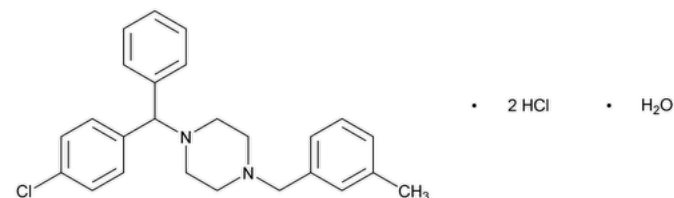


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Meclizine Hydrochloride



$C_{25}H_{27}ClN_2 \cdot 2HCl \cdot H_2O$ 481.89

$C_{25}H_{27}ClN_2 \cdot 2HCl$ 463.88

Piperazine, 1-[(4-chlorophenyl)phenylmethyl]-4-[(3-methylphenyl)methyl]-, dihydrochloride, monohydrate;

1-(p-Chloro-α-phenylbenzyl)-4-(m-methylbenzyl)piperazine dihydrochloride monohydrate CAS RN[®]: 31884-77-2; UNII: HDP7W44CIO.

Anhydrous CAS RN[®]: 1104-22-9; UNII: L997QXC9J1.

DEFINITION

Meclizine Hydrochloride contains NLT 97.0% and NMT 102.0% of $C_{25}H_{27}ClN_2 \cdot 2HCl$, calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)

• **B.** [IDENTIFICATION TESTS—GENERAL, Chloride \(191\)](#).

Sample solution: Dissolve 25 mg in a mixture of 3 mL of 2 N nitric acid and 5 mL of alcohol.

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Mobile phase: Dissolve 1.5 g of sodium 1-heptanesulfonate in 300 mL of water, and mix this solution with 700 mL of acetonitrile. Adjust with 0.1 N sulfuric acid to a pH of 4.

Standard solution: 0.1 mg/mL of [USP Meclizine Hydrochloride RS](#) in Mobile phase

Sample solution: 0.1 mg/mL of Meclizine Hydrochloride in Mobile phase

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

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

Flow rate: 1.3 mL/min

Injection size: 20 μL

System suitability

Sample: Standard solution

Suitability requirements

Relative standard deviation: NMT 1.0%

Analysis

Samples: Standard solution and Sample solution

Calculate the percentage of meclizine hydrochloride ($C_{25}H_{27}ClN_2 \cdot 2HCl$) in the portion of Meclizine Hydrochloride taken:

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

r_U = peak response of meclizine from the Sample solution

r_S = peak response of meclizine from the Standard solution

C_S = concentration of [USP Meclizine Hydrochloride RS](#) in the Standard solution (mg/mL)

C_U = concentration of Meclizine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–102.0% on the anhydrous basis

IMPURITIES

- **RESIDUE ON IGNITION (281):** NMT 0.1%
- **ORGANIC IMPURITIES, PROCEDURE 1**

[NOTE—On the basis of the synthetic route, perform either *Procedure 1* or *Procedure 2*. *Procedure 2* is recommended when the isomeclizine impurity may be present.]

Mobile phase: Dissolve 1.5 g of sodium 1-heptanesulfonate in 300 mL of water, and mix this solution with 700 mL of acetonitrile. Adjust with 0.1 N sulfuric acid to a pH of 4.

System suitability solution: 0.01 mg/mL each of [USP Meclizine Hydrochloride RS](#) and 4-chlorobenzophenone in *Mobile phase*

Standard solution: 2.5 µg/mL of [USP Meclizine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.5 mg/mL of Meclizine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 230 nm

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

Flow rate: 1.3 mL/min

Injection size: 20 µL

System suitability

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

[NOTE—The elution order is meclizine, followed by 4-chlorobenzophenone.]

Suitability requirements

Resolution: NLT 2.0 between meclizine hydrochloride and 4-chlorobenzophenone, *System suitability solution*

Column efficiency: NLT 1800 theoretical plates, determined from the analyte peak, *Standard solution*

Tailing factor: NMT 1.5 for the analyte peak, *Standard solution*

Relative standard deviation: NMT 1.5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Allow the *Sample solution* to elute for NLT three times the retention time of meclizine hydrochloride.

Calculate the percentage of each impurity in the portion of Meclizine Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each impurity from the *Sample solution*

r_S = peak response of meclizine from the *Standard solution*

C_S = concentration of [USP Meclizine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Meclizine Hydrochloride in the *Sample solution* (mg/mL)

F = relative response factor, 0.72 for the 4-chlorobenzophenone peak and 1.0 for all other peaks

Acceptance criteria

Any individual impurity: NMT 0.5%

Total impurities: NMT 1.0%

- **ORGANIC IMPURITIES, PROCEDURE 2**

Mobile phase: Dissolve 5 g of sodium 1-heptanesulfonate in 1000 mL of water, and mix 600 mL of this solution with 400 mL of acetonitrile. Adjust with 0.1 N sulfuric acid to a pH of 4.0 ± 0.1.

System suitability solution: 2.5 µg/mL each of [USP Meclizine Hydrochloride RS](#), [USP Meclizine Related Compound A RS](#), and [USP Meclizine Related Compound B RS](#) in *Mobile phase*

Standard solution: 2.5 µg/mL of [USP Meclizine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.5 mg/mL of Meclizine Hydrochloride in *Mobile phase*. [NOTE—Store this solution no longer than 24 h.]

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

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

Column temperature: 50°

Flow rate: 2.0 mL/min

Injection size: 30 µL