Each mL of 0.1 mol/L silver nitrate VS
= 20.665 mg of $C_{12}H_{12}I_3N_2NaO_2$

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

# Sodium Iopodate Capsules

イオポダートナトリウムカプセル

Sodium Iopodate Capsules contain not less than 93% and not more than 107% of the labeled amount of sodium iopodate ($C_{12}H_{12}I_3N_2NaO_2$: 619.94).

**Method of preparation** Suspend Sodium Iopodate in fixed oil, and prepare as directed under Capsules.

**Identification** Cut open Sodium Iopodate Capsules, and take out the contents. To an amount of the contents, equivalent to 2 g of Sodium Iopodate according to the labeled amount, add 20 mL of petroleum ether, and stir well. Filter by suction through a glass filter (G4), wash the residue with three 10-mL portions of petroleum ether, and dry at 60°C for 1 hour under reduced pressure. Proceed as directed in the Identification under Sodium Iopodate.

**Assay** Take a number of Sodium Iopodate Capsules, equivalent to about 5 g of sodium iopodate ($C_{12}H_{12}I_3N_2NaO_2$), add 100 mL of water, and warm on a water bath until the capsules are completely disintegrated. Transfer this solution to a separator after cooling, add 50 mL of hexane, shake, and separate the aqueous layer. Wash the hexane layer with two 50-mL portions of water, combine the washings and the aqueous layer, and add water to make exactly 250 mL. Pipet 10 mL of this solution, add water to make exactly 500 mL. Pipet 2.5 mL of this solution, add water to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.1 g of sodium iopodate for assay, separately determined its loss on drying (in vacuum, 60°C, 3 hours), dissolve in water to make exactly 100 mL. Pipet 4 mL of this solution, add water to make exactly 100 mL, then pipet 5 mL of this solution, add water to make exactly 20 mL, and use this solution as the standard solution. Perform the test with 20 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and determine the peak areas, $A_T$ and $A_S$, of iopodate from each solution.

Amount (mg) of $C_{12}H_{12}I_3N_2NaO_2$
= amount (mg) of sodium iopodate for assay, calculated on the dried basis
$\times \frac{A_T}{A_S} \times 50$

*Operating conditions—*

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column about 4 mm in inside diameter and about 25 cm in length, packed with phenylated silica gel for liquid chromatography (μm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: Dissolve 1.7 g of tetrabutylammonium phosphate and 7.0 g of dipotassium hydrogenphosphate in 350 mL of water, adjust the pH to 7.0 with diluted phosphoric acid (1 in 10), and add water to make 410 mL. To this solution add 600 mL of methanol, and mix.

Flow rate: Adjust the flow rate so that the retention time of iopodate is about 6 minutes.

Selection of column: Dissolve 0.020 g of methyl parahydroxybenzoate in 1 mL of ethanol (95), and add water to make 100 mL. Pipet 5 mL of this solution, add water to make 100 mL, then pipet 5 mL of this solution, and add 20 mL of the standard solution. Proceed with 20 μL of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of methyl parahydroxybenzoate and iopodate in this order with the resolution between these peaks being not less than 4.

System repeatability: When repeat the test six times with the standard solution under the above operating conditions, the relative standard deviation of the peak area of iopodate is not more than 1.5%.

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

# Sodium Iotalamate Injection

イオタラム酸ナトリウム注射液

Sodium Iotalamate Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of iotalamic acid ($C_{11}H_9I_3N_2O_4$: 613.91).

**Method of preparation**

| | |
|---|---|
| **(1)** | |
| Iotalamic Acid | 645 g |
| Sodium Hydroxide | 42 g |
| Water for Injection | a sufficient quantity |
| | To make 1000 mL |
| **(2)** | |
| Iotalamic Acid | 772.5 g |
| Sodium Hydroxide | 50.5 g |
| Water for Injection | a sufficient quantity |
| | To make 1000 mL |

Prepare as directed under Injections, with the above ingredients (1) or (2).

**Description** Sodium Iotalamate Injection is a clear, colorless or pale yellow, slightly viscous liquid.

It is gradually colored by light.

**Identification** (1) To a volume of Sodium Iotalamate Injection, equivalent to 1 g of Iotalamic Acid according to the labeled amount, add 25 mL of water, and add 2.5 mL of dilute hydrochloric acid with thorough stirring: a white precipitate is produced. Filter the precipitate by suction through a glass filter (G4), wash the precipitate with two 10-mL portions of water, and dry at 105°C for 1 hour. Proceed with the precipitate as directed in the Identification (2) under Iotalamic Acid.

(2) Sodium Iotalamate Injection responds to the Qualitative Tests (1) for sodium salt.

**pH** 6.5 - 7.7

**Purity** (1) Primary aromatic amines—To a volume of Sodium Iotalamate Injection, equivalent to 0.20 g of Iotalamic Acid according to the labeled amount, add 15 mL of water, shake, add 4 mL of a solution of sodium nitrite (1 in 100) under ice-cooling, and proceed as directed in the Purity (2) under Iotalamic Acid: the absorbance is not more than 0.17.

(2) Iodine and iodide—To a volume of Sodium Iotalamate Injection, equivalent to 1.5 g of Iotalamic Acid according to the labeled amount, add 20 mL of water and 5 mL of dilute sulfuric acid, shake well, and filter the precipitate by suction through a glass filter (G4). To the filtrate add 5 mL of toluene, and shake vigorously: the toluene layer is colorless. Then add 2 mL of a solution of sodium nitrite (1 in 100), and shake vigorously: the toluene layer has no more color than the following control solution.

Control solution: Dissolve 0.25 g of potassium iodide in water to make 1000 mL. To 2.0 mL of this solution add 20 mL of water, 5 mL of dilute sulfuric acid, 5 mL of toluene and 2 mL of a solution of sodium nitrite (1 in 100), and shake vigorously.

**Bacterial endotoxins** Less than 3.4 EU/mL.

**Assay** Pipet a volume of Sodium Iotalamate Injection, equivalent to about 4 g of iotalamic acid ($C_{11}H_9I_3N_2O_4$), add water to make exactly 200 mL. Pipet 2 mL of this solution, add water to make exactly 200 mL. To exactly 5 mL of this solution add exactly 5 mL of the internal standard solution, add the mobile phase to make 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.4 g of iotalamic acid for assay, previously dried at 105°C for 4 hours, dissolve in 100 mL of water and 1 mL of sodium hydroxide TS, and add water to make exactly 200 mL. Pipet 5 mL of this solution, add water to make exactly 50 mL. To exactly 5 mL of this solution add exactly 5 mL of the internal standard solution, add the mobile phase to make 100 mL, and use this solution as the standard solution. Perform the test with 10 μL each of the sample solution and the standard solution 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 iotalamic acid to that of the internal standard.

$$\text{Amount (mg) of iotalamic acid } (C_{11}H_9I_3N_2O_4) = \text{amount (mg) of iotalamic acid for assay} \times \frac{Q_T}{Q_S}$$

*Internal standard solution*—A solution of L-tryptophan in the mobile phase (3 in 2500).

*Operating conditions*—

Detector: An ultraviolet absorption photometer (wavelength: 240 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 μm in particle diameter).

Column temperature: A constant temperature of about 20°C.

Mobile phase: To 3.9 g of phosphoric acid and 2.8 mL of triethylamine add water to make 2000 mL. To this solution add 100 mL of acetonitrile.

Flow rate: Adjust the flow rate so that the retention time of iotalamic acid is about 6 minutes.

*System suitability*—

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, iotalamic acid and the internal standard are eluted in this order with the resolution between these peaks being not less than 5.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the ratios of the peak area of iotalamic acid to that of the internal standard is not more than 1.0%.

**Containers and storage** Containers—Hermetic containers, and colored containers may be used.

Storage—Light-resistant.

# Sodium Pertechnetate ($^{99m}$Tc) Injection

過テクネチウム酸ナトリウム ($^{99m}$Tc) 注射液

Sodium Pertechnetate ($^{99m}$Tc) Injection is an aqueous solution for injection containing technetium-99*m* ($^{99m}$Tc) in the form of sodium pertechnetate.

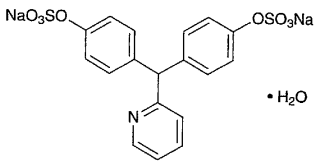
It conforms to the requirements of Sodium Pertechnetate ($^{99m}$Tc) Injection in the Minimum Requirements for Radiopharmaceuticals.

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

**Description** Sodium Pertechnetate ($^{99m}$Tc) Injection is a clear, colorless liquid.

# Sodium Picosulfate

ピコスルファートナトリウム




$C_{18}H_{13}NNa_2O_8S_2.H_2O$: 499.42

Disodium 4,4′-(pyridin-2-ylmethylene)bis(phenyl sulfate) monohydrate [*10040-45-6*, anhydride]

Sodium Picosulfate contains not less than 98.5% of $C_{18}H_{13}NNa_2O_8S_2$ (mol. wt.: 481.41), calculated on the anhydrous basis.

**Description** Sodium Picosulfate occurs as a white, crystalline powder. It is odorless and tasteless.

It is very soluble in water, soluble in methanol, slightly soluble in ethanol (99.5), and practically insoluble in diethyl ether.