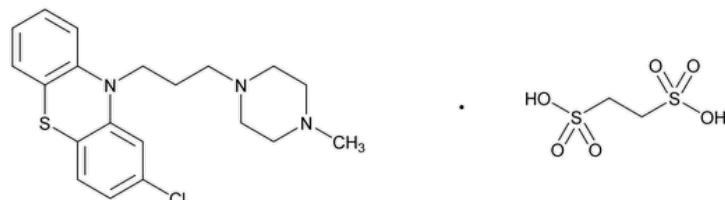


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Prochlorperazine Edisylate



$C_{20}H_{24}ClN_3S \cdot C_2H_6O_6S_2$ 564.14

10*H*-Phenothiazine, 2-chloro-10-[3-(4-methyl-1-piperazinyl)propyl]-,1,2-ethanedithiolate (1:1);

2-Chloro-10-[3-(4-methyl-1-piperazinyl)propyl]phenothiazine 1,2-ethanedithiolate (1:1) CAS RN®: 1257-78-9; UNII: PG20W5VQZS.

DEFINITION

Prochlorperazine Edisylate contains NLT 98.0% and NMT 101.5% of prochlorperazine edisylate ($C_{20}H_{24}ClN_3S \cdot C_2H_6O_6S_2$), calculated on the dried basis.

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

IDENTIFICATION

- **A. IDENTIFICATION—ORGANIC NITROGENOUS BASES (181):** Meets the requirements when [USP Prochlorperazine Maleate RS](#) is used as the standard for comparison
- **B. IDENTIFICATION TESTS—GENERAL, Sulfite(191).**
Sample: Fuse 100 mg with a few pellets of sodium hydroxide.
Acceptance criteria: The cooled melt meets the requirements.

ASSAY

PROCEDURE

Sample solution: Transfer 750 mg of Prochlorperazine Edisylate to a separator containing 40 mL of water, and shake to dissolve.

Analysis: Render the *Sample solution* alkaline with ammonium hydroxide, and extract with three 25-mL portions of ether. Wash the combined ether extracts once with 25 mL of water, discard the washing, and evaporate the ether solution on a steam bath to dryness. Dissolve the residue in 60 mL of glacial acetic acid. Titrate with 0.1 N perchloric acid VS, using crystal violet TS as the indicator. Perform a blank determination (see [Titrimetry \(541\)](#)), and make any necessary corrections. Each mL of 0.1 N perchloric acid is equivalent to 28.21 mg of prochlorperazine edisylate ($C_{20}H_{24}ClN_3S \cdot C_2H_6O_6S_2$).

Acceptance criteria: 98.0%–101.5% on the dried basis

IMPURITIES

- **RESIDUE ON IGNITION (281):** NMT 0.1%

Change to read:

- **▲SELENIUM (291), Procedures, Procedure 1 ▲** (CN 1-JUN-2023)

Sample: 100 mg of Prochlorperazine Edisylate, mixed with 100 mg of magnesium oxide

Acceptance criteria: NMT 30 ppm

- **ORDINARY IMPURITIES (466).**

Standard solution: Methanol and ammonium hydroxide (9:1)

Sample solution: Methanol and ammonium hydroxide (9:1)

Eluant: Chloroform, toluene, alcohol, and ammonium hydroxide (50:50:50:0.5)

Spray reagent: Mix 2 mL of chloroplatinic acid solution (1 in 10) and 50 mL of potassium iodide solution (4 in 100). Dilute with water to 100 mL, and acidify with 1 N hydrochloric acid.

Visualization: 1, followed by *Spray reagent*

SPECIFIC TESTS

- [Loss on Drying \(731\)](#)
- Analysis:** Dry a sample under vacuum at 100° for 3 h.
- Acceptance criteria:** NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **USP REFERENCE STANDARDS (11)**
[USP Prochlorperazine Maleate RS](#)

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

Topic/Question	Contact	Expert Committee
PROCHLORPERAZINE EDISYLATE	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](#)

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