

directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with *n*-butyl acetate to a distance of about 15 cm, and air-dry the plate. Spray evenly a solution of sulfuric acid in methanol (1 in 10) on the plate, and heat the plate at 105°C for 10 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 Not more than 0.5% (1 g, 105°C, 2 hours).

Residue on ignition Not more than 0.1% (1 g).

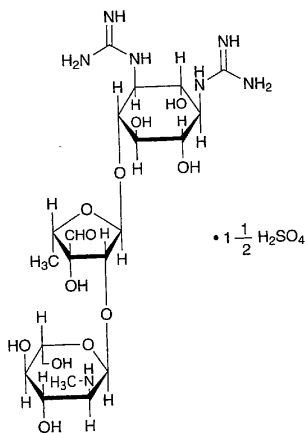
Assay Weigh accurately about 0.05 g each of Spironolactone and Spironolactone Reference Standard, previously dried at 105°C for 2 hours, dissolve in methanol to make exactly 250 mL. Pipet 5 mL each of these solutions, add methanol to make exactly 100 mL, and use these solutions as the sample solution and the standard solution, respectively. Perform the test with these solutions as directed under the Ultraviolet-visible Spectrophotometry, and determine the absorbances, A_T and A_S , of the sample solution and the standard solution at 238 nm.

$$\begin{aligned} & \text{Amount (mg) of } C_{24}H_{32}O_4S \\ &= \text{amount (mg) of Spironolactone Reference Standard} \\ & \quad \times \frac{A_T}{A_S} \end{aligned}$$

Containers and storage Containers—Tight containers.

Streptomycin Sulfate

硫酸ストレプトマイシン



$C_{21}O_{39}N_7O_{12} \cdot 1\frac{1}{2}H_2SO_4$: 728.69

O-2-Deoxy-2-methylamino- α -L-glucopyranosyl-(1 \rightarrow 2)-*O*-5-deoxy-3-*C*-formyl- α -L-lyxofuranosyl-(1 \rightarrow 4)-*N,N'*-diamidino-D-streptamine sesquisulfate [3810-74-0]

Streptomycin Sulfate conforms to the requirements of Streptomycin Sulfate in the Requirements for Antibiotic Products of Japan.

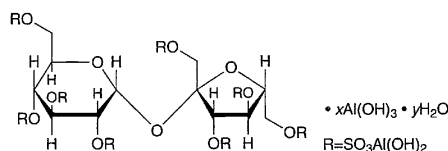
Description Streptomycin Sulfate occurs as a white to light yellowish white powder.

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

Sucralfate

Aluminum Sucrose Sulfate Ester

スクラルファート



$C_{12}H_{30}Al_8O_{51}S_8 \cdot xAl(OH)_3 \cdot yH_2O$
[54182-58-0]

Sucralfate contains not less than 17.0% and not more than 21.0% of aluminum (Al: 26.98) and not less than 34.0% and not more than 43.0% of sucrose octasulfate ester ($C_{12}H_{22}O_{35}S_8$: 982.80), calculated on the dried basis.

Description Sucralfate occurs as a white powder. It is odorless and tasteless.

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

It dissolves in dilute hydrochloric acid and in sulfuric acid-sodium hydroxide TS.

Identification (1) To 0.05 g of Sucralfate in a small test tube add 0.05 g of fresh pieces of sodium, and melt by careful heating. Immerse the test tube immediately in 100 mL of water, break the test tube, shake well, and filter. To 5 mL of the filtrate add 1 drop of sodium pentacyanonitrosylferrate (III) TS: a red-purple color develops.

(2) Dissolve 0.040 g of Sucralfate in 2 mL of dilute sulfuric acid, and add gently 2 mL of anthrone TS to make 2 layers: a blue color develops at the zone of contact, and gradually changes to blue-green.

(3) Dissolve 0.5 g of Sucralfate in 10 mL of dilute hydrochloric acid: the solution responds to the Qualitative Tests for aluminum.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Sucralfate in 10 mL of dilute sulfuric acid: the solution is clear and colorless.

(2) Chloride—Dissolve 0.5 g of Sucralfate in 30 mL of dilute nitric acid, and heat gently to boiling. After cooling, add water to make 100 mL, and to 10 mL of this solution add 3 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 0.70 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.50%).

(3) Heavy metals—Dissolve 1.0 g of Sucralfate in 20 mL of a solution of sodium chloride (1 in 5) and 1 mL of dilute hydrochloric acid, and to this solution 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: evaporate 1 mL of dilute hydrochloric acid on a water bath to dryness, and add 20 mL of a solution of