## Thallium (201Tl) Chloride Injection

塩化タリウム (201TI) 注射液

Thallium (<sup>201</sup>Tl) Chloride Injection is an aqueous solution for injection containing thallium-201 (<sup>201</sup>Tl) in the form of thallous chloride.

It conforms to the requirements of Thallium (201Tl) Chloride Injection in the Minimum Requirements for Radiopharmaceuticals.

The Insoluble Particulate Matter Test for Injections is not applied to this injection.

**Description** Thallium (<sup>201</sup>Tl) Chloride Injection is a clear, colorless liquid.

## **Theophylline**

テオフィリン

C7H8N4O2: 180.16

3,7-Dihydro-1,3-dimethyl-1*H*-purine-2,6-dione [58-55-9]

Theophylline, when dried, contains not less than 99.0% of  $C_7H_8N_4O_2$ .

**Description** Theophylline occurs as white crystals or crystalline powder. It is odorless.

It is soluble in *N,N*-dimethylformamide, slightly soluble in water, in ethanol (95) and in chloroform, and practically insoluble in diethyl ether.

It dissolves in potassium hydroxide TS and in ammonia TS.

**Identification** (1) To 2 mL of a solution of Theophylline (1 in 500) add tannic acid TS dropwise: a white precipitate is produced, and this precipitate dissolves in an excess of the reagent.

- (2) To 0.01 g of Theophylline add 10 drops of hydrogen peroxide TS and 1 drop of hydrochloric acid, and evaporate on a water bath to dryness: the residue acquires a yellow-red color. When the dish containing the residue is held upside down over a vessel containing 2 to 3 drops of ammonia TS, the residue acquires a red-purple color, which is discharged on the addition of 2 to 3 drops of sodium hydroxide TS.
- (3) Dissolve 0.01 g of Theophylline in 5 mL of water, add 3 mL of ammonia-ammonium chloride buffer solution, pH 8.0, and 1 mL of copper (II) sulfate-pyridine TS, mix, add 5 mL of chloroform, and shake the mixture: a green color develops in the chloroform layer.

Melting point 271 - 275°C

**Purity** (1) Acid—To 0.5 g of Theophylline add 75 mL of water, 2.0 mL of 0.01 mol/L sodium hydroxide VS and 1 drop of methyl red TS: a yellow color develops.

- (2) Heavy metals—Proceed with 1.0 g of Theophylline according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).
- (3) Arsenic—Prepare the test solution with 1.0 g of Theophylline according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).
- (4) Related substances—Dissolve 0.10 g of Theophylline in 3 mL of N,N-dimethylformamide, add 10 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 200 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot  $10 \,\mu$ L each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of acetone, chloroform, methanol, 1-butanol and ammonia solution (28) (3:3:2:2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.
- (5) Readily carbonizable substances—Perform the test with 0.20 g of Theophylline. The solution has no more color than diluted Matching Fluid A (1 in 5).

Loss on drying Not more than 0.5% (1 g, 105°C, 4 hours).

Residue on ignition Not more than 0.15% (1 g).

Assay Weigh accurately about 0.25 g of Theophylline, previously dried, and dissolve in 100 mL of water, add exactly 20 mL of 0.1 mol/L silver nitrate VS, shake the mixture, and titrate with 0.1 mol/L sodium hydroxide VS (indicator: 1 mL of bromothymol blue TS).

Each mL of 0.1 mol/L sodium hydroxide VS = 18.017 mg of C<sub>7</sub>H<sub>8</sub>N<sub>4</sub>O<sub>2</sub>

**Containers and storage** Containers—Well-closed containers.

## **Thiamazole**

チアマゾール

C<sub>4</sub>H<sub>6</sub>N<sub>2</sub>S: 114.17

1-Methyl-1*H*-imidazole-2-thiol [60-56-0]

Thiamazole, when dried, contains not less than 98.0% of  $C_4H_6N_2S$ .

**Description** Thiamazole occurs as white to pale yellowish white crystals or crystalline powder. It has a faint, characteristic odor, and has a bitter taste.

It is freely soluble in water and in ethanol (95), and slightly soluble in diethyl ether.

The pH of the solution (1 in 50) is between 5.0 and 7.0.

Identification (1) Dissolve 5 mg of Thiamazole in 1 mL