

Sodium Iodide (^{131}I) Solution

ヨウ化ナトリウム (^{131}I) 液

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

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

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

Sodium Iodohippurate (^{131}I) Injection

ヨウ化ヒプル酸ナトリウム (^{131}I) 注射液

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

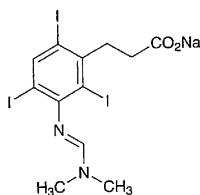
It conforms to the requirements of Sodium Iodohippurate (^{131}I) Injection in the Minimum Requirements for Radiopharmaceuticals.

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

Description Sodium Iodohippurate (^{131}I) 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



$\text{C}_{12}\text{H}_{12}\text{I}_3\text{N}_2\text{NaO}_2$: 619.94

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

Sodium Iopodate contains not less than 98.0% of $\text{C}_{12}\text{H}_{12}\text{I}_3\text{N}_2\text{NaO}_2$, 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.