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Prochlorperazine Maleate Tablets

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DEFINITION

Prochlorperazine Maleate Tablets contain an amount of Prochlorperazine Maleate equivalent to NLT 95.0% and NMT 105.0% of the labeled amount of prochlorperazine ($C_{20}H_{24}ClN_3S$).

[NOTE—Throughout the following procedures, protect the samples, Reference Standards, and solutions from light, and conduct the procedures without delay.]

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

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* (40:15:45)

Standard solution: 0.2 mg/mL of [USP Prochlorperazine Maleate RS](#) in *Mobile phase*

Sample solution: Nominally equivalent to 0.12 mg/mL of prochlorperazine in *Mobile phase* prepared as follows. Transfer an equivalent to about 12 mg of prochlorperazine from finely powdered Tablets (NLT 20), to a 100-mL volumetric flask. Add 60 mL of *Mobile phase*, sonicate for 3 min, and shake by mechanical means for 30 min. Dilute with *Mobile phase* to volume, and filter, discarding the first 10 mL of filtrate.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm. For *Identification B*, use a diode array detector in the range of 210–400 nm.

Column: 3.9-mm × 30-cm; 10 µm packing [L1](#)

Flow rate: 2 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.0%

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 Tablets taken:

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

r_U = peak response of prochlorperazine from the *Sample solution*

r_S = peak response of prochlorperazine 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: 95.0%–105.0%

PERFORMANCE TESTS

Change to read:

- [DISSOLUTION \(711\)](#).

▲Test 1▲ (RB 7-Sep-2022)

Medium: 0.1 N [hydrochloric acid](#); 500 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: [USP Prochlorperazine Maleate RS](#) at a known concentration in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter, and dilute with *Medium*, if necessary, to a concentration that is similar to that of the *Standard solution*.

Instrumental conditions

Mode: UV

Analytical wavelength: 254 nm

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of prochlorperazine ($C_{20}H_{24}ClN_3S$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (M_{r1}/M_{r2}) \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of [USP Prochlorperazine Maleate RS](#) in the *Standard solution*

V = volume of *Medium*, 500 mL

D = dilution factor for *Sample solution*, if needed

M_{r1} = molecular weight of prochlorperazine, 373.94

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

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of prochlorperazine ($C_{20}H_{24}ClN_3S$) is dissolved.

▲Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N [hydrochloric acid](#); 500 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard stock solution: 0.275 mg/mL of [USP Prochlorperazine Maleate RS](#) prepared as follows. Transfer a suitable amount of [USP Prochlorperazine Maleate RS](#) to a suitable volumetric flask. Add 10% of the flask volume of [acetonitrile](#) and 60% of the flask volume of *Medium* and sonicate to dissolve. Dilute with *Medium* to volume.

Standard solution: ($L/500$) mg/mL of prochlorperazine prepared as follows, where L is the label claim in mg/Tablet. Dilute the *Standard stock solution* with *Medium* to obtain a solution with a final concentration of 0.0165 mg/mL of [USP Prochlorperazine Maleate RS](#) for Tablets labeled to contain 5 mg and 0.033 mg/mL of [USP Prochlorperazine Maleate RS](#) for Tablets labeled to contain 10 mg.

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45- μ m pore size, discarding the first 5 mL of filtrate.

Instrumental conditions

Mode: UV

Analytical wavelength: 254 nm

Cell path length: 0.5 cm