Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-479F570C-BBB0-4B8C-8DD3-3FFDA5CCDDAE_1_en-US
DOI: https://doi.org/10.31003/USPNF_M69595_01_01
DOI Ref: yji8y

Prochlorperazine Oral Solution

DEFINITION

Prochlorperazine Oral Solution contains an amount of Prochlorperazine Edisylate equivalent to NLT 92.0% and NMT 108.0% 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.**

  Analysis: To 2 mL of Oral Solution add 3 mL of water and 3 or 4 drops of ferric chloride TS.

  Acceptance criteria: A stable red color is produced.

- **B.**

  Analysis: To 1 mL of Oral Solution add 10 mL of bromine TS, previously warmed to room temperature.

  Acceptance criteria: Essentially no color change occurs (distinction from chlorpromazine hydrochloride, which immediately produces a green color).

ASSAY

- **Procedure**

  Ion-pairing solution: Dissolve 4.33 g of sodium 1-octanesulfonate in 500 mL of water. Add 4.0 mL of glacial acetic acid, and dilute with water to 1 L.

  Mobile phase: Acetonitrile, methanol, and *Ion-pairing solution* (40:10:50)

  Diluent: A mixture containing 1000 mL of distilled water, 8.6 mL of concentrated hydrochloric acid, and 1000 mL of methanol

  Internal standard solution: 0.9 mg/mL of trifluoperazine hydrochloride in *Diluent*

  Standard stock solution: 1.0 mg/mL of USP Prochlorperazine Maleate RS in *Diluent*

  Standard solution: 0.09 mg/mL of trifluoperazine hydrochloride from *Internal standard solution* and 0.1 mg/mL of USP Prochlorperazine Maleate RS from *Standard stock solution*, in *Diluent*

  Sample solution: Transfer a quantity of Oral Solution, equivalent to 10.0 mg of prochlorperazine, to a 100-mL volumetric flask, add 10.0 mL of the *Internal standard solution*, and dilute with *Diluent* to volume.

  Chromatographic system

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

  Mode: LC

  Detector: UV 254 nm

  Column: 3.9-mm × 15-cm; 10-µm packing L1

  Flow rate: 1.5 mL/min

  Injection volume: 10 µL

  System suitability

  Sample: *Standard solution*

  [Note—The relative retention times for prochlorperazine and trifluoperazine are 1.0 and 1.3, respectively.]

  Suitability requirements

  Resolution: NLT 2.0 between prochlorperazine and the internal standard

  Tailing factor: NMT 2.0

  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 Oral Solution taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

R_U = peak response ratio of prochlorperazine to the internal standard from the *Sample solution*

R_S = peak response ratio of prochlorperazine to the internal standard from the *Standard solution*

C_S = concentration of USP Prochlorperazine Maleate RS in the *Standard solution* (mg/mL)

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

M_{r1} = molecular weight of prochlorperazine, 373.94

M_{r2} = molecular weight of prochlorperazine maleate, 606.09

Acceptance criteria: 92.0%–108.0%

PERFORMANCE TESTS

• **Deliverable Volume ⟨698⟩:** Meets the requirements for Oral Solution packaged in multi-unit containers

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements for Oral Solution packaged in single-unit containers

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 ORAL SOLUTION	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-479F570C-BBB0-4B8C-8DD3-3FFDA5CCDDAE_1_en-US

DOI: https://doi.org/10.31003/USPNF_M69595_01_01

DOI ref: yji8y