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Carbinoxamine Maleate Tablets

DEFINITION

Carbinoxamine Maleate Tablets contain NLT 93.0% and NMT 107.0% of the labeled amount of carbinoxamine maleate ($C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$).

IDENTIFICATION

Delete the following:

▲• A.

Standard solution: 0.02 mg/mL of [USP Carbinoxamine Maleate RS](#) in dilute sulfuric acid (1 in 70)

Sample solution: Nominally 0.02 mg/mL of carbinoxamine maleate in dilute sulfuric acid (1 in 70), from the Tablets, as directed under [Salts of Organic Nitrogenous Bases \(501\)](#).

Analytical wavelength: 263 ± 2 nm

Acceptance criteria: The absorptivity of the *Sample solution* at 263 nm is within 7.0% of that of the *Standard solution*. ▲2S (USP41)

Add the following:

▲• A. The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲2S (USP41)

Add the following:

▲• B. The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay. ▲2S (USP41)

ASSAY

Change to read:

• PROCEDURE

▲**Solution A:** 2.72 g/L of [monobasic potassium phosphate](#). Adjust with [phosphoric acid](#) to a pH of 4.0.

Solution B: [Methanol](#) and [acetonitrile](#) (80:20)

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	75	25
2	75	25
10	25	75
15	25	75
16	75	25
20	75	25

Diluent 1: [0.1 N hydrochloric acid](#)

Diluent 2: [Methanol](#), [acetonitrile](#), and [water](#) (200:50:750)

System suitability solution: 0.1 mg/mL of [USP Carbinoxamine Maleate RS](#) and 0.01 mg/mL each of [USP Carbinoxamine Related Compound A RS](#) and [USP Carbinoxamine Related Compound B RS](#) in *Diluent 2*

Standard solution: 0.1 mg/mL of [USP Carbinoxamine Maleate RS](#) in *Diluent 2*

Sample solution: Nominally 0.1 mg/mL of carbinoxamine maleate prepared as follows. Transfer a suitable amount of powder from finely powdered Tablets (NLT 20) to a suitable volumetric flask. Add 70% of the flask volume of *Diluent 1* and shake for 15 min, then dilute with

Diluent 2 to volume. Centrifuge the solution and filter the supernatant by passing through a suitable filter of 0.45-µm pore size, discarding the first 2–3 mL of filtrate. Inject the freshly prepared solution immediately.

Chromatographic system

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

Mode: LC

Detector: UV 225 nm. For *Identification A*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 15-cm; 5-µm packing [L7](#)

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 4.0 between carbinoxamine related compound A and carbinoxamine related compound B, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of carbinoxamine maleate ($C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$) in the portion of Tablets taken:

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

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

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

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

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

▲2S (USP41)

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

Change to read:

• [DISSOLUTION \(711\)](#)

Medium: [Water](#); 900 mL

Apparatus 2: 50 rpm

Time: 45 min

Standard solution: [USP Carbinoxamine Maleate RS](#) in *Medium* with a concentration similar to that expected in the *Sample solution*

Sample solution: Filter a portion of the solution under test and dilute with *Medium* as needed.

Instrumental conditions

Mode: UV

Analytical wavelength: Maximum absorbance at about 260 nm

Analysis

Samples: *Standard solution* and *Sample solution*

▲Calculate the percentage of the labeled amount of carbinoxamine maleate ($C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$) dissolved:

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

A_U = absorbance from the *Sample solution*

A_S = absorbance of carbinoxamine maleate from the *Standard solution*

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

V = volume of *Medium*, 900 mL

D = dilution factor for the *Sample solution*

L = label claim (mg/Tablet)

▲2S (USP41)

Tolerances: NLT 75% (Q) of the labeled amount of carbinoxamine maleate ($C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$) is dissolved.

