Atropine sulfate tablets (Atropini sulfatis compressi)

**Category.** Antispasmodic drug.

**Additional information.** Strength in the current WHO Model list of essential medicines: 1 mg.

**Requirements**

Comply with the monograph for "Tablets".

Atropine sulfate tablets contain not less than 90.0% and not more than 110.0% of the amount of \((C_{17}H_{23}NO_3)_2H_2SO_4H_2O\) stated on the label.

**Identity tests**

A. Carry out the test as described under 1.14.1 Thin-layer chromatography, using silica gel R1 as the coating substance and a mixture of 5 volumes of chloroform R, 4 volumes of acetone R, and 1 volume of diethylamine R as the mobile phase. Apply separately to the plate 5 μl of each of the following two solutions. For solution (A) shake a quantity of the powdered tablets equivalent to 10 mg of Atropine sulfate with 2 mL of ethanol (~750 g/l) TS, centrifuge, and use the supernatant liquid. For solution (B) dissolve 25 mg of atropine sulfate RS in 5 mL of ethanol (~750 g/l) TS. After removing the plate from the chromatographic chamber, heat it at 105 °C for 20 minutes, allow to cool, and spray with potassium iodobismuthate TS2. Examine the chromatogram in daylight.

The principal spot obtained with solution A corresponds in position, appearance, and intensity with that obtained with solution B.

B. Triturate a quantity of the powdered tablets equivalent to 1 mg of Atropine sulfate with 1 drop of ammonia (~260 g/l) TS, add 2 mL of chloroform R, and triturate again thoroughly. Filter the chloroform layer and evaporate. To the residue add about 0.2 mL of fuming nitric acid R and evaporate to dryness on a water-bath; a yellow residue is obtained. To the cooled residue add 2 mL of acetone R and about 0.2 mL of potassium hydroxide/methanol TS; a deep violet colour is produced.

C. A filtered solution of the powdered tablets in water yields the reactions described under 2.1 General identification tests as characteristic of sulfates.

**Assay.** Weigh and powder 20 tablets. Transfer a quantity of the powder equivalent to about 2.5 mg of Atropine sulfate, accurately weighed, into a 50-mL volumetric flask, add 30 mL of water, shake well, dilute to volume, and filter. Discard the first few mL of filtrate and use the successive clear filtrate as the test solution. For the reference solution use 25 mg of atropine sulfate RS, accurately weighed and previously dried to constant mass at 120 °C, dissolve in sufficient water to produce 25 mL, and mix well. Dilute 5 mL of this solution to 100 mL with water (= 50 μg of anhydrous atropine sulfate per mL). Transfer 2 mL of each of the test solution and the reference solution to two 60-mL separating funnels containing 10 mL of chloroform R. Add 2 mL of bromocresol green TS1, shake for 2 minutes, and allow to stand until two layers are formed.

Measure the absorbance of the chloroform layers of the test solution and the reference solution at the maximum at about 420 nm against a solvent cell containing chloroform R.

Calculate the amount in mg of \((C_{17}H_{23}NO_3)_2H_2SO_4H_2O\) in the sample being examined using the following formula: 1.027 \((M/10)(A_u/A_s)\), in which \(M\) is the mass in mg of atropine sulfate RS in the reference solution and \(A_u\) and \(A_s\) are the absorbances for the test solution and the reference solution, respectively.

**Uniformity of content.** Individually transfer 10 powdered tablets to 10 separate stoppered test-tubes, to each add 6 mL of water, accurately measured, shake thoroughly for 30 minutes, centrifuge, and use the clear solution as the test solution. For the reference solution weigh accurately 25 mg of atropine sulfate RS, previously dried to constant mass at 120 °C, dissolve in sufficient water to produce 25 mL, and mix well. Dilute 5 mL of this solution to 100 mL with water (= 50 μg of anhydrous atropine sulfate per mL). Transfer 2 mL of each of the solutions to be examined and the reference solution to two 60-mL separating funnels containing 10 mL of chloroform R. Add 2 mL of bromocresol green TS1, shake for 2 minutes, and allow to stand until two layers are formed.

Measure the absorbance of the chloroform layers of the solutions to be examined and the reference solution at the maximum at about 420 nm against a solvent cell containing chloroform R.

Calculate the content of \((C_{17}H_{23}NO_3)_2H_2SO_4H_2O\) in mg, using the following formula: 1.027 \((M/10)(A_u/A_s)\), in which \(M\) is the mass in mg of atropine sulfate RS in the reference solution and \(A_u\) and \(A_s\) are the absorbances for the solutions examined and the reference solution, respectively.

The tablets comply with the test for 5.1 Uniformity of content for single-dose preparations.