Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Mar-2019
Document Type: USP Monographs
DocId: GUID-17BA6BA9-D4A7-43DE-A999-2FAE070CFA1F_5_en-US
DOI: https://doi.org/10.31003/USPNF_M12920_05_01
DOI Ref: mj3sd

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.

Change to read:

• **Uniformity of Dosage Units ⟨905⟩:** ▲Meet the requirements▲2S *(USP41)*

IMPURITIES

Change to read:

• **▲Organic Impurities**

Solution A, Solution B, Mobile phase, Diluent 1, Diluent 2, and **System suitability solution:** Prepare as directed in the *Assay*.

Standard stock solution: 0.028 mg/mL of USP Carbinoxamine Maleate RS (equivalent to 0.02 mg/mL of ▲carbinoxamine)▲ (ERR 1-Mar-2019) and 0.02 mg/mL each of USP Carbinoxamine Related Compound A RS and USP Carbinoxamine Related Compound B RS in *Diluent 2*

Standard solution: 0.0014 mg/mL of USP Carbinoxamine Maleate RS (equivalent to 0.001 mg/mL of ▲carbinoxamine)▲ (ERR 1-Mar-2019) and 0.001 mg/mL each of USP Carbinoxamine Related Compound A RS and USP Carbinoxamine Related Compound B RS in *Diluent 2*, from *Standard stock solution*

Sample solution: Nominally 1.0 mg/mL of carbinoxamine maleate prepared as follows. Transfer a suitable quantity of powder from finely powdered Tablets (NLT 20) to a suitable volumetric flask. Add 75% of the flask volume of *Diluent 1*, shake for 15 min, and 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

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*

Relative standard deviation: NMT 5.0% for each corresponding compound present in the *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carbinoxamine related compound A and carbinoxamine related compound B 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 related compound A or carbinoxamine related compound B from the *Sample solution*

r_S = peak response of the corresponding Reference Standard from the *Standard solution*

C_S = concentration of the corresponding Reference Standard in the *Standard solution* (mg/mL)

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

Calculate the percentage of each unspecified degradation product in the portion of Tablets taken:

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

r_U = peak response of each unspecified degradation product from the *Sample solution*

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

C_S = concentration of USP Carbinoxamine Maleate RS▲(as the free base)▲ (ERR 1-Mar-2019) in the *Standard solution* (mg/mL)

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

Acceptance criteria: See *Table 2*. The reporting threshold is 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Carbinoxamine related compound C[a,b]	0.68	—
Carbinoxamine	1.0	—
Carbinoxamine related compound B	1.25	0.2
Carbinoxamine related compound A	1.36	0.2
Each unspecified degradation product	—	0.2
Total degradation products	—	2.0

[a] Process impurity included for identification only and not included in the calculation of total degradation products.

[b] *N*,*N*-Dimethyl-2-[phenyl(pyridin-2-yl)methoxy]ethan-1-amine.

▲2S *(USP41)*

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight, light-resistant containers, ▲and store at controlled room temperature.▲2S *(USP41)*

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Carbinoxamine Maleate RS

▲ USP Carbinoxamine Related Compound A RS
(4-Chlorophenyl)(pyridin-2-yl)methanone.
$C_{12}H_8ClNO$ 217.65

USP Carbinoxamine Related Compound B RS
(4-Chlorophenyl)(pyridin-2-yl)methanol.
$C_{12}H_{10}ClNO$ 219.67▲2S *(USP41)*

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
CARBINOXAMINE MALEATE TABLETS	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 42(2)

Current DocID: GUID-17BA6BA9-D4A7-43DE-A999-2FAE070CFA1F_5_en-US

DOI: https://doi.org/10.31003/USPNF_M12920_05_01

DOI ref: mj3sd