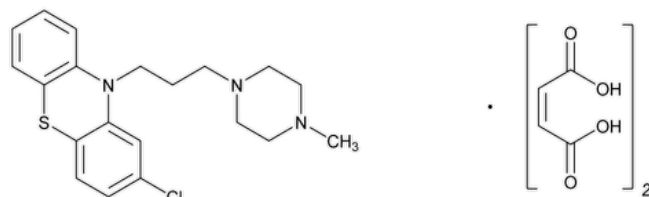


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Prochlorperazine Maleate



$C_{20}H_{24}ClN_3S \cdot 2C_4H_4O_4$ 606.09

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

2-Chloro-10-[3-(4-methylpiperazin-1-yl)propyl]phenothiazine maleate (1:2) CAS RN®: 84-02-6; UNII: 11T801JTL6.

DEFINITION

Prochlorperazine Maleate contains NLT 98.0% and NMT 102.0% of prochlorperazine maleate ($C_{20}H_{24}ClN_3S \cdot 2C_4H_4O_4$), calculated on the dried basis.

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

IDENTIFICATION

Change to read:

- **A.** ▲ **SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197A or 197K. ▲ (CN 1-May-2020)
- **B.** The retention time 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*. Sonicate to dissolve, if needed, prior to final dilution.

Sample solution: 0.2 mg/mL of Prochlorperazine Maleate in *Mobile phase*. Sonicate to dissolve, if needed, prior to final dilution.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 10-μm packing L1 or 4.6-mm × 25-cm; 5-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 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of prochlorperazine maleate ($C_{20}H_{24}ClN_3S \cdot 2C_4H_4O_4$) in the portion of Prochlorperazine Maleate taken:

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

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 = concentration of Prochlorperazine Maleate in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• ORGANIC IMPURITIES

Buffer: 1.36 g/L of [sodium acetate](#) trihydrate in water (0.01 M). Add 2.0 mL of [triethylamine](#) and 6.0 mL of [glacial acetic acid](#) per L of solution.

Solution A: *Buffer*

Solution B: [Acetonitrile](#)

Mobile phase: See [Table 1](#). Return to original conditions, and re-equilibrate the system for about 10 min.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
20	65	35
25	65	35
55	35	65
65	35	65

Diluent: Acetonitrile and water (40:60)

Impurity stock solution: 0.16 mg/mL of [USP Prochlorperazine Related Compound A RS](#) in *Diluent*

Standard stock solution: 0.16 mg/mL of [USP Prochlorperazine Maleate RS](#) in *Diluent*

System suitability solution: 1.6 µg/mL each of [USP Prochlorperazine Maleate RS](#) and [USP Prochlorperazine Related Compound A RS](#) in *Diluent* from the *Standard stock solution* and the *Impurity stock solution*, respectively

Standard solution: 6.4 µg/mL of [USP Prochlorperazine Maleate RS](#) in *Diluent* from the *Standard stock solution*

Sensitivity solution: 0.32 µg/mL of [USP Prochlorperazine Maleate RS](#) in *Diluent* from the *Standard solution*

Sample solution: 0.64 mg/mL of Prochlorperazine Maleate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Column temperature: 50 ± 5°

Flow rate: 2.0 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution*, *Standard solution*, and *Sensitivity solution*

Suitability requirements

Resolution: NLT 2.0 between prochlorperazine related compound A and prochlorperazine, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each individual impurity in the portion of Prochlorperazine Maleate taken:



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