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Oxymetazoline Hydrochloride Nasal Solution

DEFINITION

Oxymetazoline Hydrochloride Nasal Solution is a 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 ($C_{16}H_{24}N_2O \cdot HCl$).

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.

ASSAY

• PROCEDURE

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

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 Nasal Solution.

Sample solution: Nasal Solution

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

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 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 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):** 4.0–6.5

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 NASAL 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:

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