

Thallium (^{201}Tl) Chloride Injection

塩化タリウム (^{201}Tl) 注射液

Thallium (^{201}Tl) Chloride Injection is an aqueous solution for injection containing thallium-201 (^{201}Tl) in the form of thallos chloride.

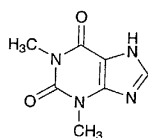
It conforms to the requirements of Thallium (^{201}Tl) Chloride Injection in the Minimum Requirements for Radiopharmaceuticals.

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

Description Thallium (^{201}Tl) Chloride Injection is a clear, colorless liquid.

Theophylline

テオフィリン



$\text{C}_7\text{H}_8\text{N}_4\text{O}_2$: 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 $\text{C}_7\text{H}_8\text{N}_4\text{O}_2$.

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 μL 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 $\text{C}_7\text{H}_8\text{N}_4\text{O}_2$

Containers and storage Containers—Well-closed containers.

Thiamazole

チアマゾール



$\text{C}_4\text{H}_6\text{N}_2\text{S}$: 114.17
1-Methyl-1*H*-imidazole-2-thiol [60-56-0]

Thiamazole, when dried, contains not less than 98.0% of $\text{C}_4\text{H}_6\text{N}_2\text{S}$.

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

of water, shake with 1 mL of sodium hydroxide TS, and add 3 drops of sodium pentacyanonitrosylferrate (III) TS: a yellow color develops, and it gradually changes to yellow-green to green. To this solution add 1 mL of acetic acid (31): it changes to blue.

(2) To 2 mL of a solution of Thiamazole (1 in 200) add 1 mL of sodium carbonate TS and 1 mL of diluted Folin's TS (1 in 5): a deep blue color develops.

Melting point 144 – 147°C

Purity (1) Selenium—Proceed with 0.10 g of Thiamazole as directed under the Oxygen Flask Combustion Method, using 25 mL of diluted nitric acid (1 in 30) as the absorbing liquid, and prepare the test solution. Apply a small amount of water to the upper part of apparatus A, pull out C carefully, and transfer the test solution to a beaker. Wash C, B and the inner side of A with 25 mL of water, and combine the washings with the test solution. Boil gently for 10 minutes, cool to room temperature, add water to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh exactly 0.040 g of selenium, dissolve in 100 mL of diluted nitric acid (1 in 2), heat to dissolve on a water bath if necessary, and add water to make exactly 1000 mL. Pipet 5 mL of this solution, and add water to make exactly 200 mL. To 2 mL of this solution, exactly measured, add diluted nitric acid (1 in 60) to make exactly 50 mL, and use this solution as the standard solution. Pipet 40 mL each of the sample solution and the standard solution into separate beakers, and adjust each solution with ammonia solution (28) to a pH of 1.8 to 2.2. To each solution add 0.2 g of hydroxylammonium chloride, shake gently to dissolve, then add 5 mL of 2,3-diaminonaphthalene TS, shake, and allow to stand for 100 minutes. Transfer these solutions to corresponding separators, rinse the beakers with 10 mL of water, combine the rinsings in the respective separators, shake well with 5.0 mL of cyclohexane for 2 minutes, and extract. Centrifuge the cyclohexane extracts to remove any water remaining in these solutions. Perform the test with these solutions as directed under the Ultraviolet-visible Spectrophotometry, using a solution prepared with 40 mL of diluted nitric acid (1 in 60) in the same manner as the blank. The absorbance of the sample solution at the wavelength of maximum absorbance at about 378 nm does not exceed the absorbance of the standard solution.

(2) Heavy metals—Proceed with 1.0 g of Thiamazole according to Method 2, 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 Thiamazole according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

Loss on drying Not more than 0.5% (1 g, 105°C, 2 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay Weigh accurately about 0.25 g of Thiamazole, previously dried, dissolve in 75 mL of water, add 15 mL of 0.1 mol/L sodium hydroxide VS from a burette, and add 30 mL of 0.1 mol/L silver nitrate VS with stirring. Add 1 mL of bromothymol blue TS, and titrate with 0.1 mol/L sodium hydroxide VS, until a persistent blue-green color is produced. Determine the total volume of 0.1 mol/L sodium hydroxide VS consumed.

Each mL of 0.1 mol/L sodium hydroxide VS
= 11.417 mg of C₄H₆N₂S

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Thiamazole Tablets

チアマゾール錠

Thiamazole Tablets contain not less than 94% and not more than 106% of the labeled amount of thiamazole (C₄H₆N₂S: 114.17).

Method of preparation Prepare as directed under Tablets, with Thiamazole.

Identification (1) To a quantity of powdered Thiamazole Tablets, equivalent to 0.05 g of Thiamazole according to the labeled amount, add 20 mL of hot ethanol (95), shake for 15 minutes, filter, and evaporate the filtrate on a water bath to dryness. Dissolve the residue in 10 mL of water, filter if necessary, and use this solution as the sample solution. To 1 mL of the sample solution add 1 mL of sodium hydroxide TS, shake, and add 3 drops of sodium pentacyanonitrosylferrate (III) TS: a yellow color develops, and it gradually changes to yellow-green to green. To this solution add 1 mL of acetic acid (31): it changes to blue.

(2) With 2 mL of the sample solution obtained in (1), proceed as directed in the Identification (2) under Thiamazole.

Assay Weigh accurately and powder not less than 20 Thiamazole Tablets. Weigh accurately a quantity of the powder, equivalent to about 0.15 g of thiamazole (C₄H₆N₂S), add 80 mL of water, shake for 15 minutes, add water to make exactly 100 mL, and centrifuge. Filter, discard the first 20 mL of the filtrate, pipet 50 mL of the subsequent filtrate, add 1 mL of bromothymol blue TS, and if a blue color develops, neutralize with 0.1 mol/L hydrochloric acid VS until the color of the solution changes to green. To this solution add 4.5 mL of 0.1 mol/L sodium hydroxide VS from a burette, add 15 mL of 0.1 mol/L silver nitrate VS while stirring, and titrate with 0.1 mol/L sodium hydroxide VS. Continue the titration until a persistent blue-green color is produced, and determine the total volume of 0.1 mol/L sodium hydroxide VS consumed.

Each mL of 0.1 mol/L sodium hydroxide VS
= 11.417 mg of C₄H₆N₂S

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.