

of phenolphthalein IS and 0.10 ml of sodium hydroxide (0.1 mol/L) VS, a pink colour is produced.

Particle Size Sift 10.0 g through a No. 8 sieve, any masses may be pressed gently to powder if necessary, then sift. Not less than 85.0% of the powder passes through the sieve.

Residue on ignition Not more than 0.2% (0841).

Arsenic Immerse 0.50 g in 15 ml of ammonia TS for 3 hours and filter. Evaporate 5 ml of the filtrate on a water bath to dryness, add 1 ml of nitric acid and evaporate to dryness again. Add 5 ml of hydrochloric acid and 23 ml of water, carry out the limit test for arsenic (0822, method 1); complies with the requirement (0.0012%).

Assay Weigh accurately about 35 mg, previously dried over phosphorous pentoxide for 4 hours, carry out the method for oxygen flask combustion (0703), using 5 ml of hydrogen peroxide TS and 10 ml of water as the absorbing liquid. When the combustion is complete, cool the combustion flask in ice bath with frequent shaking for 20 minutes. When the fumes produced is completely absorbed, boil the solution for 2 minutes, cool to room temperature, add 2 drops of phenolphthalein IS and titrate with sodium hydroxide (0.1 mol/L) VS. Perform a blank determination and make any necessary correction. Each ml of sodium hydroxide (0.1 mol/L) VS is equivalent to 1.603 mg of S.

Category Insecticide.

Storage Preserve in tightly closed containers.

Preparation Sulfur Ointment

Sulfur Ointment

Sulfur Ointment contains not less than 9.0% and not more than 11.0% of sulfur (S).

Description Yellow ointment; odour, characteristic of sulfur.

Identification (1) Dissolve about 0.5 g in 5 ml of sodium hydroxide TS by heating, filter, cool to room temperature, and add 1 drop of sodium nitroprusside solution (1→100), a blue-purple colour is produced.

(2) Heat 1 g to melt in a test tube. An irritating odour gas evolves, which turn a strip of filter paper wetted with lead acetate TS to black.

Other requirements Complies with the general requirements for ointment (0109).

Assay Heat about 0.5 g, accurately weighed, with 40 ml of 5% sodium sulfite solution under reflux for about 1.5 hours until the sulfur is completely dissolved. Cool and allow the ointment base to solidify, filter. Wash the residue with 30 ml of hot water, cool, filter, and repeat the washing operation for several times. Combine the filtrate and washings, add 10 ml of formaldehyde TS and 6 ml of acetic acid, dilute to 150 ml with water, add starch IS and titrate with iodine (0.05 mol/L) VS. Each ml of iodine (0.05 mol/L) VS is equivalent to 3.206 mg of S.

Category As described under Sublimed Sulfur.

Strength 10%

Storage Preserve in well closed containers, stored at a temperature below 30°C.

Sucralfate

[54182-58-0]

Sucralfate is sucrose octakis (hydrogen sulfate) aluminum complex. It contains not less than 18.0% and not more than 22.0% of Al and not less than 8.5% and not more than 12.5% of S, calculated on the dried basis.

Description A white or almost white powder; odourless; hygroscopic.

Practically insoluble in water, in ethanol and in chloroform. freely soluble in dilute hydrochloric acid and in dilute sulfuric acid; sparingly soluble in dilute nitric acid.

Identification (1) Dissolve about 0.1 g in 1 ml of dilute hydrochloric acid by boiling, cool, neutralize with sodium hydroxide TS and add slowly to warm alkaline cupric tartrate TS. A red cuprous oxide precipitate is produced.

(2) Dissolve 0.1 g in 1 ml of dilute hydrochloric acid, add barium chloride TS and filter if a precipitate is produced. Boil the filtrate, a lot of white precipitate is produced.

(3) Dissolve about 0.1 g in 1 ml of dilute hydrochloric acid, make alkaline with ammonia TS, boil and filter. Dissolve the precipitate in hydrochloric acid, the solution yields the reactions characteristic of aluminum salts (0301).

Neutralizing capacity To about 0.5 g, accurately weighed, in a 250 ml conical flask add accurately 100 ml of hydrochloric acid (0.1 mol/L) VS, stopper, shake frequently for 1 hour at 37°C, cool to room temperature, filter. To 50 ml, accurately measured, of the successive filtrate add a few drops of bromophenol blue IS. Titrate with sodium hydroxide (0.1 mol/L) VS. Each g consumed not less than 130 ml of hydrochloric acid (0.1 mol/L) VS, calculated on the dried basis.

Acidity Heat 0.20 g with 20 ml of water on a boiling water bath for 2-3 minutes, cool to room temperature, pH 3.5-5.5 (0631).

Clarity of acidic solution A solution of 1.0 g in 10 ml of dilute hydrochloric acid is clear. Any opalescence produced is not more pronounced than that of reference suspension 3 (0902, method 1).

Chlorides Transfer 0.10 g in a 100 ml volumetric flask, add 30 ml of 2 mol/L nitric acid, dilute with water to volume, and mix well. Carry out the limit test for chlorides (0801), using 10.0 ml of this solution. Any opalescence produced is not more pronounced than that of a reference solution prepared by using 5.0 ml of sodium chloride standard solution (0.50%).

α -methylpyridine Carry out the method for gas chromatography (0521).

Test solution Pulverize and accurately weigh a quantity of the substance being examined, transfer 2.0 g with 5.0 ml of water in a 10 ml test tube with stopper. Heat on a water bath at 80-90°C for 30 minutes, shake frequently, cool and transfer it to a centrifugal tube and centrifuge, use the supernate.

Reference solution Dissolve a quantity of α -methylpyridine CRS, accurately weighed, in water to produce a solution of 20 μ g per ml.

Chromatographic conditions Use a column packed with ethylvinylbenzene cross-linked with divinylbenzene porous polymer beads (diameter 0.18-0.25 mm); maintain the

column temperature at 200-225°C. The injection volume is 2 µl.

Procedure Inject separately the test solution and the reference solution into the chromatograph and record the chromatograms.

Limits In the chromatogram of the test solution, the peak height of α -methylpyridine is not greater than that of the principal peak in the chromatogram obtained with the reference solution (0.005%).

Loss on drying When dried at 105°C for 3 hours, loses not more than 14.0% of its weight (0831).

Heavy metals Dissolve 1.0 g in 20 ml of hydrochloric acid solution (9→100), by stirring, make alkaline with ammonia TS, add 2 ml of ammonia TS in excess and allow to stand for a few minutes, a precipitate is produced. Filter wash the precipitate with a quantity of water, combine the filtrate and washings, dilute with water to 25 ml, Carry out the limit test for heavy metals (0821, method 3); not more than 0.001%.

Arsenic To 1.0 g add 10 ml of dilute sulfuric acid and 5 ml of bromine TS, heat to boiling, cool, add a few drops of acidic stannous chloride TS to colour fading, add 3 ml of hydrochloric acid and a quantity of water to produce 28 ml. Carry out the limit test for arsenic (0822, method 1), not more than 0.0002%.

Assay Aluminum Dissolve about 1.0 g, accurately weighed, in 10 ml of dilute hydrochloric acid in a 200 ml volumetric flask, dilute with water to volume, and mix. Neutralize 20 ml, accurately measured, with ammonia TS until the precipitate is just produced, add dropwise dilute hydrochloric acid until the precipitate is just dissolved. Add 20 ml of acetic acid-ammonium acetate BS (pH 6.0) and then 25 ml, accurately measured, of disodium edetate (0.05 mol/L) VS. Boil for 3-5 minutes, cool to room temperature and add 1 ml of xylenol orange IS. Titrate with Zinc (0.05 mol/L) VS until the colour changes from yellow to red. Perform a blank determination and make any necessary correction. Each ml of disodium edetate (0.05 mol/L) VS is equivalent to 1.349 mg of aluminum (Al).

Sulfur Boil gently about 1.0 g, accurately weighed, in a beaker with 10 ml of nitric acid solution (1→2) and 10 ml of water for 10 minutes, cool, make alkaline with ammonia TS and add 5 ml of ammonia TS in excess, boil for 1 minute, and allow to cool. Transfer it to a 100 ml volumetric flask, dilute with water to volume, mix well. Filter with dry filter paper, discard the initial filtrate and measure accurately 10 ml of successive filtrate, acidify with hydrochloric acid (1 mol/L) VS and add 3 drops of hydrochloric acid (1 mol/L) VS in excess. Add 10 ml, accurately measured, of barium chloride-magnesium chloride solution (dissolve 6 g barium chloride and 5 g magnesium chloride in water and dilute with water to 500 ml), mix well. Allow it to stand for a few minutes, add 15 ml of ammonia-ammonia chloride BS (pH 10.0), 5 ml of triethanolamine solution (1→2) and a small amount of eriochrome black T indicator mixture, titrate with disodium edetate (0.05 mol/L) VS. Perform a blank determination and make any necessary correction. Each ml of disodium edetate (0.05 mol/L) VS is equivalent to 1.603 mg of S.

Category Antacid.

Storage Preserve in a tightly closed containers, stored in a dry place.

Preparation (1) Sucralfate Capsules
(2) Sucralfate Chewable Tablets

- (3) Sucralfate Dispersible Tablets
(4) Sucralfate Oral Suspension

Sucralfate Capsules

Sucralfate Capsules contain not less than 15.0% and not more than 21.0% of the labelled amount of sucralfate, calculated with reference to aluminum (Al).

Identification To a quantity of the contents equivalent to about 0.5 g of sucralfate, add 10 ml each of water and dilute hydrochloric acid, shake to dissolve sucralfate and filter. The filtrate complies with the tests for Identification described under Sucralfate.

Neutralizing capacity Mix the contents obtained from the test for weight variation of contents, an accurately weighed quantity equivalent to about 0.5 g of sucralfate, comply with the test for Neutralizing capacity described under Sucralfate. Each g consumed not less than 120 ml of hydrochloric acid (0.1 mol/L) VS.

Other requirements Comply with the general requirements for capsules (0103). In the disintegration test, no particle of the contents remaining on the gauze within time limits.

Assay Mix the contents obtained from the test for Weight variation of contents, weigh accurately a quantity equivalent to about 1 g of sucralfate into a 200 ml volumetric flask. Add 10 ml of dilute hydrochloric acid and shake to dissolve sucralfate, dilute with water to volume, mix well and filter. Measure accurately 20 ml of the successive filtrate, carry out the Assay of Aluminium described under Sucralfate. Each ml of disodium edetate (0.05 mol/L) VS is equivalent to 1.349 mg of Al.

Category As described under Sucralfate.

Strength 0.25 g

Storage Preserve in a tightly closed containers.

Sucralfate Chewable Tablets

Sucralfate Chewable Tablets contain not less than 15.0% and not more than 21.0% of the labelled amount of sucralfate, calculated with reference to aluminum (Al).

Description White tablets.

Identification To a quantity of the powdered tablets equivalent to about 0.5 g of sucralfate, add 10 ml each of water and dilute hydrochloric acid, shake to dissolve sucralfate and filter. The filtrate complies with the tests for Identification described under Sucralfate.

Neutralizing capacity Weigh accurately a quantity of the powdered tablets obtained in Assay, equivalent to about 0.5 g of sucralfate, comply with the test for Neutralizing capacity described under Sucralfate. Each g consumed not less than 120 ml of hydrochloric acid (0.1 mol/L) VS.

Other requirements Comply with the general requirements for tablets (0101).

Assay Weigh accurately and finely powder 20 tablets. Weigh accurately a quantity equivalent to about 1 g of sucralfate into a 200 ml volumetric flask. Add 10 ml of dilute hydrochloric

acid and shake to dissolve sucralfate, dilute with water to volume, mix well and filter. Measure accurately 20 ml of the successive filtrate, carry out the Assay of Aluminium described under Sucralfate. Each ml of disodium edetate (0.05 mol/L) VS is equivalent to 1.349 mg of aluminum (Al).

Category As described under Sucralfate.

Strength (1) 0.25 g (2) 0.5 g (3) 1.0 g

Storage Preserve in a tightly closed containers.

Sucralfate Dispersible Tablets

Sucralfate Dispersible Tablets contain not less than 15.0% and not more than 21.0% of the labelled amount of sucralfate, calculated with reference to aluminum (Al).

Description White tablets.

Identification To a quantity of the powdered tablets equivalent to about 0.5 g of sucralfate, add 10 ml each of water and dilute hydrochloric acid, shake to dissolve sucralfate and filter. The filtrate complies with the tests for Identification described under Sucralfate.

Neutralizing capacity Weigh accurately a quantity of the powdered tablets obtained in Assay, equivalent to about 0.5 g of sucralfate, comply with the test for Neutralizing capacity described under Sucralfate. Each g consumed not less than 120 ml of hydrochloric acid (0.1 mol/L) VS.

Other requirements Comply with the general requirements for tablets (0101).

Assay Weigh accurately and finely powder 20 tablets. Weigh accurately a quantity equivalent to about 1 g of sucralfate into a 200 ml volumetric flask. Add 10 ml of dilute hydrochloric acid and shake to dissolve sucralfate, dilute with water to volume, mix well and filter. Measure accurately 20 ml of the successive filtrate, carry out the Assay of Aluminium described under Sucralfate. Each ml of disodium edetate (0.05 mol/L) VS is equivalent to 1.349 mg of aluminum (Al).

Category As described under Sucralfate.

Strength 0.25 g

Storage Preserve in a tightly closed containers, stored in a dry place.

Sucralfate Oral Suspension

Sucralfate Oral Suspension contains not less than 16.0% and not more than 24.0% of the labelled amount of sucralfate, calculated with reference to aluminum (Al).

Description A white or almost white creamy suspension.

Identification Weigh a quantity equivalent to about 0.5 g of sucralfate into a beaker, add 100 ml of water and stir thoroughly, allow to stand. Shake the precipitate with 10 ml of dilute hydrochloric acid and filter. The filtrate complies with the tests for Identification described under Sucralfate.

Relative density 1.030-1.090 (for strength 10%); 1.120-1.200 (for strength 20%) (0601).

Neutralizing capacity Weigh accurately a quantity equivalent to about 0.5 g of sucralfate, comply with the test for Neutralizing capacity described under Sucralfate. Calculate on the basis relative density. Each g consumed not less than 120 ml of hydrochloric acid (0.1 mol/L) VS.

pH 4.5-6.5 (0631).

Particle size After shaking thoroughly, mix several drops with a quantity of water, examine under a microscope in 3 fields of view, using 300-400 X magnification. Not less than 85% of the particles have a dimension of not more than 10 µm.

Other requirements Complies with the general requirements for oral suspension (0123).

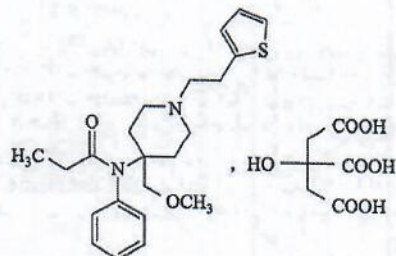
Assay Weigh accurately a quantity equivalent to about 1 g of sucralfate into a 200 ml volumetric flask. Add 10 ml of dilute hydrochloric acid and shake to dissolve sucralfate, dilute with water to volume, mix well. Measure accurately 20 ml, carry out the Assay of Aluminium described under Sucralfate. Calculate the content on the basis of relative density. Each ml of disodium edetate (0.05 mol/L) VS is equivalent to 1.349 mg of aluminum (Al).

Category As described under Sucralfate.

Strength (1) 5 ml : 1 g
(2) 10 ml : 1 g
(3) 200 ml : 20 g
(4) 120 ml : 24 g
(5) 200 ml : 40 g

Storage Preserve in tightly closed containers, stored in a cool and dry place and protect from light.

Sufentanil Citrate



$C_{22}H_{30}N_2O_2S \cdot C_6H_5O_7$, 578.69 [60561-17-3]

Sufentanil Citrate is *N*-[4-(methoxymethyl)-1-[2-(2-thienyl)ethyl]-4-piperidyl] propionanilide citrate. It contains not less than 99.0% of $C_{22}H_{30}N_2O_2S \cdot C_6H_5O_7$, calculated on the dried basis.

Description A white or almost white crystalline powder. Freely soluble in methanol, soluble in ethanol and in water, slightly soluble in acetone and in chloroform.

Melting range 137-143°C, with decomposition (0612).

Identification (1) Weigh about 5 mg of the substance being examined, add a quantity of water to dissolve, add 1-2 drops of phosphomolybdic acid TS, a white precipitate is formed.

(2) The infrared absorption spectrum (0402) is concordant with the reference spectrum (IR Album No. 1320).

(3) Yields the reactions characteristic of citrates (0301).