clear and colorless.

(2) Chloride—To 0.40 g of Sodium Bicarbonate add 4 mL of dilute nitric acid, heat to boil, cool, and add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.45 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.040%).

(3) Carbonate—Dissolve 1.0 g of Sodium Bicarbonate in 20 mL of freshly boiled and cooled water with very gentle swirling at a temperature not exceeding 15°C. Add 2.0 mL of 0.1 mol/L hydrochloric acid VS and 2 drops of phenolphthalein TS: no red color develops immediately.

(4) Ammonium—Heat 1.0 g of Sodium Bicarbonate: the gas evolved does not change moistened red litmus paper to blue.

(5) Heavy metals—Dissolve 4.0 g of Sodium Bicarbonate in 5 mL of water and 4.5 mL of hydrochloric acid, and evaporate on a water bath to dryness. Dissolve the residue in 2 mL of dilute acetic acid, 35 mL of water and 1 drop of ammonium TS, dilute with water to 50 mL, and perform the test using this solution as the test solution. Prepare the control solution as follows: evaporate 4.5 mL of hydrochloric acid to dryness, and add 2 mL of dilute acetic acid, 2.0 mL of Standard Lead Solution and water to make 50 mL (not more than 5 ppm).

(6) Arsenic—Dissolve 1.0 g of Sodium Bicarbonate in 3 mL of water and 2 mL of hydrochloric acid, and perform the test using this solution as the test solution with Apparatus B (not more than 2 ppm).

Assay Weigh accurately about 2 g of Sodium Bicarbonate, dissolve in 25 mL of water, and titrate with 0.5 mol/L sulfuric acid VS. When the color of the solution changes from blue to yellow-green, boil with caution, cool, and continue the titration until a greenish yellow color develops (indicator: 2 drops of bromocresol green TS).

Each mL of 0.5 mol/L sulfuric acid VS
= 84.01 mg of $NaHCO_3$

Containers and storage Containers—Tight containers.

Sodium Bicarbonate Injection

炭酸水素ナトリウム注射液

Sodium Bicarbonate Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of sodium hydrogen carbonate ($NaHCO_3$: 84.01).

Method of preparation Prepare as directed under Injections, with Sodium Bicarbonate.

Description Sodium Bicarbonate Injection is a clear, colorless liquid.

Identification To a volume of Sodium Bicarbonate Injection, equivalent to 1 g of Sodium Bicarbonate according to the labeled amount, add water to make 30 mL: the solution responds to the Qualitative Tests for sodium salt and for bicarbonate.

Purity Carbonate—To a volume of Sodium Bicarbonate Injection, equivalent to 0.10 g of Sodium Bicarbonate according to the labeled amount, add water, freshly boiled and cooled to 10°C, to make a 1.0 w/v% solution, and determine the pH immediately: the pH of this solution is between 7.9 and 8.6.

Bacterial endotoxins Less than 5.0 EU/mEq.

Assay Measure exactly a volume of Sodium Bicarbonate Injection, equivalent to about 2 g of sodium hydrogen carbonate ($NaHCO_3$), titrate with 0.5 mol/L sulfuric acid VS, and proceed as directed in the Assay under Sodium Bicarbonate.

Each mL of 0.5 mol/L sulfuric acid VS
= 84.01 mg of $NaHCO_3$

Containers and storage Containers—Hermetic containers.

Sodium Borate

ホウ砂

$Na_2B_4O_7.10H_2O$: 381.37

Sodium Borate contains not less than 99.0% and not more than 103.0% of $Na_2B_4O_7.10H_2O$.

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

It is freely soluble in glycerin, soluble in water, and practically insoluble in ethanol (95), in ethanol (99.5) and in diethyl ether.

When placed in dry air, Sodium Borate effloresces and is coated with a white powder.

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

pH Dissolve 1.0 g of Sodium Borate in 20 mL of water: the pH of this solution is between 9.1 and 9.6.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of Sodium Borate in 20 mL of water by warming slightly: the solution is clear and colorless.

(2) Carbonate or bicarbonate—Dissolve 1.0 g of powdered Sodium Borate in 20 mL of freshly boiled and cooled water, and add 3 mL of dilute hydrochloric acid: the solution does not effervesce.

(3) Heavy metals—Dissolve 1.5 g of Sodium Borate in 25 mL of water and 7 mL of 1 mol/L hydrochloric acid TS, add 1 drop of phenolphthalein TS, and add ammonia TS until a pale red color develops. Then add dilute acetic acid until the solution becomes colorless again, add 2 mL of dilute acetic acid, and add water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution as follows: to 3.0 mL of Standard Lead Solution add 2 mL of dilute acetic acid and water to make 50 mL (not more than 20 ppm).

(4) Arsenic—Prepare the test solution with 0.40 g of Sodium Borate according to Method 1, and perform the test using Apparatus B (not more than 5 ppm).

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 $Na_2B_4O_7.10H_2O$

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 toluensulfonchloramide 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.