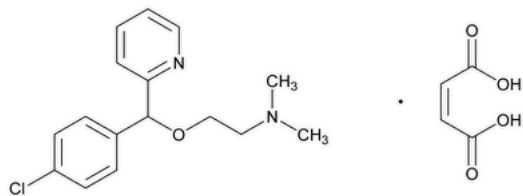


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Carbinoxamine Maleate



$C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$ 406.86
Ethanamine, 2-[(4-chlorophenyl)-2-pyridinylmethoxy]-N,N-dimethyl-, (Z)-2-butenedioate (1:1);
2-[p-Chloro-α-[2-(dimethylamino)ethoxy]benzyl]pyridine maleate (1:1) CAS RN®: 3505-38-2.

DEFINITION

Carbinoxamine Maleate contains NLT 98.0% and NMT 102.0% of carbinoxamine maleate ($C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy](#): 197A or 197K [▲](#) (CN 1-May-2020)
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** 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**

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: [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*

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

Sample solution: 0.1 mg/mL of Carbinoxamine Maleate in *Diluent*

Chromatographic system

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

Mode: LC

Detector: UV 225 nm. For *Identification B*, 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 0.73%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carbinoxamine maleate ($C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$) in the portion of Carbinoxamine Maleate 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 = concentration of Carbinoxamine 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**

Solution A, Solution B, Mobile phase, Diluent, System suitability solution, and Chromatographic system: Proceed as directed in the Assay.

Standard stock solution: 0.07 mg/mL of [USP Carbinoxamine Maleate RS](#) (equivalent to 0.05 mg/mL of carbinoxamine) and 0.05 mg/mL each of [USP Carbinoxamine Related Compound A RS](#), [USP Carbinoxamine Related Compound B RS](#), and [USP Carbinoxamine Related Compound C RS](#) (as the free base) in *Diluent*

Standard solution: 0.0014 mg/mL of [USP Carbinoxamine Maleate RS](#) (equivalent to 0.001 mg/mL of carbinoxamine) and 0.001 mg/mL each of [USP Carbinoxamine Related Compound A RS](#), [USP Carbinoxamine Related Compound B RS](#), and [USP Carbinoxamine Related Compound C RS](#) (as the free base) in *Diluent*, from *Standard stock solution*

Sample solution: 1.0 mg/mL of Carbinoxamine Maleate in *Diluent*

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, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of carbinoxamine related compound A, carbinoxamine related compound B, and carbinoxamine related compound C in the portion of Carbinoxamine Maleate taken:

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

r_U = peak response of carbinoxamine related compound A, carbinoxamine related compound B, or carbinoxamine related compound C 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 = concentration of Carbinoxamine Maleate in the *Sample solution* (mg/mL)

Calculate the percentage of any other individual unspecified impurity in the portion of Carbinoxamine Maleate taken:

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

r_U = peak response of any other individual unspecified impurity from the *Sample solution*

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