Acepromazine Maleate contains NLT 98.0% and NMT 101.0% of acepromazine maleate ($C_{19}H_{22}N_2OS \cdot C_4H_4O_4$), calculated on the anhydrous basis.

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)
- **B.** The retention time of the major peak for acepromazine 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

Sample solution: 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 Acepromazine Maleate taken:

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

r_U = peak area response from the *Sample solution*

r_S = peak area response from the *Standard solution*

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

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](#)

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

Topic/Question	Contact	Expert Committee
ACEPROMAZINE MALEATE	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. PF 29(6)

Current DocID: GUID-4931EEC7-CE84-4DA3-AB2E-0D16ED840FBF_4_en-US

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