

(potency), dissolve each in a suitable amount of water, add exactly 10 mL of the internal standard solution, 6.5 mL of acetonitrile and water to make 50 mL, and use these solutions as the sample solution and the standard solution, respectively. Perform the test with 10  $\mu$ L each of these solutions as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios,  $Q_T$  and  $Q_S$ , of the peak area of aspoxicillin to that of the internal standard of each solution.

$$\begin{aligned} & \text{Amount } [\mu\text{g (potency)}] \text{ of } C_{21}H_{27}N_5O_7S \\ & = \text{amount [mg (potency)] of Aspoxicillin Reference} \\ & \quad \text{Standard} \times \frac{Q_T}{Q_S} \times 1000 \end{aligned}$$

**Internal standard solution**—A solution of *N*-(3-hydroxyphenyl)acetamide (1 in 1000).

**Operating conditions**—

**Detector:** An ultraviolet absorption photometer (wavelength: 280 nm).

**Column:** A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5  $\mu$ m in particle diameter).

**Column temperature:** A constant temperature of about 40°C.

**Mobile phase:** To 130 mL of acetonitrile add potassium dihydrogenphosphate TS, pH 3.0 to make 1000 mL.

**Flow rate:** Adjust the flow rate so that the retention time of aspoxicillin is about 3 minutes.

**System suitability**—

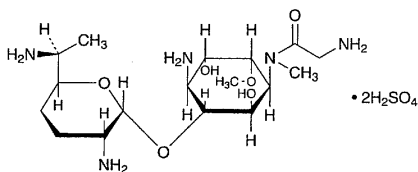
**System performance:** When the procedure is run with 10  $\mu$ L of the standard solution under the above operating conditions, aspoxicillin and the internal standard are eluted in this order with the resolution between these peaks being not less than 8.

**System repeatability:** When the test is repeated 6 times with 10  $\mu$ L of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of aspoxicillin to that of the internal standard is not more than 0.8%.

**Containers and storage** Containers—Tight containers.

## Astromicin Sulfate

硫酸アストロマイシン



$C_{17}H_{35}N_5O_6 \cdot 2H_2SO_4$ : 601.65

4-Amino-1-(2-amino-*N*-methylacetyl-amino)-1,4-dideoxy-3-*O*-(2,6-diamino-2,3,4,6,7-pentadeoxy- $\beta$ -*L*-lyxo-heptopyranosyl)-6-*O*-methyl-1*L*-chiro-inositol disulfate [72275-67-3]

Astromicin Sulfate conforms to the requirements of

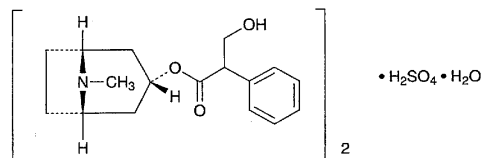
Astromicin Sulfate in the Requirements for Antibiotic Products of Japan.

**Description** Astromicin Sulfate occurs as white to light yellowish white powder or masses.

It is very soluble in water, sparingly soluble in ethylene glycol, and practically insoluble in methanol, in ethanol (95) and in diethyl ether.

## Atropine Sulfate

硫酸アトロピン



$(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4 \cdot H_2O$ : 694.83

(1*R*,3*r*,5*S*)-8-Methyl-8-azabicyclo[3.2.1]oct-3-yl [(*RS*)-3-hydroxy-2-phenyl]propanoate hemisulfate hemihydrate [5908-99-6]

Atropine Sulfate, when dried, contains not less than 98.0% of  $(C_{17}H_{23}NO_3)_2 \cdot H_2SO_4$  (mol. wt.: 676.82).

**Description** Atropine Sulfate occurs as colorless crystals or a white, crystalline powder. It is odorless.

It is very soluble in water and in acetic acid (100), freely soluble in ethanol (95), and practically insoluble in diethyl ether.

**Melting point:** 188 – 194°C (with decomposition). Introduce a capillary tube charged with dried sample into a bath previously heated to 180°C, and continue to heat at a rate of rise of about 3°C per minute.

It is affected by light.

**Identification (1)** To 1 mg of Atropine Sulfate add 3 drops of fuming nitric acid, and evaporate the mixture on a water bath to dryness. Dissolve the residue in 1 mL of *N,N*-dimethylformamide, and add 5 to 6 drops of tetraethylammonium hydroxide TS: a red-purple color develops.

**(2)** To 2 mL of a solution of Atropine Sulfate (1 in 50) add 4 to 5 drops of hydrogen tetrachloroaurate (III) TS: a lusterless, yellowish white precipitate is formed.

**(3)** To 5 mL of a solution of Atropine Sulfate (1 in 25) add 2 mL of ammonia TS, and allow to stand for 2 to 3 minutes. Collect the precipitate, wash with water, and dry in a desiccator (in vacuum, silica gel) for 4 hours: it melts between 115°C and 118°C.

**(4)** A solution of Atropine Sulfate (1 in 20) responds to the Qualitative Tests for sulfate.

**Purity (1)** Clarity and color of solution —Dissolve 0.5 g of Atropine Sulfate in 10 mL of water: the solution is clear and colorless.

**(2)** Acid—Dissolve 1.0 g of Atropine Sulfate in 20 mL of water, and add 0.30 mL of 0.02 mol/L sodium hydroxide VS and 1 drop of methyl red-methylene blue TS: a green color develops.