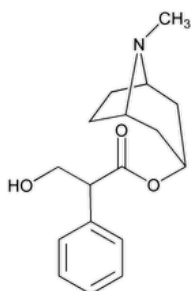


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Atropine



$C_{17}H_{23}NO_3$ 289.37

Benzeneacetic acid, α -(hydroxymethyl)-8-methyl-8-azabicyclo[3.2.1]oct-3-yl ester, *endo*-(\pm);

1 α H,5 α H-Tropan-3 α -ol (\pm)-tropate (ester) CAS RN®: 51-55-8; UNII: 7C0697DR9I.

DEFINITION

Atropine contains NLT 99.0% and NMT 100.5% of atropine ($C_{17}H_{23}NO_3$), calculated on the anhydrous basis.

[CAUTION—Handle Atropine with exceptional care, because it is highly potent.]

IDENTIFICATION

• A.

Standard: 36 mg of [USP Atropine Sulfate RS](#)

Sample: 30 mg

Analysis: Dissolve the *Standard* and *Sample* in individual 60-mL separators with the aid of 5-mL portions of water. To each separator add 1.5 mL of 1 N sodium hydroxide solution and 10 mL of chloroform. Shake for 1 min, allow the layers to separate, and pass the chloroform extracts through separate filters of 2 g of anhydrous granular sodium sulfate supported on pledgets of glass wool. Extract each aqueous layer with two additional 10-mL portions of chloroform, filtering and combining with the respective main extracts. Evaporate the chloroform solutions under reduced pressure to dryness, and dissolve each residue in 10 mL of carbon disulfide.

Acceptance criteria: The IR absorption spectrum, determined in a 1-mm cell, of the solution of the *Sample* exhibits maxima only at the same wavelengths as that of the solution of the *Standard*.

• B.

Sample solution: A solution (1 in 50) in 3 N hydrochloric acid

Analysis: Add gold chloride TS to the *Sample solution*.

Acceptance criteria: A lusterless precipitate is formed (distinction from hyoscyamine, which, similarly treated, yields a lustrous precipitate).

ASSAY

• PROCEDURE

Sample: 400 mg of Atropine

Analysis: Dissolve the *Sample* in 50 mL of glacial acetic acid. Titrate with 0.1 N perchloric acid VS to a green endpoint, using 1 drop of crystal violet TS. Perform a blank determination (see [Titrimetry \(541\)](#)). Each mL of 0.1 N perchloric acid is equivalent to 28.94 mg of atropine ($C_{17}H_{23}NO_3$).

Acceptance criteria: 99.0%–100.5% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• LIMIT OF FOREIGN ALKALOIDS AND OTHER IMPURITIES

Standard solution: 24 mg/mL of [USP Atropine Sulfate RS](#) in methanol

Sample solution A: 20 mg/mL of Atropine in methanol

Sample solution B: 1 mg/mL of Atropine in methanol

Chromatographic system

(See [Chromatography \(621\)](#), [Thin-Layer Chromatography](#).)

Mode: TLC

Adsorbent: 0.5-mm layer of chromatographic silica gel

Application volume: See *Analysis*.

Developing solvent system: Chloroform, acetone, and diethylamine (5:4:1)

Spray reagent: Potassium iodoplatinate TS

Analysis

Samples: *Standard solution*, 5 µL; *Sample solution A*, 25 µL; *Sample solution B*, 1 µL

Apply the *Samples* to the TLC plate. Allow the spots to dry, and develop the chromatogram in the *Developing solvent system* until the solvent front has moved three-fourths of the length of the plate. Allow the solvent to evaporate. Locate the spots on the plate by spraying with *Spray reagent*.

Acceptance criteria: NMT 0.2%; the R_f value of the principal spot of each *Sample solution* corresponds to that of the *Standard solution*; no secondary spot of *Sample solution A* exhibits intensity equal to or greater than the principal spot of *Sample solution B*.

• [READILY CARBONIZABLE SUBSTANCES TEST \(271\)](#)

Sample solution: 200 mg in 5 mL of 2 N sulfuric acid

Acceptance criteria: The solution has no more color than *Matching Fluid A*, and the solution is colored no more than light yellow upon the addition of 0.2 mL of nitric acid.

SPECIFIC TESTS

• [OPTICAL ROTATION, Angular Rotation \(781\)](#)

Sample solution: 1 g, previously dried at 105° for 1 h, in sufficient 50% alcohol (w/w) to obtain a volume of 20 mL at 25° (using a 200-mm tube)

Acceptance criteria: -0.70° to +0.05° (limit of hyoscyamine)

• [MELTING RANGE OR TEMPERATURE \(741\)](#): 114°–118°

• [WATER DETERMINATION, Method I \(921\)](#): NMT 0.2%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• [USP REFERENCE STANDARDS \(11\)](#)

[USP Atropine Sulfate RS](#)

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

Topic/Question	Contact	Expert Committee
ATROPINE	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

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