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Pilocarpine Hydrochloride Ophthalmic Solution

DEFINITION

Pilocarpine Hydrochloride Ophthalmic Solution is a sterile, buffered, aqueous solution of pilocarpine hydrochloride. It contains NLT 90.0% and NMT 110.0% of the labeled amount of pilocarpine hydrochloride ($C_{11}H_{16}N_2O_2 \cdot HCl$). It may contain suitable antimicrobial agents and stabilizers, and suitable additives to increase its viscosity.

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

Solution A: Ammonium hydroxide in isopropyl alcohol (1 in 50)

Mobile phase: *n*-Hexane and *Solution A* (700:300)

Standard solution: 1.6 mg/mL of [USP Pilocarpine Hydrochloride RS](#) in methanol

Sample solution: Nominally equivalent to 1.6 mg/mL of pilocarpine hydrochloride from a volume of Ophthalmic Solution diluted with methanol

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; packing L3

Flow rate: 2 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time for pilocarpine hydrochloride is 16 min.]

Suitability requirements

Relative standard deviation: NMT 2.0% for pilocarpine hydrochloride for three replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of pilocarpine hydrochloride ($C_{11}H_{16}N_2O_2 \cdot HCl$) in each mL 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 Pilocarpine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- [STERILITY TESTS \(71\)](#): Meets the requirements
- [pH \(791\)](#): 3.5–5.5

ADDITIONAL REQUIREMENTS

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

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

Topic/Question	Contact	Expert Committee
PILOCARPINE HYDROCHLORIDE OPHTHALMIC SOLUTION	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

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