

Sodium Iodide (¹³¹I) Solution

ヨウ化ナトリウム (¹³¹I) 液

Sodium Iodide (¹³¹I) Solution contains iodine-131 (¹³¹I) in the form of sodium iodide.

It conforms to the requirements of Sodium Iodide (¹³¹I) Solution in the Minimum Requirements for Radiopharmaceuticals.

Description Sodium Iodide (¹³¹I) Solution is a clear, colorless liquid. It is odorless, or has an odor due to the preservatives or stabilizers.

Sodium Iodohippurate (¹³¹I) Injection

ヨウ化ヒプル酸ナトリウム (¹³¹I) 注射液

Sodium Iodohippurate (¹³¹I) Injection is an aqueous solution for injection containing iodine-131 (¹³¹I) in the form of sodium *o*-iodohippurate.

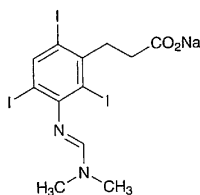
It conforms to the requirements of Sodium Iodohippurate (¹³¹I) Injection in the Minimum Requirements for Radiopharmaceuticals.

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

Description Sodium Iodohippurate (¹³¹I) Injection is a clear, colorless liquid. It is odorless or has an odor of the preservatives or stabilizers.

Sodium Iopodate

イオポダートナトリウム



$C_{12}H_{12}I_3N_2NaO_2$: 619.94

Monosodium 3-[3-(dimethylaminomethylene)amino-2,4,6-triiodophenyl]propanoate [1221-56-3]

Sodium Iopodate contains not less than 98.0% of $C_{12}H_{12}I_3N_2NaO_2$, calculated on the dried basis.

Description Sodium Iopodate occurs as a white to light yellowish white powder. It is odorless, and has a slightly bitter taste.

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

The pH of a solution of Sodium Iopodate (1 in 10) is between 8.9 and 9.9.

It is gradually colored by light.

Identification (1) Heat 0.1 g of Sodium Iopodate over a flame: a purple gas evolves.

(2) Determine the infrared absorption spectrum of Sodium Iopodate, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

(3) Sodium Iopodate responds to the Qualitative Tests (1) for sodium salt.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Sodium Iopodate in 5 mL of water: the solution is clear and colorless or pale yellow.

(2) Primary aromatic amines—Dissolve 0.20 g of Sodium Iopodate in 6 mL of water, add 4 mL of a sodium nitrite solution (1 in 100) and 10 mL of 1 mol/L hydrochloric acid TS, shake, and allow to stand for 2 minutes. Add 5 mL of ammonium amidosulfate TS, shake well, allow to stand for 1 minute, and add 0.4 mL of a solution of 1-naphthol in ethanol (95) (1 in 10), 15 mL of sodium hydroxide TS and water to make exactly 50 mL. Perform the test as directed under the Ultraviolet-visible Spectrophotometry, and determine the absorbance of this solution at 485 nm using the blank solution prepared in the same manner as the control: the absorbance is not more than 0.16.

(3) Soluble halides—Dissolve 2.5 g of Sodium Iopodate in 20 mL of water and 2.5 mL of ammonia TS, add 20 mL of dilute nitric acid and water to make 100 mL, allow to stand for 15 minutes with occasional shaking, and filter. Discard the first 10 mL of the filtrate, take the subsequent 25 mL in a Nessler tube, and add ethanol (95) to make 50 mL. Proceed as directed under the Chloride Limit Test, using this solution as the test solution. Prepare the control solution with 0.10 mL of 0.01 mol/L hydrochloric acid VS, add 6 mL of dilute nitric acid and water to make 25 mL, and add ethanol (95) to make 50 mL.

(4) Iodine—Dissolve 0.20 g of Sodium Iopodate in 2.0 mL of sodium hydroxide TS, add 2.5 mL of 0.5 mol/L sulfuric acid TS, allow to stand for 10 minutes with occasional shaking, add 5 mL of chloroform, shake, and allow to stand: no color develops in the chloroform layer.

(5) Heavy metals—Proceed with 2.0 g of Sodium Iopodate according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(6) Arsenic—Prepare the test solution with 0.6 g of Sodium Iopodate according to Method 3, and perform the test using Apparatus B (not more than 3.3 ppm).

Loss on drying Not more than 1.0% (1 g, in vacuum, 60°C, 3 hours).

Assay Transfer about 0.5 g of Sodium Iopodate, accurately weighed, to a saponification flask, dissolve in 40 mL of sodium hydroxide TS, add 1 g of zinc powder, boil for 30 minutes under a reflux condenser, and filter after cooling. Wash the flask and the filter paper with 50 mL of water, and combine the filtrate and the washings. To the solution add 5 mL of acetic acid (100), and titrate with 0.1 mol/L silver nitrate VS (indicator: 1 mL of tetrabromophenolphthalein ethyl ester TS) until the precipitate turns from yellow to green.

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 μ L 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.

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

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 (μ m 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 μ L 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.