

Assay Weigh accurately about 2 g of Sodium Borate, dissolve in 50 mL of water, and titrate with 0.5 mol/L hydrochloric acid VS (indicator: 3 drops of methyl red TS).

Each mL of 0.5 mol/L hydrochloric acid VS
= 95.34 mg of $\text{Na}_2\text{B}_4\text{O}_7 \cdot 10\text{H}_2\text{O}$

Containers and storage Containers—Tight containers.

Sodium Bromide

臭化ナトリウム

NaBr: 102.89

Sodium Bromide, when dried, contains not less than 99.0% of NaBr.

Description Sodium Bromide occurs as colorless or white crystals or crystalline powder. It is odorless.

It is freely soluble in water, and soluble in ethanol (95).

It is hygroscopic, but not deliquescent.

Identification A solution of Sodium Bromide (1 in 10) responds to the Qualitative Tests for sodium salt and for bromide.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Sodium Bromide in 3 mL of water: the solution is clear and colorless.

(2) Alkali—Dissolve 1.0 g of Sodium Bromide in 10 mL of water, add 0.10 mL of 0.05 mol/L sulfuric acid VS and 1 drop of phenolphthalein TS, heat to boil, and cool: the solution is colorless.

(3) Chloride—Make a calculation from the result obtained in the Assay. Not more than 97.9 mL of 0.1 mol/L silver nitrate VS is consumed for 1 g of Sodium Bromide.

(4) Sulfate—Perform the test with 2.0 g of Sodium Bromide. Prepare the control solution with 1.0 mL of 0.005 mol/L sulfuric acid VS (not more than 0.024%).

(5) Iodide—Dissolve 0.5 g of Sodium Bromide in 10 mL of water, add 2 to 3 drops of iron (III) chloride TS and 1 mL of chloroform, and shake: no red-purple color develops in the chloroform layer.

(6) Bromate—Dissolve 1.0 g of Sodium Bromide in 10 mL of freshly boiled and cooled water, and add 2 drops of potassium iodide TS, 1 mL of starch TS and 3 drops of dilute sulfuric acid. Shake the mixture gently, and allow to stand for 5 minutes: no blue color develops.

(7) Heavy metals—Proceed with 2.0 g of Sodium Bromide according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(8) Barium—Dissolve 0.5 g of Sodium Bromide in 10 mL of water, add 0.5 mL of dilute hydrochloric acid and 1 mL of potassium sulfate TS, and allow to stand for 10 minutes: no turbidity is produced.

(9) Arsenic—Prepare the test solution with 1.0 g of Sodium Bromide according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

Loss on drying Not more than 5.0% (1 g, 110°C, 4 hours).

Assay Weigh accurately about 0.4 g of Sodium Bromide,

previously dried, and dissolve in 50 mL of water. Add 10 mL of dilute nitric acid and 50 mL of 0.1 mol/L silver nitrate VS, exactly measured, and titrate the excess silver nitrate with 0.1 mol/L ammonium thiocyanate VS (indicator: 2 mL of ammonium iron (III) sulfate TS). Perform a blank determination.

Each mL of 0.1 mol/L silver nitrate VS
= 10.289 mg of NaBr

Containers and storage Containers—Tight containers.

Sodium Chloride

塩化ナトリウム

NaCl: 58.44

Sodium Chloride, when dried, contains not less than 99.5% of NaCl.

Description Sodium Chloride occurs as colorless or white crystals or crystalline powder. It is odorless, and has a saline taste.

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

Identification A solution of Sodium Chloride (1 in 20) responds to the Qualitative Tests for sodium salt and for chloride.

pH Dissolve 1.0 g of Sodium Chloride in 10 mL of water: the pH of this solution is between 4.5 and 7.0.

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

(2) Bromide—Dissolve 1.0 g of Sodium Chloride in water to make 100 mL. To 5 mL of the solution add 3 drops of dilute hydrochloric acid and 1 mL of chloroform, and add dropwise 3 drops of sodium toluenesulfonchloramide TS with shaking: no yellow to yellow-red color develops in the chloroform layer.

(3) Iodide—Dissolve 0.5 g of Sodium Chloride in 10 mL of water, add 3 drops of iron (III) chloride TS and 1 mL of chloroform, and shake. Allow to stand for 30 minutes, and shake again: no red-purple color develops in the chloroform layer.

(4) Heavy metals—Proceed with 5 g of Sodium Chloride according to Method 1, and perform the test. Prepare the control solution with 1.5 mL of Standard Lead Solution (not more than 3 ppm).

(5) Barium—Dissolve 3.0 g of Sodium Chloride in water to make 30 mL, and filter. To 10 mL of the filtrate add 2 mL of dilute sulfuric acid, and allow to stand for 2 hours: the solution has no more turbidity than the following control solution.

Control solution: To 10 mL of the filtrate add 2 mL of water, and allow to stand for 2 hours.

(6) Calcium or magnesium—Dissolve 0.20 g of Sodium Chloride in 20 mL of water, add 2 mL of ammonia TS, 2 mL of ammonium oxalate TS and 2 mL of disodium hydrogenphosphate TS, and then allow to stand for 5 minutes: no turbidity is produced.

(7) Arsenic—Prepare the test solution with 1.0 g of Sodium Chloride 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, 130°C, 2 hours).

Assay Weigh accurately about 0.2 g of Sodium Chloride, previously dried, dissolve in 50 mL of water, and titrate with 0.1 mol/L silver nitrate VS while shaking vigorously (indicator: 3 drops of fluorescein sodium TS).

Each mL of 0.1 mol/L silver nitrate VS
= 5.844 mg of NaCl

Containers and storage Containers—Tight containers.

10% Sodium Chloride Injection

10% 塩化ナトリウム注射液

10% Sodium Chloride Injection is an aqueous solution for injection. It contains not less than 9.5 w/v% and not more than 10.5 w/v% of sodium chloride (NaCl: 58.44).

Method of preparation

Sodium Chloride	100 g
Distilled Water for Injection	a sufficient quantity
To make 1000 mL	

Prepare as directed under Injections, with the above ingredients.

Description 10% Sodium Chloride Injection is a clear, colorless liquid. It has a saline taste.

It is neutral.

Identification 10% Sodium Chloride Injection responds to the Qualitative Tests for sodium salt and for chloride.

Bacterial endotoxins Less than 3.6 EU/mL.

Assay Pipet 10 mL of 10% Sodium Chloride Injection, and add water to make exactly 100 mL. Pipet 20 mL of this solution, add 30 mL of water, and titrate, with vigorous shaking, with 0.1 mol/L silver nitrate VS (indicator: 3 drops of fluorescein sodium TS).

Each mL 0.1 mol/L silver nitrate VS
= 5.844 mg of NaCl

Containers and storage Containers—Hermetic containers.

Isotonic Sodium Chloride Solution

0.9% Sodium Chloride Injection

Isotonic Salt Solution

Isotonic Sodium Chloride Injection

生理食塩液

Isotonic Sodium Chloride Solution is an aqueous solution for injection. It contains not less than 0.85

w/v% and not more than 0.95 w/v% of sodium chloride (NaCl: 58.44).

Method of preparation

Sodium Chloride	9 g
Water for Injection	a sufficient quantity
To make 1000 mL	

Prepare as directed under Injections, with the above ingredients.

No preservative is added.

Description Isotonic Sodium Chloride Solution is a clear, colorless liquid. It has a slightly saline taste.

Identification Isotonic Sodium Chloride Solution responds to the Qualitative Tests for sodium salt and for chloride.

pH 4.5 – 8.0

Purity (1) Heavy metals—Concentrate 100 mL of Isotonic Sodium Chloride Solution to about 40 mL on a water bath, and add 2 mL of dilute acetic acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 3.0 mL of Standard Lead Solution and 2 mL of dilute acetic acid, and add water to make 50 mL (not more than 0.3 ppm).

(2) Arsenic—Prepare the test solution with 20 mL of Isotonic Sodium Chloride Solution, and perform the test using Apparatus B (not more than 0.1 ppm).

Bacterial endotoxins Less than 0.50 EU/mL.

Assay Measure exactly 20 mL of Isotonic Sodium Chloride Solution, add 30 mL of water, and titrate with 0.1 mol/L silver nitrate VS with vigorous shaking (indicator: 3 drops of fluorescein sodium TS).

Each mL of 0.1 mol/L silver nitrate VS
= 5.844 mg of NaCl

Containers and storage Containers—Hermetic containers. Plastic containers for aqueous injections may be used.

Sodium Chromate (⁵¹Cr) Injection

クロム酸ナトリウム (⁵¹Cr) 注射液

Sodium Chromate (⁵¹Cr) Injection is an aqueous solution for injection containing chromium-51 (⁵¹Cr) in the form of sodium chromate.

It conforms to the requirements of Sodium Chromate (⁵¹Cr) Injection in the Minimum Requirements for Radiopharmaceuticals.

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

Description Sodium Chromate (⁵¹Cr) Injection is a clear, light yellow liquid. It is odorless or has an odor of the preservatives.