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Prochlorperazine Edisylate Injection

DEFINITION

Prochlorperazine Edisylate Injection is a sterile solution of Prochlorperazine Edisylate in Water for Injection. It contains an amount of prochlorperazine edisylate equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of prochlorperazine ($C_{20}H_{24}ClN_3S$).

[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

ASSAY

• **Procedure**

Buffer: 2.68 g/L of dibasic sodium phosphate heptahydrate in water, adjusted with phosphoric acid to a pH of 3.0

Mobile phase: Acetonitrile and *Buffer* (7:3)

Standard solution: Equivalent to 0.1 mg/mL of prochlorperazine, from USP Prochlorperazine Maleate RS in *Mobile phase*

Sample solution: Transfer a portion of Injection, equivalent to 10 mg of prochlorperazine, to a 100-mL volumetric flask, and dilute with *Mobile phase* to volume.

Chromatographic system

(See *Chromatography (621), System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; packing L1

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 3000 theoretical plates

Tailing factor: NMT 2.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of prochlorperazine ($C_{20}H_{24}ClN_3S$) in the portion of Injection taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of prochlorperazine in the *Standard solution* (mg/mL)

C_U = nominal concentration of prochlorperazine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** NMT 17.9 USP Endotoxin Units/mg of prochlorperazine
- **pH ⟨791⟩:** 4.2–6.2
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, protected from light.
- **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 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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