

Purity (1) Clarity and color of solution—Dissolve 0.25 g of Sodium Prasterone Sulfate in 50 mL of water: the solution is clear and colorless.

(2) Chloride—Dissolve 1.0 g of Sodium Prasterone Sulfate in 20 mL of acetone and 20 mL of water, 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 as follows: to 0.30 mL of 0.01 mol/L hydrochloric acid VS add 20 mL of acetone, 6 mL of dilute nitric acid and water to make 50 mL (not more than 0.011%).

(3) Sulfate—To 1.2 g of Sodium Prasterone Sulfate add 20 mL of water, shake vigorously for 5 minutes, and filter. To 10 mL of the filtrate add 20 mL of acetone, 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution as follows: to 0.40 mL of 0.005 mol/L sulfuric acid VS add 20 mL of acetone, 1 mL of dilute hydrochloric acid and water to make 50 mL (not more than 0.032%).

(4) Heavy metals—Proceed with 2.0 g of Sodium Prasterone Sulfate 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).

(5) Other steroids—Dissolve 0.10 g of Sodium Prasterone Sulfate in 10 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 200 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μ L each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform, methanol and water (75:22:3) to a distance of about 10 cm, and air-dry the plate. Spray evenly a mixture of sulfuric acid and ethanol (95) (1:1) on the plate, and heat at 80°C for 5 minutes: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying 8.0 – 9.0% (0.5 g, in vacuum, phosphorus (V) oxide, 60°C, 3 hours).

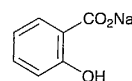
Assay Weigh accurately about 0.25 g of Sodium Prasterone Sulfate, dissolve in 30 mL of water. Apply this solution to a chromatographic column 10 mm in inside diameter, previously prepared by pouring 5 mL of strongly acidic ion-exchange resin (H type) for column chromatography, and elute at the rate of 4 mL per minute. Wash the chromatographic column with 100 mL of water, combine the washings with above effluent solution, and titrate with 0.05 mol/L sodium hydroxide VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L sodium hydroxide VS
= 19.524 mg of $C_{19}H_{27}NaO_5S$

Containers and storage Containers—Tight containers.

Sodium Salicylate

サリチル酸ナトリウム



$C_7H_5NaO_3$: 160.10

Monosodium 2-hydroxybenzoate [54-21-7]

Sodium Salicylate, when dried, contains not less than 99.5% of $C_7H_5NaO_3$.

Description Sodium Salicylate occurs as white, crystals or crystalline powder.

It is very soluble in water, freely soluble in acetic acid (100), and soluble in ethanol (95).

It is gradually colored by light.

Identification (1) Determine the infrared absorption spectrum of Sodium Salicylate, 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.

(2) A solution of Sodium Salicylate (1 in 20) responds to the Qualitative Tests for sodium salt.

pH The pH of a solution of 2.0 g of Sodium Salicylate in 20 mL of water is between 6.0 and 8.0.

Purity (1) Clarity of solution—Dissolve 1.0 g of Sodium Salicylate in 10 mL of water: the solution is clear, and its absorbance at 420 nm determined as directed under the Ultraviolet-visible Spectrophotometry is not more than 0.02.

(2) Chloride—Dissolve 0.5 g of Sodium Salicylate in 15 mL of water, add 6 mL of dilute nitric acid and ethanol (95) to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.30 mL of 0.01 mol/L hydrochloric acid VS, 28 mL of ethanol (95), 6 mL of dilute nitric acid and water to make 50 mL (not more than 0.021%).

(3) Sulfate—Dissolve 0.25 g of Sodium Salicylate in 5 mL of water, and add 0.5 mL of barium chloride TS: the solution shows no change.

(4) Sulfite and thiosulfate—Dissolve 1.0 g of Sodium Salicylate in 20 mL of water, add 1 mL of hydrochloric acid, and filter. Add 0.15 mL of 0.05 mol/L iodine VS to the filtrate: a yellow color develops.

(5) Heavy metals—Proceed with 1.0 g of Sodium Salicylate according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(6) Arsenic—To 1.0 g of Sodium Salicylate in a decomposition flask add 5 mL of nitric acid and 2 mL of sulfuric acid, and heat carefully until white fumes are evolved. After cooling, add 2 mL of nitric acid, and heat. After cooling, add several 2-mL portions of hydrogen peroxide (30), and heat until the solution is colorless to pale yellow. Repeat the procedure of adding nitric acid and hydrogen peroxide (30) and heating, if necessary. After cooling, add 2 mL of a saturated solution of ammonium oxalate monohydrate, and heat until white fumes are evolved. After cooling, add water

to make 5 mL, and perform the test with this solution using Apparatus B (not more than 2 ppm).

Loss on drying Not more than 0.5% (1 g, 105°C, 2 hours).

Assay Weigh accurately about 0.3 g of Sodium Salicylate, previously dried, dissolve in 50 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 16.010 mg of $C_7H_5NaO_3$

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Sodium Thiosulfate

チオ硫酸ナトリウム

$Na_2S_2O_3 \cdot 5H_2O$: 248.18

Sodium Thiosulfate, when dried, contains not less than 99.0% of $Na_2S_2O_3$ (mol. wt.: 158.11).

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

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

It effloresces in dry air, and is deliquescent in moist air.

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

pH Dissolve 1.0 g of Sodium Thiosulfate in 10 mL of water: the pH of the solution is between 6.0 and 8.0.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Sodium Thiosulfate in 10 mL of water: the solution is clear and colorless.

(2) Heavy metals—Dissolve 1.0 g of Sodium Thiosulfate in 10 mL of water, add slowly 5 mL of dilute hydrochloric acid, and evaporate on a water bath to dryness. Add 15 mL of water to the residue, boil gently for 2 minutes, and filter. Heat the filtrate to boil, and add bromine TS to the hot filtrate to produce a clear solution and provide a slight excess of bromine. Boil the solution to expel the bromine. Cool, add 1 drop of phenolphthalein TS, and add dropwise sodium hydroxide TS until a slight red color is produced. 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 as follows: to 2.0 mL of Standard Lead Solution add 2 mL of dilute acetic acid and water to make 50 mL (not more than 20 ppm).

(3) Calcium—Dissolve 1.0 g of Sodium Thiosulfate in 10 mL of water, add 2 mL of ammonium oxalate TS, and allow to stand for 4 minutes: no turbidity is produced.

(4) Arsenic—To 0.40 g of Sodium Thiosulfate add 3 mL of nitric acid and 5 mL of water, evaporate on a water bath to dryness, and perform the test with the residue. Prepare the test solution according to Method 2, and perform the test using Apparatus B (not more than 5 ppm).

Loss on drying 32.0 – 37.0% (1 g, dry first over silica gel for 2 hours in vacuum, and then dry at 105°C for 3 hours).

Assay Weigh accurately about 0.4 g of Sodium Thiosulfate, previously dried, dissolve in 30 mL of water, and titrate with 0.05 mol/L iodine VS (indicator: 1 mL of starch TS).

Each mL of 0.05 mol/L iodine VS
= 15.811 mg of $Na_2S_2O_3$

Containers and storage Containers—Tight containers.

Sodium Thiosulfate Injection

チオ硫酸ナトリウム注射液

Sodium Thiosulfate Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of sodium thiosulfate ($Na_2S_2O_3 \cdot 5H_2O$: 248.18).

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

Description Sodium Thiosulfate Injection is a clear, colorless liquid.

Identification Sodium Thiosulfate Injection responds to the Qualitative Tests for sodium salt and for thiosulfate.

Pyrogen Perform the test with Sodium Thiosulfate Injection stored in a container in a volume exceeding 10 mL: it meets the requirements of the Pyrogen Test.

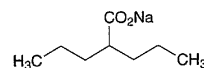
Assay Measure exactly a volume of Sodium Thiosulfate Injection, equivalent to about 0.5 g of sodium thiosulfate ($Na_2S_2O_3 \cdot 5H_2O$), add water to make 30 mL, and titrate with 0.05 mol/L iodine VS (indicator: 1 mL of starch TS).

Each mL of 0.05 mol/L iodine VS
= 24.819 mg of $Na_2S_2O_3 \cdot 5H_2O$

Containers and storage Containers—Hermetic containers.

Sodium Valproate

バルプロ酸ナトリウム



$C_8H_{15}NaO_2$: 166.19
Monosodium 2-propylpentanoate [1069-66-5]

Sodium Valproate, when dried, contains not less than 98.5% of $C_8H_{15}NaO_2$.

Description Sodium Valproate occurs as a white, crystalline powder. It has a characteristic odor and a slightly bitter taste.

It is very soluble in water, freely soluble in formic acid, in ethanol (95), in ethanol (99.5) and in acetic acid (100), and