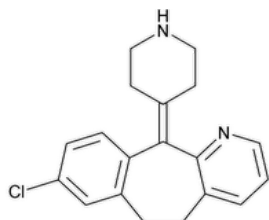


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Desloratadine



$C_{19}H_{19}ClN_2$ 310.82

Benzo[5,6]cyclohepta[1,2-*b*]pyridine, 8-chloro-6,11-dihydro-11-(4-piperidinylidene)-, 5*H*-;

8-Chloro-6,11-dihydro-11-(piperidin-4-ylidene)-5*H*-benzo[5,6]cyclohepta[1,2-*b*]pyridine CAS RN[®]: 100643-71-8; UNII: FVF865388R.

DEFINITION

Desloratadine contains NLT 98.0% and NMT 102.0% of desloratadine ($C_{19}H_{19}ClN_2$), calculated on the anhydrous and solvent-free basis.

IDENTIFICATION

Change to read:

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

Buffer: Dissolve 0.865 g of sodium dodecyl sulfate in water, add 0.5 mL of trifluoroacetic acid, and dilute with water to 1 L.

Mobile phase: Acetonitrile and *Buffer* (43:57)

System suitability solution: 0.08 mg/mL of [USP Desloratadine RS](#) and 0.2 µg/mL of [USP Desloratadine Related Compound B RS](#) in *Mobile phase*

Standard solution: 0.08 mg/mL of [USP Desloratadine RS](#) in *Mobile phase*

Sample solution: 0.08 mg/mL of Desloratadine in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4.6-mm × 25-cm; 4-µm packing L1

Column temperature 35°

Flow rate: 1 mL/min

Injection volume: 100 µL

Run time: NLT 2 times the retention time of desloratadine

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between desloratadine related compound B and desloratadine, *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 desloratadine ($C_{19}H_{19}ClN_2$) in the portion of Desloratadine taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 98.0%–102.0% on the anhydrous and solvent-free basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

• **ORGANIC IMPURITIES, PROCEDURE 1**

Use *Organic Impurities, Procedure 1*, when the impurity profile includes desloratadine related compound B or fluorodesloratadine.

Buffer, Mobile phase, System suitability solution, Sample solution, and Chromatographic system: Proceed as directed in the Assay.

Standard solution: 0.08 µg/mL of [USP Desloratadine RS](#) in *Mobile phase*

System suitability

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

Suitability requirements

Resolution: NLT 2.0 between desloratadine related compound B and desloratadine, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 10.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Desloratadine 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 desloratadine from the *Standard solution*

C_S = concentration of [USP Desloratadine RS](#) in the *Standard solution* (µg/mL)

C_U = concentration of Desloratadine in the *Sample solution* (µg/mL)

F = relative response factor (see [Table 1](#))

Acceptance criteria: See [Table 1](#). The reporting threshold is 0.05%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Fluorodesloratadine ^a	0.8	0.6	0.2
Desloratadine related compound B	0.9	0.6	0.3
Desloratadine	1.0	—	—
Any other individual unspecified impurity	—	1.00	0.10
Total impurities	—	—	0.4

^a 8-Chloro-11-fluoro-11-(piperidin-4-yl)-6,11-dihydro-5H-benzo[5,6]cyclohepta[1,2-b]pyridine.