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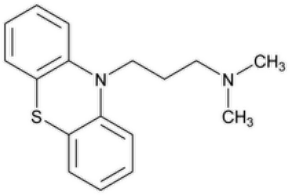
Promazine Hydrochloride



• HCl

$C_{17}H_{20}N_2S \cdot HCl$ 320.88

10-*H*-Phenothiazine-10-propanamine, *N*,*N*-dimethyl-, monohydrochloride;

10-3-(Dimethylamino)propylphenothiazine monohydrochloride CAS RN®: 53-60-1; UNII: U16EOR79U4.

DEFINITION

Promazine Hydrochloride, dried at 105° for 2 h, contains NLT 98.0% and NMT 102.0% of promazine hydrochloride ($C_{17}H_{20}N_2S \cdot HCl$).

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

IDENTIFICATION

• **A. SPECTROSCOPIC IDENTIFICATION TESTS ⟨197⟩, *Infrared Spectroscopy*:** 197K

Change to read:

• **B. ▲SPECTROSCOPIC IDENTIFICATION TESTS ⟨197⟩, *Ultraviolet-Visible Spectroscopy*:** 197U▲ (USP 1-May-2022)

Analytical wavelengths: 252 and 301 nm

Diluent: 0.1 N hydrochloric acid

Sample solution A: 50 µg/mL of previously dried Promazine Hydrochloride in *Diluent*

Sample solution B: 5 µg/mL of Promazine Hydrochloride from *Sample solution A* in *Diluent*

Blank: *Diluent*

Analysis: Determine the absorbance of *Sample solution A* at 301 nm and the absorbance of *Sample solution B* at 252 nm.

Calculate the absorbance ratio:

$$\text{Result} = 10 \times (A_{252}/A_{301})$$

A_{252} = absorbance of *Sample solution B* at 252 nm

A_{301} = absorbance of *Standard solution A* at 301 nm

Acceptance criteria: 7.1–7.9

• **C. IDENTIFICATION TESTS—GENERAL ⟨191⟩, *Chemical Identification Tests, Chloride*:** Meets the requirements

ASSAY

Change to read:

• **PROCEDURE**

[NOTE—Use low-actinic glassware.]

Diluent: 0.1 N hydrochloric acid

Standard solution: 50 µg/mL of USP Promazine Hydrochloride RS in *Diluent*

Sample solution: 50 µg/mL of previously dried Promazine Hydrochloride in *Diluent*

Instrumental conditions

▲(See *Ultraviolet-Visible Spectroscopy ⟨857⟩*.)▲ (USP 1-May-2022)

Mode: UV

Analytical wavelength: 301 nm

Cell: 1 cm

Blank: *Diluent*

Analysis

Samples: *Standard solution* and *Sample solution*

Without delay, concomitantly determine the absorbances of the *Standard solution* and the *Sample solution*.

Calculate the percentage of promazine hydrochloride ($C_{17}H_{20}N_2S \cdot HCl$) in the portion of Promazine Hydrochloride taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Promazine Hydrochloride RS in the *Standard solution* (µg/mL)

C_U = concentration of Promazine Hydrochloride in the *Sample solution* (µg/mL)

Acceptance criteria: 98.0%–102.0% on the previously dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

Delete the following:

▲• **Selenium ⟨291⟩**

Sample: 100 mg of Promazine Hydrochloride and 200 mg of magnesium oxide

Acceptance criteria: The absorbance of the *Test Solution* is NMT one-half that of the *Standard Solution* (NMT 0.003%)▲ (USP 1-May-2022)

• **Organic Impurities**

[Note—Perform this test under conditions of subdued light and with no unnecessary delays between the preparation of the solutions and the development of the chromatographic plate.]

Standard stock solution: 0.4 mg/mL of USP Promazine Hydrochloride RS in methanol

Standard solutions: See *Table 1*. Dilute the *Standard stock solution* with methanol to obtain *Standard solutions* having the following compositions.

Table 1

Standard Solution	Dilution	Concentration (µg/mL)	Percentage (%, for comparison with *Sample solution*)
A	Undiluted	400	2.0
B	1 in 2	200	1.0
C	3 in 10	120	0.6
D	1 in 10	40	0.2

Sample solution: 20 mg/mL of Promazine Hydrochloride in methanol

Chromatographic system

(See *Chromatography ⟨621⟩, General Procedures, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 10 µL

Developing solvent system: Toluene, alcohol, and ammonium hydroxide (95:15:1)

Analysis

Samples: *Standard solutions* and *Sample solution*

Apply separately the *Standard solutions* and the *Sample solution* to a thin-layer chromatographic plate coated with the *Adsorbent*, and allow to dry. Position the plate in a chromatographic chamber and develop the chromatograms in the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate by air drying for 15 min. Examine the plate under short-wavelength UV light. Compare the intensities of any secondary spots observed in the chromatogram of the *Sample solution* with those of the principal spots in the chromatograms of the *Standard solutions*.

Acceptance criteria: The sum of the intensities of secondary spots obtained from the *Sample solution* corresponds to NMT 2.0% of related compounds, with no single impurity corresponding to more than 1.0%.

SPECIFIC TESTS

• **Completeness and Clarity of Solution:** A solution of Promazine Hydrochloride in water (1 in 10) and a solution of Promazine Hydrochloride in chloroform (1 in 10) are practically clear and show NMT a light yellow color.

• **Melting Range or Temperature ⟨741⟩, *Class I*:** 172°–182°, but the range between beginning and end of melting does not exceed 3°

• **pH ⟨791⟩**

Sample solution: A solution of Promazine Hydrochloride in water (1 in 20)

Acceptance criteria: 4.2–5.2

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Promazine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
PROMAZINE HYDROCHLORIDE	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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