

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-Dec-2014
 Document Type: USP Monographs
 DocId: GUID-EA7E2B76-1E0A-44D3-A80B-6618BEBD4DDD_1_en-US
 DOI: https://doi.org/10.31003/USPNF_M59635_01_01
 DOI Ref: b7rp8

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Oxymetazoline Hydrochloride Ophthalmic Solution

DEFINITION

Oxymetazoline Hydrochloride Ophthalmic Solution is a sterile, buffered solution of Oxymetazoline Hydrochloride in water adjusted to a suitable tonicity. It contains NLT 90.0% and NMT 110.0% of the labeled amount of oxymetazoline hydrochloride ($C_{16}H_{24}N_2O \cdot HCl$). 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

Mobile phase: Methanol, 1 M sodium acetate, glacial acetic acid, and water (40:10:4:46)

Standard solution: Prepare a solution of [USP Oxymetazoline Hydrochloride RS](#) in *Mobile phase* having a known concentration approximately equal to the labeled concentration of the Ophthalmic Solution.

Sample solution: Use the Ophthalmic Solution.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm or diode array. [NOTE—Use diode array detector to perform *Identification* test B.]

Column: 4.6-mm × 25-cm; packing L9

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for five replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of oxymetazoline hydrochloride ($C_{16}H_{24}N_2O \cdot HCl$) 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 Oxymetazoline Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of oxymetazoline hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- **pH (791):** 5.8–6.8
- **STERILITY TESTS (71):** Meets the requirements

ADDITIONAL REQUIREMENTS

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

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

| Topic/Question | Contact | Expert Committee |
|--|---|---------------------------|
| OXYMETAZOLINE HYDROCHLORIDE OPHTHALMIC SOLUTION | Documentary Standards Support | SM52020 Small Molecules 5 |
| REFERENCE STANDARD SUPPORT | RS Technical Services RSTECH@usp.org | SM52020 Small Molecules 5 |

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 39(5)

Current DocID: GUID-EA7E2B76-1E0A-44D3-A80B-6618BEBD4DDD_1_en-US

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