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Naphazoline Hydrochloride Nasal Solution

DEFINITION

Naphazoline Hydrochloride Nasal Solution is a solution of Naphazoline Hydrochloride in water adjusted to a suitable pH and tonicity. It contains NLT 90.0% and NMT 110.0% of the labeled amount of naphazoline hydrochloride ($C_{14}H_{14}N_2 \cdot HCl$).

IDENTIFICATION

- **A.** The retention time of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Mobile phase: Dissolve 1.1 g of sodium 1-heptanesulfonate in 400 mL of water. Add 250 mL of acetonitrile and 10 mL of glacial acetic acid, and dilute with water to 1000 mL. Sonicate for 10 min to obtain a solution having a pH of about 3.5.

Standard solution: 0.25 mg/mL of [USP Naphazoline Hydrochloride RS](#) in water

Sample solution: Equivalent to 0.25 mg/mL of naphazoline hydrochloride in water from Nasal Solution

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 4-mm × 30-cm; packing L11

Flow rate: 2 mL/min

Injection volume: 15 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of naphazoline hydrochloride ($C_{14}H_{14}N_2 \cdot HCl$) in the portion of Nasal Solution 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 = nominal concentration of naphazoline hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **USP REFERENCE STANDARDS (11).**
[USP Naphazoline Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
NAPHAZOLINE HYDROCHLORIDE NASAL SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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