

Melting point 192 – 196°C (with decomposition).

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Sulfisoxazole in 5 mL of sodium hydroxide TS and 20 mL of water: the solution is clear and colorless to pale yellow.

(2) Acid—To 1.0 g of Sulfisoxazole add 50 mL of water, warm at 70°C for 5 minutes, allow to stand in an ice bath for 1 hour, and filter. To 25 mL of the filtrate add 2 drops of methyl red TS and 0.20 mL of 0.1 mol/L sodium hydroxide VS: a yellow color develops.

(3) Heavy metals—Proceed with 1.0 g of Sulfisoxazole 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).

Loss on drying Not more than 0.5% (2 g, 105°C, 4 hours).

Residue on ignition Not more than 0.10% (1 g).

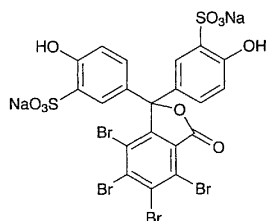
Assay Weigh accurately about 1 g of Sulfisoxazole, previously dried, dissolve in 50 mL of methanol by warming, cool and titrate with 0.2 mol/L sodium hydroxide VS (indicator: 3 drops of phenolphthalein TS). Perform a blank determination using a mixture of 50 mL of methanol and 18 mL of water, and make any necessary correction.

$$\begin{aligned} \text{Each mL of 0.2 mol/L sodium hydroxide VS} \\ = 53.46 \text{ mg of } C_{11}H_{13}N_3O_3S \end{aligned}$$

Containers and storage Containers—Well-closed containers.

Sulfobromophthalein Sodium

スルホブロモフタレインナトリウム



$C_{20}H_8Br_4Na_2O_{10}S_2$: 838.00

Disodium 5,5'-(4,5,6,7-tetrabromo-1,3-dihydro-3-oxo-isobenzofuranylidene)bis(2-hydroxybenzenesulfonate) [71-67-0]

Sulfobromophthalein Sodium, when dried, contains not less than 96.0% and not more than 104.0% of $C_{20}H_8Br_4Na_2O_{10}S_2$.

Description Sulfobromophthalein Sodium occurs as a white, crystalline powder. It is odorless.

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

It is hygroscopic.

Identification (1) Dissolve 0.02 g of Sulfobromophthalein Sodium in 10 mL of water, and add 1 mL of sodium carbonate TS: a blue-purple color is produced. Add 1 mL of dilute hydrochloric acid to the solution: the color of

the solution disappears.

(2) Transfer 0.2 g of Sulfobromophthalein Sodium to a porcelain crucible, mix well with 0.5 g of anhydrous sodium carbonate, and ignite until the mixture is charred. After cooling, add 15 mL of hot water to the residue, heat for 5 minutes on a water bath, filter, and render the filtrate slightly acid with hydrochloric acid: the solution responds to the Qualitative Tests for bromide, and the Qualitative Tests (1) and (2) for sulfate.

(3) Sulfobromophthalein Sodium responds to the Qualitative Tests (1) for sodium salt.

pH The pH of a solution of 1.0 g of Sulfobromophthalein Sodium in 20 mL of water is between 4.0 and 5.5.

Purity (1) Clarity and color of solution—Dissolve 0.5 g of Sulfobromophthalein Sodium in 10 mL of water: the solution is clear and colorless to pale yellow.

(2) Chloride—Perform the test with 2.0 g of Sulfobromophthalein Sodium. Prepare the control solution with 0.10 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.002%).

(3) Sulfate—To 10 mL of a solution of Sulfobromophthalein Sodium (1 in 500) add 5 drops of dilute hydrochloric acid, heat to boil, and add 1 mL of hot barium chloride TS: the solution is clear when observed 1 minute after the addition of the barium chloride TS.

(4) Calcium—Weigh accurately about 5 g of Sulfobromophthalein Sodium, transfer to a porcelain dish, heat gently to char, and heat strongly between 700°C and 750°C until the residue is incinerated. After cooling, add 10 mL of dilute hydrochloric acid, and heat for 5 minutes on a water bath. Transfer the contents to a flask with 50 mL of water, and add 5 mL of 8 mol/L potassium hydroxide TS and 0.1 g of NN indicator. Titrate with 0.01 mol/L disodium dihydrogen ethylenediamine tetraacetate VS until the red-purple color of the solution changes to blue.

$$\begin{aligned} \text{Each mL of 0.01 mol/L disodium dihydrogen} \\ \text{ethylenediamine tetraacetate VS} \\ = 0.4008 \text{ mg of Ca} \end{aligned}$$

The content of calcium (Ca: 40.08) is not more than 0.05%.

(5) Heavy metals—Proceed with 1.0 g of Sulfobromophthalein Sodium 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—Transfer 0.65 g of Sulfobromophthalein Sodium to a crucible, add 10 mL of a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 50), fire to burn, then heat gently until the residue is incinerated. If any carbon remains, moisten the residue with a small amount of nitric acid, and incinerate again by ignition. After cooling, add 10 mL of dilute sulfuric acid, and heat until white fumes are evolved. After cooling, add 5 mL of water to the residue, and perform the test using Apparatus B with this solution as the test solution (not more than 3.1 ppm).

Loss on drying Not more than 5.0% (0.5 g, 105°C, 3 hours).

Residue on ignition 14.0 – 19.0% (after drying, 0.5 g, 700 – 750°C).

Assay Dissolve about 0.1 g of Sulfobromophthalein Sodium, previously dried and accurately weighed, in water to

make exactly 500 mL. Pipet 5 mL of this solution, and add a solution of anhydrous sodium carbonate (1 in 100) to make exactly 200 mL. Perform the test with this solution as directed under the Ultraviolet-visible Spectrophotometry. Determine the absorbance A of this solution at the wavelength of maximum absorption at about 580 nm, using water as the blank.

$$\begin{aligned} & \text{Amount (mg) of } C_{20}H_8Br_4Na_2O_{10}S_2 \\ &= \frac{A}{881} \times 200,000 \end{aligned}$$

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

Sulfobromophthalein Sodium Injection

スルホブロモフタレインナトリウム注射液

Sulfobromophthalein Sodium Injection is an aqueous solution for Injection. It contains not less than 94% and not more than 106% of the labeled amount of sulfobromophthalein sodium ($C_{20}H_8Br_4Na_2O_{10}S_2$; 838.00).

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

Description Sulfobromophthalein Sodium Injection is a clear and colorless or pale yellow liquid.

pH: 5.0 – 6.0

Identification (1) Measure a volume of Sulfobromophthalein Sodium Injection, equivalent to 0.02 g of Sulfobromophthalein Sodium according to the labeled amount, and proceed as directed in the Identification (1) under Sulfobromophthalein Sodium.

(2) Measure a volume of Sulfobromophthalein Sodium Injection, equivalent to 0.1 g of Sulfobromophthalein Sodium according to the labeled amount, add 0.5 g of anhydrous sodium carbonate, and evaporate on a water bath to dryness. Ignite the residue until it is charred. Proceed as directed in the Identification (2) under Sulfobromophthalein Sodium.

Pyrogen Add isotonic sodium chloride solution to Sulfobromophthalein Sodium Injection to make a 0.5 w/v% solution of Sulfobromophthalein Sodium according to the labeled amount. Inject into each of the rabbits 5 mL of this solution per kg of body mass: it meets the requirements of the Pyrogen Test.

Assay Measure exactly a volume of Sulfobromophthalein Sodium Injection, equivalent to about 0.1 g of sulfobromophthalein sodium ($C_{20}H_8Br_4Na_2O_{10}S_2$), add water to make exactly 500 mL, and proceed as directed in the Assay under Sulfobromophthalein Sodium.

$$\begin{aligned} & \text{Amount (mg) of sulfobromophthalein sodium} \\ & (C_{20}H_8Br_4Na_2O_{10}S_2) \\ &= \frac{A}{881} \times 200,000 \end{aligned}$$

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

Sulfur

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S: 32.07

Sulfur, when dried, contains not less than 99.5% of S.

Description Sulfur occurs as a light yellow to yellow powder. It is odorless and tasteless.

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

Identification (1) Ignite Sulfur: it burns with a blue flame and gives a pungent odor of sulfur dioxide.

(2) Dissolve 5 mg of Sulfur in 5 mL of sodium hydroxide TS by heating in a water bath, cool, and add 1 drop of sodium pentacyanonitrosylferrate (III) TS: a blue-purple color develops.

(3) Boil 1 mg of sulfur with 2 mL of pyridine and 0.2 mL of sodium hydrogen carbonate TS: a blue color develops.

Purity (1) Clarity of solution—Dissolve 1.0 g of Sulfur in a mixture of 20 mL of a solution of sodium hydroxide (1 in 6) and 2 mL of ethanol (95) by boiling: the solution is clear. Dissolve 2.0 g of Sulfur in 10 mL of carbon disulfide: the solution is almost clear or slightly opalescent.

(2) Acid or alkali—Shake 2.0 g of Sulfur with 50 mL of freshly boiled and cooled water, and add 2 drops of phenolphthalein TS: no red color develops. Further add 1.0 mL of 0.1 mol/L sodium hydroxide VS: a red color develops.

(3) Arsenic—Prepare the test solution with 0.20 g of Sulfur according to Method 3, and perform the test using Apparatus B (not more than 10 ppm).

Loss on drying Not more than 1.0% (1 g, in vacuum, not more than 0.67 kPa, silica gel, 4 hours).

Residue on ignition Not more than 0.25% (1 g).

Assay Weigh accurately about 0.4 g of Sulfur, previously dried, dissolve in 20 mL of potassium hydroxide-ethanol TS and 10 mL of water by boiling, cool, and add water to make exactly 100 mL. Transfer exactly 25 mL of the solution to a 400-mL beaker, add 50-mL of hydrogen peroxide TS, and heat on a water bath for 1 hour. Acidify the solution with dilute hydrochloric acid, add 200 mL of water, heat to boil, add hot barium chloride TS dropwise until no more precipitate is formed, and heat on a water bath for 1 hour. Collect the precipitate, and wash with water until the last washing shows no opalescence with silver nitrate TS. Dry the precipitate, heat strongly to constant mass, and weigh as barium sulfate ($BaSO_4$; 233.39). Perform a blank determination, and make any necessary correction.

$$\begin{aligned} & \text{Amount (mg) of sulfur (S)} \\ &= \text{amount (mg) of barium sulfate (BaSO}_4\text{)} \times 0.13739 \end{aligned}$$