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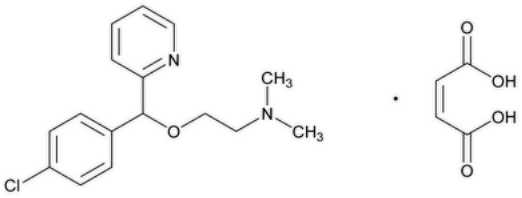
Carbinoxamine Maleate



$C_{16}H_{19}ClN_2O \cdot C_4H_4O_4$ 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*

C_S = concentration of USP Carbinoxamine Maleate RS (as the free base) in the *Standard solution* (mg/mL)

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

Acceptance criteria: See *Table 2*.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Carbinoxamine related compound C	0.68	0.1
Carbinoxamine	1.0	—
Carbinoxamine related compound B	1.25	0.1
Carbinoxamine related compound A	1.36	0.1
Any other individual unspecified impurity	—	0.10
Total impurities	—	1.5

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample: In a solution (1 in 100)

Acceptance criteria: 4.6–5.1

• **Loss on Drying** ⟨731⟩

Analysis: Dry at 105° for 2 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **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

USP Carbinoxamine Related Compound C RS

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

$C_{16}H_{20}N_2O \cdot C_2H_2O_4$ 346.38

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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