

(3) Other alkaloids—Dissolve 0.25 g of Atropine Sulfate in 1 mL of diluted hydrochloric acid (1 in 10), add water to make 15 mL, and use this solution as the sample solution.

(i) To 5 mL of the sample solution add 2 to 3 drops of hydrogen hexachloroplatinate (IV) TS: no precipitate is formed.

(ii) To 5 mL of the sample solution add 2 mL of ammonia TS, and shake vigorously: the turbidity of the solution is not greater than that of the following control solution.

Control solution: To 0.30 mL of 0.01 mol/L hydrochloric acid VS add 6 mL of dilute nitric acid and water to make 50 mL. To this solution add 1 mL of silver nitrate TS, and allow 7 mL of the mixture to stand for 5 minutes.

(4) Hyoscyamine—Weigh accurately about 1 g of Atropine Sulfate, previously dried, and dissolve in water to make exactly 10 mL: the specific optical rotation $[\alpha]_D^{20}$ of this solution in a 100-mm cell is between -0.60° and $+0.10^\circ$.

(5) Readily carbonizable substances—Take 0.20 g of Atropine Sulfate, and perform the test: the solution has no more color than Matching Fluid A.

Loss on drying Not more than 4.0% (0.5 g, in vacuum, phosphorus (V) oxide, 110°C , 4 hours).

Residue on ignition Not more than 0.1% (0.5 g).

Assay Dissolve about 0.25 g of Atropine Sulfate, previously dried and accurately weighed, in 30 mL of acetic acid (100). If necessary, dissolve it by warming, and cool. Titrate with 0.05 mol/L perchloric acid VS until the color of the solution changes from purple through blue to blue-green (indicator: 3 drops of crystal violet TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L perchloric acid VS
= 33.841 mg of $(\text{C}_{17}\text{H}_{23}\text{NO}_3)_2 \cdot \text{H}_2\text{SO}_4$

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Atropine Sulfate Injection

硫酸アトロピン注射液

Atropine Sulfate Injection is an aqueous solution for injection. It contains not less than 93% and not more than 107% of the labeled amount of atropine sulfate $[(\text{C}_{17}\text{H}_{23}\text{NO}_3)_2 \cdot \text{H}_2\text{SO}_4 \cdot \text{H}_2\text{O}: 694.83]$.

Method of preparation Prepare as directed under Injections, with Atropine Sulfate.

Description Atropine Sulfate Injection is a clear, colorless liquid.

pH: 4.0 - 6.0

Identification (1) Evaporate a volume of Atropine Sulfate Injection, equivalent to 1 mg of Atropine Sulfate according to the labeled amount, on a water bath to dryness. Proceed with the residue as directed in the Identification (1) under Atropine Sulfate.

(2) Heat an exactly measured volume of Atropine Sulfate Injection, equivalent to 5 mg of Atropine Sulfate according to the labeled amount, on a water bath to a volume

of 5 mL, and use this solution as the sample solution. Separately, weigh accurately 0.050 g of Atropine Sulfate Reference Standard, dissolve in ethanol (95) to make exactly 10 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 50 μL of the sample solution and 10 μL of the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of chloroform and diethylamine (9:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly hydrogen hexachloroplatinate (IV)-potassium iodide TS on the plate: the spots obtained from the sample solution and the standard solution show a purple color and the same Rf value.

(3) Atropine Sulfate Injection responds to the Qualitative Tests for sulfate.

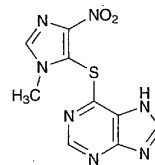
Assay To an exactly measured volume of Atropine Sulfate Injection, equivalent to about 5 mg of atropine sulfate $[(\text{C}_{17}\text{H}_{23}\text{NO}_3)_2 \cdot \text{H}_2\text{SO}_4 \cdot \text{H}_2\text{O}]$, add water to make exactly 100 mL, and use this solution as the sample solution. Separately, dissolve about 5 mg of Atropine Sulfate Reference Standard (determine previously its loss on drying in the same manner as directed under Atropine Sulfate), accurately weighed, in water to make exactly 100 mL, and use this solution as the standard solution. Pipet 4 mL each of the sample solution and standard solution, add 2 mL of sodium hydroxide TS, 10 mL of potassium hydrogen phthalate buffer solution, pH 5.6, and 20 mL of chloroform to each of the solutions, and shake vigorously for 5 minutes. Cool down to about 10°C , centrifuge, and collect the chloroform layer. Perform the test with these solutions as directed under the Ultraviolet-visible Spectrophotometry using chloroform as the blank. Determine the absorbances, A_T and A_S , of the subsequent solutions of the sample solution and the standard solution at 416 nm, respectively.

Amount (mg) of atropine sulfate
 $[(\text{C}_{17}\text{H}_{23}\text{NO}_3)_2 \cdot \text{H}_2\text{SO}_4 \cdot \text{H}_2\text{O}]$
= amount (mg) of Atropine Sulfate Reference Standard,
calculated on the dried basis
 $\times \frac{A_T}{A_S} \times 1.0266$

Containers and storage Containers—Hermetic containers.
Storage—Light-resistant.

Azathioprine

アザチオプリン



$\text{C}_9\text{H}_7\text{N}_7\text{O}_2\text{S}$: 277.26
6-(1-Methyl-4-nitro-1H-imidazol-5-ylthio)purine
[446-86-6]