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Oxymetazoline Hydrochloride



$C_{16}H_{24}N_2O \cdot HCl$ 296.84

Phenol, 3-[(4,5-dihydro-1H-imidazol-2-yl)methyl]-6-(1,1-dimethylethyl)-2,4-dimethyl-, monohydrochloride;

6-*tert*-Butyl-3-(2-imidazolin-2-ylmethyl)-2,4-dimethylphenol monohydrochloride CAS RN®: 2315-02-8.

DEFINITION

Oxymetazoline Hydrochloride contains NLT 98.5% and NMT 101.5% of oxymetazoline hydrochloride ($C_{16}H_{24}N_2O \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197M](#) ▲ (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** [IDENTIFICATION TESTS—GENERAL, Chloride \(191\)](#).
Sample solution: 50 mg in 3 mL of water
Analysis: To the *Sample solution* add 1 mL of 6 N ammonium hydroxide. Filter, and acidify the filtrate with nitric acid.
Acceptance criteria: The filtrate meets the requirements.

ASSAY

• PROCEDURE

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

Standard solution: 0.5 mg/mL of [USP Oxymetazoline Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.5 mg/mL of Oxymetazoline Hydrochloride in *Mobile phase*

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 0.55% for five replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oxymetazoline hydrochloride ($C_{16}H_{24}N_2O \cdot HCl$) in the portion of Oxymetazoline Hydrochloride 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 = concentration of Oxymetazoline Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.5%–101.5% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **ORGANIC IMPURITIES**

Buffer: 1.36 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 3.0.

Mobile phase: See [Table 1](#). Return to the original conditions, and re-equilibrate the system.

Table 1

Time (min)	Buffer (%)	Acetonitrile (%)
0	70	30
5	70	30
20	15	85
35	15	85

System suitability solution: 1.0 mg/mL of [USP Oxymetazoline Hydrochloride RS](#) and 1.5 µg/mL of [USP Oxymetazoline Related Compound A RS](#) in water

Standard solution: 1.0 µg/mL of [USP Oxymetazoline Hydrochloride RS](#) and 1.5 µg/mL of [USP Oxymetazoline Related Compound A RS](#) in water

Sample solution: 1.0 mg/mL of Oxymetazoline Hydrochloride in water

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 1.5 between oxymetazoline related compound A and oxymetazoline peaks

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oxymetazoline related compound A in the portion of Oxymetazoline Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of oxymetazoline related compound A from the *Sample solution*

r_S = peak response of oxymetazoline related compound A from the *Standard solution*

C_S = concentration of [USP Oxymetazoline Related Compound A RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Oxymetazoline Hydrochloride in the *Sample solution* (mg/mL)

Calculate the percentage of each individual unspecified impurity in the portion of Oxymetazoline Hydrochloride taken: