Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-Dec-2014
Document Type: USP Monographs
DocId: GUID-AC1F362C-076A-4B62-84AF-F9FA4E978A99_1_en-US
DOI: https://doi.org/10.31003/USPNF_M55730_01_01
DOI Ref: aq168

Naphazoline Hydrochloride Ophthalmic Solution

DEFINITION

Naphazoline Hydrochloride Ophthalmic Solution is a sterile, buffered solution of Naphazoline Hydrochloride in water adjusted to a suitable tonicity. It contains NLT 90.0% and NMT 115.0% of the labeled amount of naphazoline hydrochloride ($C_{14}H_{14}N_2 \cdot HCl$). It contains a suitable preservative.

IDENTIFICATION

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

ASSAY

- **Procedure**

Buffer: Dissolve 3 g of monobasic potassium phosphate in 1 L of water, and add 3 mL of triethylamine. Adjust with phosphoric acid to a pH of 3.

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

Standard solution: 0.05 mg/mL of USP Naphazoline Hydrochloride RS in *Mobile phase*

Sample solution: Equivalent to 0.05 mg/mL of naphazoline hydrochloride in *Mobile phase* from Ophthalmic Solution

Chromatographic system

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

Mode: LC

Detector: UV 285 nm or diode array. [Note—Use diode array detector to perform *Identification* test *B*.]

Column: 4.6-mm × 15-cm; packing L10

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

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 Ophthalmic 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%–115.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 5.5–7.0

• **Sterility Tests ⟨71⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight 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 OPHTHALMIC 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. PF 39(5)

Current DocID: GUID-AC1F362C-076A-4B62-84AF-F9FA4E978A99_1_en-US

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