(3) Determine the absorption spectrum of a solution of Sultiame in methanol (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

Melting point 185 - 188°C

Purity (1) Chloride—Dissolve 1.0 g of Sultiame in 20 mL of sodium hydroxide TS by warming, cool, and add 2 mL of acetic acid (100) and water to make 100 mL. After shaking, filter, and discard the first 10 mL of the filtrate. To the subsequent 40 mL add 6 mL of dilute nitric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution as follows: to 0.25 mL of 0.01 mol/L hydrochloric acid VS add 8 mL of sodium hydroxide TS, 0.8 mL of acetic acid (100), 6 mL of dilute nitric acid and water to make 50 mL (not more than 0.022%).

(2) Sulfate—Dissolve 1.0 g of Sultiame in 20 mL of sodium hydroxide TS by warming, cool, and add 8 mL of dilute hydrochloric acid and water to make 100 mL. After shaking, filter, and discard the first 10 mL of the filtrate. To the subsequent 40 mL add 1 mL of dilute hydrochloric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution as follows: to 0.40 mL of 0.005 mol/L sulfuric acid VS add 8 mL of sodium hydroxide TS, 4.2 mL of dilute hydrochloric acid and water to make 50 mL (not more than 0.048%).

(3) Heavy metals—Proceed with 2.0 g of Sultiame according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

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

(5) Related substances—Dissolve 0.10 g of Sultiame in methanol to make exactly 20 mL, and use this solution as the sample solution. Separately, dissolve 0.010 g of sulfanilamide in methanol to make exactly 100 mL. Pipet 10 mL of this solution, add methanol to make exactly 100 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 20 μL 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 chloroform, methanol and ammonia solution (28) (30:8:1) to a distance of about 12 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): 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, 3 hours).

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

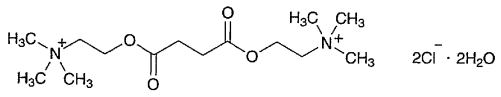
Assay Weigh accurately about 0.8 g of Sultiame, previously dried, dissolve in 70 mL of *N,N*-dimethylformamide, and titrate with 0.2 mol/L tetramethylammonium hydroxide VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.2 mol/L tetramethylammonium hydroxide VS
= 58.07 mg of $C_{10}H_{14}N_2O_4S_2$

Containers and storage Containers—Well-closed containers.

Suxamethonium Chloride

塩化スキサメトニウム



$C_{14}H_{30}Cl_2N_2O_4.2H_2O$: 397.34
2,2′-Succinyldioxybis(*N*-ethyl-*N,N,N*-trimethylammonium) dichloride dihydrate [*6101-15-1*]

Suxamethonium Chloride contains not less than 98.0% of $C_{14}H_{30}Cl_2N_2O_4$ (mol. wt.: 361.31), calculated on the anhydrous basis.

Description Suxamethonium Chloride occurs as a white, crystalline powder.

It is freely soluble in water, in methanol and in acetic acid (100), slightly soluble in ethanol (95), very slightly soluble in acetic anhydride, and practically insoluble in diethyl ether.

Identification (1) Determine the infrared absorption spectrum of Suxamethonium Chloride as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers.

(2) A solution of Suxamethonium Chloride (1 in 20) responds to the Qualitative Tests for chloride.

pH The pH of a solution of Suxamethonium Chloride (1 in 100) is between 4.0 and 5.0.

Melting point 159 - 164°C (hydrate form).

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Suxamethonium Chloride in 10 mL of water: the solution is clear and colorless.

(2) Related substances—Dissolve 0.25 g of Suxamethonium Chloride in 5 mL of water, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add water to make exactly 200 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 1 μL each of the sample solution and the standard solution on a plate of cellulose for thin-layer chromatography. Develop the plate with a mixture of a solution of ammonium acetate (1 in 100), acetone, n-butanol and formic acid (20:20:20:1) to a distance of about 10 cm, and dry the plate at 105°C for 15 minutes. Spray evenly platinic chloride-potassium iodide TS on the plate, and allow to stand for 15 minutes: the spots other than the principal spot from the sample solution are not more intense than the spot from the standard solution.

Water 8.0 - 10.0% (0.4 g, direct titration).

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

Assay Weigh accurately about 0.4 g of Suxamethonium Chloride, dissolve in 80 mL of a mixture of acetic anhydride

and acetic acid (100) (7:3), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration).

Each mL of 0.1 mol/L perchloric acid VS
= 18.065 mg of $C_{14}H_{30}Cl_2N_2O_4$

Containers and storage Containers—Tight containers.

Suxamethonium Chloride for Injection

注射用塩化スキサメトニウム

Suxamethonium Chloride for Injection is a preparation for injection which is dissolved before use. It contains not less than 93% and not more than 107% of the labeled amount of suxamethonium chloride ($C_{14}H_{30}Cl_2N_2O_4$: 361.31).

The is concentration of Suxamethoium Chloride for Injection should be stated as the amount of suxamethonium chloride ($C_{14}H_{30}Cl_2N_2O_4$).

Method of preparation Prepare as directed under Injections, with Suxamethonium Chloride.

Description Suxamethonium Chloride for Injection occurs as a white, crystalline powder or mass.

Identification Take an amount of Suxamethonium Chloride for Injection, equivalent to 0.05 g of Suxamethonium Chloride according to the labeled amount, dissolve in water to make 10 mL, and use this solution as the sample solution. Separately, dissolve 0.05 g of suxamethonium chloride for thin-layer chromatography in 10 mL of water, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 1 μL each of the sample solution and the standard solution on a plate of cellulose for thin-layer chromatography. Develop the plate with a mixture of a solution of ammonium acetate (1 in 100), acetone, 1-butanol and formic acid (20:20:20:1) to a distance of about 10 cm, and dry the plate at 105°C for 15 minutes. Spray evenly platinic chloride-potassium iodide TS on the plate: the spots obtained from the sample solution and the standard solution are blue-purple in color and have similar *R*f.

pH The pH of a solution of Suxamethonium Chloride for Injection (1 in 100) is between 4.0 and 5.0.

Purity Related substances—Take an amount of Suxamethonium Chloride for Injection, equivalent to 0.25 g of Suxamethonium Chloride according to the labeled amount, and proceed as directed in the Purity (2) under Suxamethonium Chloride.

Assay Weigh accurately the contents of not less than 10 preparations of Suxamethonium Chloride for Injection. Weigh accurately about 0.5 g of the contents, and proceed as directed in the Assay under Suxamethonium Chloride.

Each mL of 0.1 mol/L perchloric acid VS
= 18.065 mg of $C_{14}H_{30}Cl_2N_2O_4$

Containers and storage Containers—Hermetic containers.

Suxamethonium Chloride Injection

塩化スキサメトニウム注射液

Suxamethonium Chloride Injection is an aqueous solution for injection. It contains not less than 93% and not more than 107% of the labeled amount of suxamethonium chloride ($C_{14}H_{30}Cl_2N_2O_4$: 361.31).

The concentration of Suxamethonium Chloride Injection should be stated as the amount of suxamethonium chloride ($C_{14}H_{30}Cl_2N_2O_4$).

Method of preparation Prepare as directed under Injections, with Suxamethonium Chloride.

Description Suxamethonium Chloride Injection is a clear, colorless liquid.

Identification Take a volume of Suxamethonium Chloride Injection, equivalent to 0.05 g of Suxamethonium Chloride according to the labeled amount, add water to make 10 mL, and use this solution as the sample solution. Separately, dissolve 0.05 g of suxamethonium chloride for thin-later chromatography in 10 mL of water, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 1 μL each of the sample solution and the standard solution on a plate of cellulose for thin-layer chromatography. Develop the plate with a mixture of a solution of ammonium acetate (1 in 100), acetone, 1-butanol and formic acid (20:20:20:1) to a distance of about 10 cm, and dry the plate at 105°C for 15 minutes. Spray evenly platinic chloride-potassium iodide TS on the plate: the spots obtained from the sample solution and the standard solution are blue-purple in color and have similar *R*f.

pH 3.0 - 5.0

Purity Hydrolysis products—Perform the preliminary neutralization with 0.1 mol/L sodium hydroxide VS in the Assay: not more than 0.7 mL of 0.1 mol/L sodium hydroxide VS is required for each 200 mg of Suxamethonium Chloride ($C_{14}H_{30}Cl_2N_2O_4$) taken.

Assay Transfer to a separator an accurately measured volume of Suxamethonium Chloride Injection, equivalent to about 0.2 g of suxamethonium chloride ($C_{14}H_{30}Cl_2N_2O_4$), add 30 mL of freshly boiled and cooled water, and wash the solution with five 20-mL portions of diethyl ether. Combine the diethyl ether washings, and extract the combined diethyl ether layer with two 10-mL portions of freshly boiled and cooled water. Wash the combined water extracts with two 10-mL portions of diethyl ether. Combine the solution and the water extracts, add 2 drops of bromothymol blue TS, and neutralize with 0.1 mol/L sodium hydroxide VS. Add accurately measured 25 mL of 0.1 mol/L sodium hydroxide VS, and boil for 40 minutes under a reflux condenser, and cool. Titrate the excess sodium hydroxide with 0.1 mol/L hydrochloric acid VS. Transfer 50 mL of the freshly boiled and cooled water to a flask, add 2 drops of bromothymol blue TS, neutralize the solution with 0.1 mol/L sodium hydroxide VS, and perform a blank determination.

Each mL of 0.1 mol/L sodium hydroxide VS
= 18.065 mg of $C_{14}H_{30}Cl_2N_2O_4$