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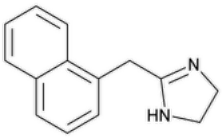
Naphazoline Hydrochloride



$C_{14}H_{14}N_2 \cdot HCl$ 246.74

1*H*-Imidazole, 4,5-dihydro-2-(1-naphthalenylmethyl)-, monohydrochloride;

2-(1-Naphthylmethyl)-2-imidazoline monohydrochloride CAS RN®: 550-99-2; UNII: MZ1131787D.

DEFINITION

Naphazoline Hydrochloride contains NLT 98.0% and NMT 102.0% of naphazoline hydrochloride ($C_{14}H_{14}N_2 \cdot HCl$), calculated on the dried 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*.

• **C.** **Identification Tests—General, *Chloride*⟨191⟩**

Sample solution: 10 mg/mL in water

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Buffer: In a 1000-mL volumetric flask, dissolve 3.0 g of monobasic potassium phosphate in 800 mL of water. Add 3.0 mL of triethylamine, adjust with phosphoric acid to a pH of 3.0, and dilute with water to volume.

Mobile phase: Acetonitrile and *Buffer* (20:80)

Standard solution: 0.05 mg/mL of USP Naphazoline Hydrochloride RS in water

Sample solution: 0.05 mg/mL of Naphazoline Hydrochloride in water

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 4.0-mm × 25-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 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 naphazoline hydrochloride ($C_{14}H_{14}N_2 \cdot HCl$) in the portion of Naphazoline Hydrochloride 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 Naphazoline Hydrochloride RS in the *Standard solution* (mg/mL)

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

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

IMPURITIES

- **Residue on Ignition ⟨281⟩:** NMT 0.2%
- **Organic Impurities**

Solution A: Acetonitrile, glacial acetic acid, and water (30:0.5:70)

Mobile phase: 1.1 g/L of anhydrous sodium 1-octanesulfonate in *Solution A*

System suitability solution: 0.025 mg/mL of USP Naphazoline Hydrochloride RS and 0.05 mg/mL of 1-naphthylacetic acid in *Mobile phase*

Standard solution: 0.5 µg/mL each of USP Naphazoline Hydrochloride RS and USP Naphazoline Related Compound A RS in *Mobile phase*

Sample solution: 0.5 mg/mL of Naphazoline Hydrochloride in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm

Column: 4.0-mm × 25-cm; 3-µm or 5-µm packing L7

Flow rate: 1 mL/min

Injection volume: 20 µL

Run time: NLT 3 times the retention time of the naphazoline peak

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 5.0 between the naphazoline and 1-naphthylacetic acid peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of naphazoline related compound A in the portion of Naphazoline Hydrochloride taken:

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

r_U = peak response of naphazoline related compound A from the *Sample solution*

r_S = peak response of naphazoline related compound A from the *Standard solution*

C_S = concentration of USP Naphazoline Related Compound A RS in the *Standard solution* (mg/mL)

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

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

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

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

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

C_S = concentration of USP Naphazoline Hydrochloride RS in the *Standard solution* (mg/mL)

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

Acceptance criteria

Individual impurities: See *Table 1*. Disregard any impurity peaks less than 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Naphazoline related compound A	0.76	0.1
Naphazoline	1.0	—
1-Naphthylacetic acid	1.4	0.10
Any individual unspecified	—	0.10

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Name	Relative Retention Time	Acceptance Criteria, NMT (%)
impurity		
Total impurities	—	0.5

SPECIFIC TESTS

- **pH** ⟨791⟩

  Sample solution: 10 mg/mL in carbon dioxide-free water

  Acceptance criteria: 5.0–6.6. The *Sample solution* is clear and colorless.

- **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 Naphazoline Hydrochloride RS

  USP Naphazoline Related Compound A RS

  N-(2-Aminoethyl)-2-(naphthalen-1-yl)acetamide.

  $C_{14}H_{16}N_2O$ 228.29

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

Topic/Question	Contact	Expert Committee
NAPHAZOLINE HYDROCHLORIDE	Documentary Standards Support	SM32020 Small Molecules 3

Chromatographic Database Information: Chromatographic Database

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