

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-E86CBAF1-B661-415A-9304-92731625C8BE_2_en-US
 DOI: https://doi.org/10.31003/USPNF_M64990_02_01
 DOI Ref: kfx8y

© 2025 USPC
 Do not distribute

Pilocarpine Hydrochloride

$C_{11}H_{16}N_2O_2 \cdot HCl$ 244.72
 2(3*H*)-Furanone, 3-ethylidihydro-4-[(1-methyl-1*H*-imidazol-5-yl)methyl]-, monohydrochloride, (3*S*-*cis*)-;
 Pilocarpine monohydrochloride CAS RN[®]: 54-71-7; UNII: 0WW6D218XJ.

DEFINITION

Pilocarpine Hydrochloride contains NLT 98.0% and NMT 102.0% of $C_{11}H_{16}N_2O_2 \cdot HCl$, calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197M](#) ▲ (CN 1-MAY-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#): Meets the requirements

Sample solution: 50 mg/mL

ASSAY

PROCEDURE

Buffer: 4.4 g/L of dibasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 6.5 ± 0.1 .

Mobile phase: Acetonitrile, methanol, and *Buffer* (2:35:63)

Standard solution: 0.5 mg/mL of [USP Pilocarpine Hydrochloride RS](#) in water. [NOTE—Sonicate if necessary.]

System suitability solution: Transfer a known quantity of [USP Pilocarpine Hydrochloride RS](#) in a suitable volumetric flask, and add water, equivalent to 10% of the volume of the flask, to dissolve. [NOTE—Sonicate as needed.] Add 0.1 N sodium hydroxide, equivalent to 10% of the volume of the flask, quench immediately with the same volume of 0.1 N hydrochloric acid, and mix. Dilute with water to volume. [NOTE—The initial concentration of [USP Pilocarpine Hydrochloride RS](#) is 0.5 mg/mL. Isopilocarpine is formed in the *System suitability solution* preparation.]

Sample solution: 0.5 mg/mL of Pilocarpine Hydrochloride in water. [NOTE—Sonicate if necessary.]

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 15-cm; 3-μm packing L11

Column temperature: 35°

Flow rate: 1.0 mL/min

Injection size: 10 μL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between isopilocarpine and pilocarpine, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

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

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_{11}H_{16}N_2O_2 \cdot HCl$ in the portion of Pilocarpine Hydrochloride taken:

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

r_U = peak area from the *Sample solution*

r_s = peak area from the *Standard solution*

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

C_u = concentration of Pilocarpine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

ORGANIC IMPURITIES

• PROCEDURE 1: RELATED COMPOUNDS

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

Sensitivity solution: 0.25 µg/mL of [USP Pilocarpine Hydrochloride RS](#) in water from the *Standard solution*

Chromatographic system

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

Mode: LC

Detector: UV 215 nm

Column: 4.6-mm × 15-cm; 3-µm packing L11

Column temperature: 35°

Flow rate: 1.0 mL/min

Run time: NLT 5 times the retention time of the pilocarpine peak

Injection size: 10 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.5 between isopilocarpine and pilocarpine, *System suitability solution*

Signal-to-noise ratio: NLT 10 for the pilocarpine peak, *Sensitivity solution*

Relative standard deviation: NMT 2.0% for the pilocarpine peak, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Pilocarpine Hydrochloride taken:

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

r_u = peak area of each individual impurity from the *Sample solution*

r_s = peak area of pilocarpine from the *Standard solution*

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

C_u = concentration of Pilocarpine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria

Individual impurities: See [Impurity Table 1](#). [NOTE—Disregard any unspecified impurity peaks less than 0.05%.]

Total impurities: NMT 1.0%

Impurity Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Isopilocarpine ^a	0.94	1.0
Pilocarpine	1.00	—
Pilocarpic acid ^b	1.15	0.5
Isopilocarpic acid ^c	1.19	0.1



Documents

Document Sharing Hub