

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

イオウ

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).

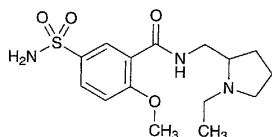
**Assay** Weigh accurately about 0.4 g of Sulfur, previously dried, dissolve in 20 mL of potassium hydroxide-ethanol TS and 10 mL of water by boiling, cool, and add water to make exactly 100 mL. Transfer exactly 25 mL of the solution to a 400-mL beaker, add 50-mL of hydrogen peroxide TS, and heat on 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.

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

**Containers and storage** Containers—Well-closed containers.

## Sulpiride

スルピリド



$C_{15}H_{23}N_3O_4S$ : 341.43

*N*-(1-Ethylpyrrolidin-2-ylmethyl)-2-methoxy-5-sulfamoylbenzamide [15676-16-1]

Sulpiride, when dried, contains not less than 98.5% of  $C_{15}H_{23}N_3O_4S$ .

**Description** Sulpiride is a white, crystalline powder. It is odorless.

It is freely soluble in acetic acid (100) and in dilute acetic acid, sparingly soluble in methanol, slightly soluble in ethanol (95) and in acetone, and practically insoluble in water, in diethyl ether and in chloroform.

It is soluble in dilute hydrochloric acid and in 0.05 mol/L sulfuric acid TS.

Melting point: 175 – 182°C (with decomposition).

**Identification (1)** Dissolve 0.01 g of Sulpiride in 5 mL of dilute hydrochloric acid and 20 mL of water. To 5 mL of this solution add 1 mL of Dragendorff's TS: a reddish orange precipitate is produced.

(2) To 0.5 g of Sulpiride add 3 mL of sodium hydroxide solution (3 in 10), and heat: the gas evolved changes moistened red litmus paper to blue.

(3) Dissolve 0.1 g of Sulpiride in 0.05 mol/L sulfuric acid to make 100 mL. Dilute 5 mL of the solution with water to make 100 mL. Determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

**Purity (1)** Clarity of solution—Dissolve 2.0 g of Sulpiride in 7 mL of dilute acetic acid, and add water to make 20 mL: the solution is clear. Perform the test as directed under the Ultraviolet-visible Spectrophotometry, using water as the blank: the absorbance at a wavelength of 450 nm does not exceed 0.020.

(2) Heavy metals—Proceed with 2.0 g of Sulpiride as directed under Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(3) Arsenic—Prepare the test solution with 1.0 g of Sulpiride according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(4) Related substances—Dissolve 0.050 g of Sulpiride in 10 mL of methanol, and use this solution as the sample solution. Dilute 1 mL of the sample solution, accurately measured, with methanol to make exactly 100 mL. Dilute 5 mL

of this solution, accurately measured, with methanol to make exactly 10 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 20  $\mu$ 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 1-butanol, water and acetic acid (100) (4:2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): spots other than the principal spot from the sample solution have no more color than the spot from the standard solution. When the plate is exposed to iodine vapor for 30 minutes, the spots other than the principal spot from the sample solution have no more color than the spot from the standard solution.

**Loss on drying** Not more than 0.5% (1 g, 105°C, 3 hours).

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

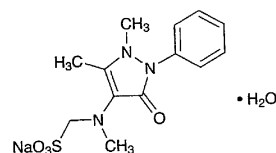
**Assay** Dissolve about 0.4 g of Sulpiride, previously dried and accurately weighed, in 80 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS (indicator: 2 drops of crystal violet TS) until the color of the solution changes from violet through blue to bluish green. Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS  
= 34.143 mg of  $C_{15}H_{23}N_3O_4S$

**Containers and storage** Containers—Well-closed containers.

## Sulpyrine

スルピリン



$C_{13}H_{16}N_3NaO_4S \cdot H_2O$ : 351.35

Monosodium [(1,5-dimethyl-3-oxo-2-phenyl-2,3-dihydro-1*H*-pyrazol-4-yl)methylamino]methanesulfonate monohydrate [5907-38-0]

Sulpyrine contains not less than 98.5% of  $C_{13}H_{16}N_3NaO_4S$  (mol. wt.: 333.34), calculated on the dried basis.

**Description** Sulpyrine occurs as white to light yellow crystals or crystalline powder. It is odorless, and has a bitter taste.

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

It is colored by light.

**Identification (1)** Add 2 drops of dilute sulfuric acid and 1 mL of chlorinated lime TS to 3 mL of a solution of Sulpyrine (1 in 15): a deep blue color develops at first, but the color immediately turns red, then gradually changes to yellow.