

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%.

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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.