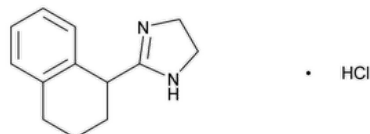


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Tetrahydrozoline Hydrochloride



$C_{13}H_{16}N_2 \cdot HCl$

236.74

1*H*-Imidazole, 4,5-dihydro-2-(1,2,3,4-tetrahydro-1-naphthalenyl)-, monohydrochloride;

2-(1,2,3,4-Tetrahydro-1-naphthyl)-2-imidazoline monohydrochloride CAS RN®: 522-48-5; UNII: 0Yzt43HS7D.

DEFINITION

Tetrahydrozoline Hydrochloride contains NLT 98.0% and NMT 102.0% of tetrahydrozoline hydrochloride ($C_{13}H_{16}N_2 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

- **A. [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy](#):** 197A or 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C. [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Chemical Identification Tests, Chloride](#)**

Sample solution: 5 mg/mL

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Buffer: 2.64 g/L of [dibasic ammonium phosphate](#) in [water](#); adjusted with [ammonium hydroxide](#) to a pH of 9.0

Mobile phase: [Acetonitrile](#) and *Buffer* (15:85)

Standard solution: 0.025 mg/mL of [USP Tetrahydrozoline Hydrochloride RS](#) in [water](#)

Sample solution: 0.025 mg/mL of Tetrahydrozoline Hydrochloride in [water](#)

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 3.5-μm packing [L1](#)

Column temperature: 37°

Flow rate: 1.2 mL/min

Injection volume: 25 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of tetrahydrozoline hydrochloride ($C_{13}H_{16}N_2 \cdot HCl$) in the portion of Tetrahydrozoline Hydrochloride taken:

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

r_U = peak area from the *Sample solution*

r_s = peak area from the *Standard solution*

C_s = concentration of [USP Tetrahydrozoline Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_u = concentration of Tetrahydrozoline Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- **RESIDUE ON IGNITION** (281): NMT 0.1%

Change to read:

• ORGANIC IMPURITIES

▲ **Buffer:** Dissolve 4 g of [sodium dodecyl sulfate](#) in 600 mL [water](#). Add 3 mL of [triethylamine](#) and adjust with [orthophosphoric acid](#) to a pH of 2.0.

Mobile phase: [Methanol](#), [acetonitrile](#), and *Buffer* (26.5: 26.5: 47)

System suitability solution: 2 mg/mL of [USP Tetrahydrozoline Hydrochloride RS](#), and 2 µg/mL each of [USP Tetrahydrozoline Related Compound A RS](#), [USP Tetrahydrozoline Related Compound B RS](#), [USP Tetrahydrozoline Related Compound C RS](#), [USP Tetrahydrozoline Related Compound D RS](#), and [USP Tetrahydrozoline Related Compound E RS](#) in *Mobile phase*

Standard solution: 2 µg/mL of [USP Tetrahydrozoline Hydrochloride RS](#) in *Mobile phase*

Sensitivity solution: 1 µg/mL of [USP Tetrahydrozoline Hydrochloride RS](#) in *Mobile phase* from the *Standard solution*

Sample solution: 2 mg/mL of Tetrahydrozoline Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 210 nm

Column: 4.6-mm × 15-cm; 4-µm packing [L87](#)

Flow rate: 1.0 mL/min

Injection volume: 10 µL

Run time: NLT 3 times the retention time of tetrahydrozoline

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between tetrahydrozoline and tetrahydrozoline related compound B, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of any individual impurity in the portion of Tetrahydrozoline Hydrochloride taken:

$$\text{Result} = (r_u/r_s) \times (C_s/C_u) \times (1/F) \times 100$$

r_u = peak response of any individual impurity from the *Sample solution*

r_s = peak response of tetrahydrozoline from the *Standard solution*

C_s = concentration of [USP Tetrahydrozoline Hydrochloride RS](#) in the *Standard solution* (µg/mL)

C_u = concentration of Tetrahydrozoline Hydrochloride 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