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Pilocarpine Hydrochloride Tablets

DEFINITION

Pilocarpine Hydrochloride Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of pilocarpine hydrochloride ($C_{11}H_{16}N_2O_2 \cdot HCl$).

IDENTIFICATION

- **A.** The retention time of the major peak of the *Sample solution* corresponds to the major peak 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

Solution A: 10 N [sodium hydroxide](#), 85% [phosphoric acid](#), [triethylamine](#), and [water](#) (7:6:1:500). Adjust with 10 N [sodium hydroxide](#) to a pH of 3.0.

Mobile phase: [Methanol](#) and *Solution A* (3:100)

Standard solution: 50 µg/mL of [USP Pilocarpine Hydrochloride RS](#)

System suitability solution: Transfer 10 mL of the *Standard solution* to a test tube. Add 100 µL of 2 N [sodium hydroxide](#), mix well, and allow it to stand for 5 min. Add 100 µL of 2 N [hydrochloric acid](#) and mix well. [NOTE—This preparation contains pilocarpine, isopilocarpine, and two unidentified compounds.]

Sample stock solution: Nominally 0.1 mg/mL of pilocarpine hydrochloride in water prepared as follows. Place Tablets, equivalent to 50 mg of pilocarpine hydrochloride, in a 500-mL volumetric flask. Fill the flask 75% full with [water](#). Stir for at least 30 min or more if necessary, until the Tablets are completely disintegrated and the powder is finely dispersed. Dilute with [water](#) to volume.

Sample solution: Nominally 50 µg/mL of pilocarpine hydrochloride in water from *Sample stock solution*. Pass a suitable amount of solution through a PVDF filter of 0.45-µm pore size, and discard the first 5 mL of the filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm. For *Identification B*, use a diode array detector in the range of 190–400 nm.

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

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

[NOTE—The relative retention times for isopilocarpine, pilocarpine, and two unidentified peaks are 0.9, 1.0, 1.2, and 1.5, respectively.]

Suitability requirements

Resolution: NLT 1.2 between isopilocarpine and pilocarpine; NLT 1.2 between pilocarpine and the peak at a relative retention time of 1.2; NLT 1.2 between the peaks at relative retention times of 1.2 and 1.5, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

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 the portion of Tablets taken:

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

r_U = peak response of pilocarpine hydrochloride from the *Sample solution*

r_s = peak response of pilocarpine hydrochloride from the *Standard solution*

C_s = concentration of [USP Pilocarpine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of pilocarpine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Medium: 0.1 N [hydrochloric acid](#); 500 mL

Apparatus 2: 50 rpm

Time: 45 min

Buffer solution: 13.5 mL of [phosphoric acid](#) and 3.0 mL of [triethylamine](#) in 1000 mL of [water](#). Adjust with phosphoric acid or 10 N [sodium hydroxide](#) to a pH of 3.

Mobile phase: [Methanol](#) and *Buffer solution* (3:17)

Standard stock solution: 0.1 mg/mL of [USP Pilocarpine Hydrochloride RS](#) in *Medium*

Standard solution

For Tablets labeled to contain 7.5 mg: Transfer 15.0 mL of the *Standard stock solution* to a 100-mL volumetric flask, and dilute with *Medium* to volume.

For Tablets labeled to contain 5 mg: Transfer 5.0 mL of the *Standard stock solution* to a 50-mL volumetric flask, and dilute with *Medium* to volume.

Sample solution: Pass the solution under test through a suitable polyethylene filter of 45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 15-cm; packing [L1](#)

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%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pilocarpine hydrochloride ($C_{11}H_{16}N_2O_2 \cdot HCl$) dissolved:

$$\text{Result} = (r_u/r_s) \times (C_s/L) \times V \times 100$$

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)

L = label claim (mg/Tablet)

V = volume of *Medium*, 500 mL

Tolerances: NLT 75% (Q) of the labeled amount of pilocarpine hydrochloride ($C_{11}H_{16}N_2O_2 \cdot HCl$) is dissolved.

Change to read:

• [UNIFORMITY OF DOSAGE UNITS \(905\)](#): ▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

Mobile phase, Standard solution, System suitability solution, Chromatographic system, and System suitability: Proceed as directed in the Assay.