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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  $\times$  25-cm; packing L9

**Flow rate:** 1 mL/min

**Injection volume:** 20  $\mu$ L

#### 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	<a href="#">Documentary Standards Support</a>	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	SM52020 Small Molecules 5

**Chromatographic Database Information:** [Chromatographic Database](#)

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