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Xylometazoline Hydrochloride Nasal Solution

DEFINITION

Xylometazoline Hydrochloride Nasal Solution is an isotonic solution of Xylometazoline Hydrochloride in water. It contains NLT 90.0% and NMT 110.0% of the labeled amount of xylometazoline hydrochloride ($C_{16}H_{24}N_2 \cdot HCl$).

IDENTIFICATION

Change to read:

• **A.** ▲The UV spectrum of the xylometazoline peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2019)

Add the following:

▲• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.▲ (USP 1-Aug-2019)

ASSAY

Change to read:

• **Procedure**

▲**Solution A:** 1.4 g/L of monobasic potassium phosphate. Adjust with phosphoric acid to a pH of 3.0.

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	70	30
5	70	30
20	15	85
35	15	85
37	70	30
45	70	30

System suitability solution: 0.01 mg/mL each of USP Xylometazoline Hydrochloride RS and USP Xylometazoline Related Compound A RS in water

Standard solution: 0.05 mg/mL of USP Xylometazoline Hydrochloride RS in water

Sample solution: Nominally 0.05 mg/mL of xylometazoline hydrochloride from a suitable volume of Nasal Solution in water

Chromatographic system

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

Mode: LC

Detector: UV 220 nm. For *Identification A*, use a diode array detector in the range of 210–300 nm.

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

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times are given in *Table 2*.]

Suitability requirements

Resolution: NLT 2.0 between xylometazoline related compound A and xylometazoline, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of xylometazoline hydrochloride ($C_{16}H_{24}N_2 \cdot HCl$) in the portion of Nasal Solution taken:

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

r_U = peak response of xylometazoline from the *Sample solution*

r_S = peak response of xylometazoline from the *Standard solution*

C_S = concentration of USP Xylometazoline Hydrochloride RS in the *Standard solution* (mg/mL)

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

▲ (USP 1-Aug-2019)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

Add the following:

▲• **ORGANIC IMPURITIES**

Solution A, Solution B, Mobile phase, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 0.001 mg/mL of USP Xylometazoline Hydrochloride RS in water

Sensitivity solution: 0.5 µg/mL of USP Xylometazoline Hydrochloride RS from the *Standard solution* in water

Sample solution: Nominally 0.5 mg/mL of xylometazoline hydrochloride from a suitable volume of Nasal Solution in water

System suitability

Samples: *System suitability solution*, *Standard solution*, and *Sensitivity solution*

[NOTE—The relative retention times are given in *Table 2*.]

Suitability requirements

Resolution: NLT 2.0 between xylometazoline related compound A and xylometazoline, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each degradation product in the portion of Nasal Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

r_U = peak response of each degradation product from the *Sample solution*

r_S = peak response of xylometazoline from the *Standard solution*

C_S = concentration of USP Xylometazoline Hydrochloride RS in the *Standard solution* (mg/mL)

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

F = relative response factor for the corresponding degradation product (see *Table 2*)

Acceptance criteria: See *Table 2*. The reporting threshold is 0.10%.

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Xylometazoline related compound A	0.79	0.67	0.2
Xylometazoline	1.0	—	—
Any individual unspecified degradation product	—	1.0	0.2
Total degradation products	—	—	0.5▲ (USP 1-Aug-2019)

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 5.0–7.5

Add the following:

▲• **Microbial Enumeration Tests** ⟨61⟩ and **Tests for Specified Microorganisms** ⟨62⟩**:** The total aerobic microbial count does not exceed 10^2 cfu/g, and the total combined molds and yeasts count does not exceed 10^1 cfu/g. It meets the requirements of the tests for the absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.▲ (USP 1-Aug-2019)

ADDITIONAL REQUIREMENTS

Change to read:

• **Packaging and Storage:** Preserve in tight, light-resistant containers. ▲Store at controlled room temperature.▲ (USP 1-Aug-2019)

Change to read:

• **USP Reference Standards** ⟨11⟩

USP Xylometazoline Hydrochloride RS

▲ USP Xylometazoline Related Compound A RS

N-(2-Aminoethyl)-2-[4-(*tert*-butyl)-2,6-dimethylphenyl]acetamide.

$C_{16}H_{26}N_2O$ 262.39▲ (USP 1-Aug-2019)

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
XYLOMETAZOLINE 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

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