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Pilocarpine Nitrate

$C_{11}H_{16}N_2O_2 \cdot HNO_3$ 271.27

2(3*H*)-Furanone, 3-ethyldihydro-4-[(1-methyl-1*H*-imidazol-5-yl)methyl]-, (3*S*-*cis*)-, mononitrate.

Pilocarpine mononitrate CAS RN®: 148-72-1; UNII: M20T465H6J.

» Pilocarpine Nitrate contains not less than 98.5 percent and not more than 101.0 percent of $C_{11}H_{16}N_2O_2 \cdot NO_3$, calculated on the dried basis.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩—

USP Pilocarpine Nitrate RS

Identification—

Change to read:

A: ▲*Spectroscopic Identification Tests* ⟨197⟩*, Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

B: Mix a solution (1 in 10) with an equal volume of ferrous sulfate TS, and superimpose the mixture upon 5 mL of sulfuric acid contained in a test tube: the zone of contact becomes brown.

Melting range ⟨741⟩: between 171° and 176°, with decomposition, but the range between beginning and end of melting does not exceed 3°.

Specific rotation ⟨781S⟩: between +79.5° and +82.5°.

Test solution: 20 mg per mL, in water.

Loss on drying ⟨731⟩—Dry it at 105° for 2 hours: it loses not more than 2.0% of its weight.

Readily carbonizable substances ⟨271⟩—Dissolve 100 mg in 5 mL of sulfuric acid : the solution has no more color than *Matching Fluid A*.

Chloride—To 5 mL of a solution (1 in 50), acidified with nitric acid, add a few drops of silver nitrate TS: no opalescence is produced immediately.

Other alkaloids—Dissolve 200 mg in 20 mL of water, and divide the solution into two portions. To one portion add a few drops of 6 N ammonium hydroxide and to the other add a few drops of potassium dichromate TS: no turbidity is produced in either solution.

Assay—Dissolve about 600 mg of Pilocarpine Nitrate, accurately weighed, in 30 mL of glacial acetic acid, warming slightly to effect solution. Cool to room temperature, and titrate with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 27.13 mg of $C_{11}H_{16}N_2O_2 \cdot NO_3$.

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

Topic/Question	Contact	Expert Committee
PILOCARPINE NITRATE	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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