

be carried out in a manner to avoid moisture absorption.

**Residue on ignition** Not more than 1.0% (1 g).

**Assay** Perform the test according to the Cylinder-plate method as directed under the Microbial Assay for Antibiotics according to the following conditions.

(1) Test organism—*Staphylococcus epidermidis* ATCC 12228

(2) Culture medium—Use the medium in (3) Medium for other organisms under (1) Agar media for seed and base layer. Adjust the pH of the medium so that it will be 7.8 to 8.0 after sterilization.

(3) Standard solution—Weigh accurately an amount of Sisomicin Sulfate Reference Standard equivalent to about 0.025 g (potency), add 0.1 mol/L phosphate buffer solution, pH 8.0 to make exactly 25 mL, and use this solution as the standard stock solution. Keep the standard stock solution at 5°C or below and use within 7 days. Take exactly a suitable amount of the standard stock solution before use, add 0.1 mol/L phosphate buffer solution, pH 8.0 to make solutions so that each mL contains 1 μg (potency) and 0.25 μg (potency), and use these solutions as the high concentration standard solution and the low concentration standard solution, respectively.

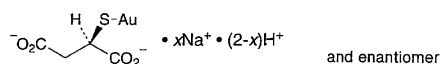
(4) Sample solution—Weigh accurately an amount of Sisomicin sulfate equivalent to about 0.025 g (potency), add 0.1 mol/L phosphate buffer solution, pH 8.0 to make exactly 25 mL. Take exactly a suitable amount of the solution, add 0.1 mol/L phosphate buffer solution, pH 8.0 to make solutions so that each mL contains 1 μg (potency) and 0.25 μg (potency), and use these solutions as the high concentration sample solution and the low concentration sample solution, respectively.

**Containers and storage** Containers—Tight containers.

Storage—Light-resistant, not exceeding -20°C, under nitrogen or argon atmosphere.

## Sodium Aurothiomalate

金チオリンゴ酸ナトリウム



Mixture of  $C_4H_3AuNa_2O_4S$ : 390.08 and

$C_4H_4AuNaO_4S$ : 368.09

Monogold monosodium monohydrogen (*RS*)-1-sulfidobutane-1,2-dioate

Monogold disodium (*RS*)-1-sulfidobutane-1,2-dioate

[12244-57-4, Sodium Aurothiomalate]

Sodium Aurothiomalate is a mixture of the monosodium salt of aurothiomalic acid ( $C_4H_4AuNaO_4S$ : 368.10) and disodium salt of aurothiomalic acid ( $C_4H_3AuNa_2O_4S$ : 390.08).

Sodium Aurothiomalate, when dried, contains not less than 49.0% and not more than 52.5% of gold (Au: 196.97).

**Description** Sodium Aurothiomalate occurs as white to light yellow powder or granules. It is odorless.

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

It is hygroscopic.

It is affected by light.

**Identification** (1) To 2 mL of a solution of Sodium Aurothiomalate (1 in 10) add 1 mL of a solution of calcium nitrate tetrahydrate (1 in 10): a white precipitate is produced, and it dissolves in dilute nitric acid and reappears on the addition of ammonium acetate TS.

(2) To 2 mL of a solution of Sodium Aurothiomalate (1 in 10) add 3 mL of silver nitrate TS: a yellow precipitate is produced, and it dissolves in an excess of ammonia TS.

(3) Place 2 mL of a solution of Sodium Aurothiomalate (1 in 10) in a porcelain crucible, add 1 mL of ammonia TS and 1 mL of hydrogen peroxide (30), evaporate to dryness, and ignite. Add 20 mL of water to the residue, and filter: the residue on the filter paper occurs as a yellow or dark yellow powder, or yellow or dark yellow granules, and the filtrate responds to the Qualitative Tests for sodium salt and for sulfate.

**pH** Dissolve 1.0 g of Sodium Aurothiomalate in 10 mL of water: the pH of this solution is between 5.8 and 6.5.

**Purity** (1) Clarity and color of solution—Dissolve 1.0 g of Sodium Aurothiomalate in 10 mL of water: the solution is clear and light yellow.

(2) Heavy metals—Proceed with 1.0 g of Sodium Aurothiomalate according to Method 2, and perform the test. Prepare the control solution with 3.0 mL of Standard Lead Solution (not more than 30 ppm).

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

**Loss on drying** Not more than 8.0% (1 g, in vacuum, phosphorus (V) oxide, 80°C, 4 hours).

**Assay** Weigh accurately about 0.025 g of Sodium Aurothiomalate, previously dried, dissolve in 2 mL of aqua regia by heating, and add water to make exactly 100 mL. Pipet 2 mL of the solution, add water to make exactly 25 mL, and use this solution as the sample solution. Pipet 5, 10 and 15 mL of Standard Gold Solution for the Atomic Absorption Spectrophotometry, add water to make exactly 25 mL, and use these solutions as the standard solutions. Perform the test with the sample solution and the standard solutions as directed under the Atomic Absorption Spectrophotometry under the following conditions. Determine the amount of gold in the sample solution using the calibration curve obtained from the absorbances of the standard solutions.

Gas: Combustible gas—Acetylene gas

Supporting gas—Air

Lamp: Gold hollow-cathode lamp

Wavelength: 242.8 nm

**Containers and storage** Containers—Tight containers.

Storage—Light-resistant.