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Prochlorperazine Suppositories

DEFINITION

Prochlorperazine Suppositories contain NLT 90.0% and NMT 110.0% of the labeled amount of prochlorperazine ($C_{20}H_{24}ClN_3S$).

[NOTE—Throughout the following procedure, 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: Place a quantity of Suppositories, equivalent to 5 mg of prochlorperazine, in a test tube. Add 4 mL of dilute hydrochloric acid (1 in 2), warm on a steam bath to melt the solid, and swirl to mix.

Acceptance criteria: A pink color develops in the aqueous layer.

• B.

Analysis: To the solution from *Identification* test A, add 10 mL of bromine TS.

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

ASSAY

• PROCEDURE

Standard solution: Transfer 40 mg of [USP Prochlorperazine Maleate RS](#) to a 250-mL separator containing 75 mL of ether. Add 0.5 mL of 6 N ammonium hydroxide, and extract with four 65-mL portions of dilute hydrochloric acid (1 in 100), collecting the aqueous extracts in a 500-mL volumetric flask. Aerate the combined extracts for 15–20 min to remove dissolved ether. Add dilute hydrochloric acid (1 in 100) to volume. Pass a portion of the solution through filter paper, discarding the first 25 mL of the filtrate. To 25.0 mL of the subsequent filtrate add dilute hydrochloric acid (1 in 100) to make 200.0 mL.

Sample solution: Weigh, mash, and then mix NLT 15 Suppositories. Transfer a weighed quantity of the mass, equivalent to 25 mg of prochlorperazine, to a 100-mL beaker. Dissolve in 50 mL of ether, and transfer to a 250-mL separator with the aid of three 25-mL portions of ether. Proceed as directed for the *Standard solution*, beginning with “Extract with four 65-mL portions of dilute hydrochloric acid (1 in 100)”.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Analytical wavelengths: 254 and 278 nm

Cell: 1 cm

Blank: Dilute hydrochloric acid (1 in 100)

Analysis

Samples: *Standard solution*, *Sample solution*, and *Blank*

Determine the absorbances of the *Standard* and *Sample solutions*, and calculate the differences in the absorbances of the two solutions at 254 and 278 nm.

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

$$\text{Result} = A_U/A_S \times (M_{r1}/M_{r2}) \times (W_S/W_U) \times 100$$

A_U = difference in the absorbances of the *Sample solution* at 254 nm and at 278 nm ($A_{254} - A_{278}$)

A_S = difference in the absorbances of the *Standard solution* at 254 nm and at 278 nm ($A_{254} - A_{278}$)

M_{r1} = molecular weight of prochlorperazine, 373.94

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

W_s = weight of [USP Prochlorperazine Maleate RS](#) in the *Standard solution* (mg)

W_u = nominal amount of prochlorperazine in the *Sample solution* (mg)

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers at a temperature below 37°. Do not expose the unwrapped Suppositories to sunlight.
- **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 SUPPOSITORIES	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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