Herb in a glass-stoppered centrifuge tube, add 40 mL of methanol, shake for 15 minutes, centrifuge, and separate the supernatant liquid. To the residue add 40 mL of methanol, and proceed in the same manner. Combine the extracts, and add methanol to make exactly 100 mL. Pipet 5 mL of the solution, add the mobile phase to make exactly 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of Swertiamarin Reference Standard (separately determine the water content), dissolve in methanol to make exactly 20 mL. Pipet 5 mL of the solution, add the mobile phase to make exactly 20 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions, and determine the peak areas, A_T and A_S, of swertiamarin in each solution.

Amount (mg) of swertiamarin ($C_{16}H_{22}O_{10}$)
= amount (mg) of Swertiamarin Reference Standard, calculated on the anhydrous basis

$$\times \frac{A_T}{A_S} \times 5$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 238 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 50°C.

Mobile phase: A mixture of water and acetonitrile (91:9).

Flow rate: Adjust the flow rate so that the retention time of swertiamarin is about 12 minutes.

System suitability—

System performance: Dissolve 1 mg each of Sweriamarin Reference Standard and theophylline in the mobile phase to make 10 mL. When the procedure is run with 10 μL of this solution under the above operating conditions, theophylline and swertiamarin are eluted in this order with the resolution of these peaks being not less than 10.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of swertiamarin is not more than 1.5%.

Swertia and Sodium Bicarbonate Powder

センブリ・重曹散

Method of preparation

Powdered Swertia Herb	30 g
Sodium Bicarbonate	700 g
Starch, Lactose or their mixture	a sufficient quantity
To make	1000 g

Prepare as directed under Powders, with the above ingredients.

Description Swertia and Sodium Bicarbonate Powder occurs as a light grayish yellow powder, having a bitter taste.

Identification (1) To 10 g of Swertia and Sodium Bicarbonate Powder add 10 mL of ethanol (95), shake for 15 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of swertiamarin for thin-layer chromatography in 1 mL of ethanol (95), and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 30 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Proceed as directed in the Identification under Swertia Herb.

(2) To 0.5 g of Swertia and Sodium Bicarbonate Powder add 10 mL of water. After stirring, centrifuge the mixture with 500 revolutions per minute. Smear, using a small glass rod, the slide glass with a small amount of the precipitate, add 1 drop of a mixture of water and glycerin (1:1), and put a cover glass on it so that the tissue section spreads evenly without overlapping each other, taking precaution against inclusion of bubbles, and use this as the preparation for microscopic examination. If the precipitate separates into two layers, proceed with the upper layer in the same manner, and use as the preparation for microscopic examination. Heat the preparation for microscopic examination in a short time: the preparation reveals the yellow-green to yellow-brown, approximately spherical pollen grains with granular patterns under a microscope. The pollen grains are about 33 μm in diameter.

(3) The supernatant liquid obtained in (2) by centrifuging responds to the Qualitative Tests (1) for bicarbonate.

Containers and storage Containers—Well-closed containers.

Talc

タルク

Talc is a native, hydrous magnesium silicate, sometimes containing a small portion of aluminum silicate.

Description Talc occurs as a white to grayish white, fine, crystalline powder. It is odorless and tasteless.

It is unctuous, and adheres readily to the skin.

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

Identification (1) Mix 0.2 g of Talc with 0.9 g of anhydrous sodium carbonate and 1.3 g of potassium carbonate, and heat the mixture in a platinum or nickel crucible until fusion is complete. Cool, and transfer the fused mixture to a beaker with the aid of 50 mL of hot water. Add hydrochloric acid until it ceases to cause effervescence, add 10 mL of hydrochloric acid, and evaporate the mixture on a water bath to dryness. Cool, add 20 mL of water, boil, and filter. Add 10 mL of a solution of methylene blue trihydrate (1 in 10,000) to the residue, and wash with water: the precipitate is blue in color.

(2) Dissolve 2 g of ammonium chloride and 5 mL of ammonia TS in the filtrate obtained in (1), filter if necessary,

and add disodium hydrogenphosphate TS: a white, crystalline precipitate is produced.

Purity (1) Acid-soluble substances—Weigh accurately about 1 g of Talc, heat with 20 mL of dilute hydrochloric acid at 50°C for 15 minutes with stirring. Cool, add water to make exactly 50 mL, and filter. Centrifuge, if necessary, until the filtrate becomes clear. To 25 mL of this filtrate add 1 mL of dilute sulfuric acid, evaporate to dryness, and ignite to constant mass at 800 ± 25°C: the amount of the residue is not more than 2.0%.

(2) Acid or alkali, and water-soluble substances—To 10.0 g of Talc, add 50 mL of water, weigh, and boil for 30 minutes, supplying water lost by evaporation. Cool, add water to restore the original mass, and filter. Centrifuge, if necessary, until the filtrate becomes clear: the filtrate is neutral. Evaporate 20 mL of the filtrate to dryness, and dry the residue at 105°C for 1 hour: the mass of the residue is not more than 4.0 mg.

(3) Water-soluble iron—Make 10 mL of the filtrate obtained in (2) weakly acidic with hydrochloric acid, and add dropwise potassium hexacyanoferrate (II) TS: the liquid does not acquire a blue color.

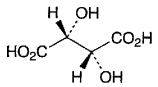
(4) Arsenic—To 0.5 g of Talc add 5 mL of dilute sulfuric acid, and heat gently to boiling with shaking. Cool immediately, filter, and wash the residue with 5 mL of dilute sulfuric acid, then with 10 mL of water. Combine the filtrate and the washings, evaporate to 5 mL on a water bath, and perform the test using apparatus B with this solution as the test solution (not more than 4 ppm).

Loss on drying Not more than 5.0% (1 g, 450 - 550°C, 3 hours).

Containers and storage Containers—Well-closed containers.

Tartaric Acid

酒石酸



$C_4H_6O_6$: 150.09
(2*R*,3*R*)-2,3-Dihydroxybutanedioic acid [*87-69-4*]

Tartaric Acid, when dried, contains not less than 99.7% of $C_4H_6O_6$.

Description Tartaric Acid occurs as colorless crystals or a white, crystalline powder. It is odorless, and has a strong acid taste.

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

A solution of Tartaric Acid (1 in 10) is dextrorotatory.

Identification (1) Ignite Tartaric Acid gradually: it decomposes and an odor of burning sugar is perceptible.

(2) A solution of Tartaric Acid (1 in 10) changes blue litmus paper to red, and responds to the Qualitative Tests for tartrate.

Purity (1) Sulfate—Perform the test with 0.5 g of Tartaric Acid. Prepare the control solution with 0.50 mL of 0.005 mol/L sulfuric acid VS (not more than 0.048%).

(2) Oxalate—Dissolve 1.0 g of Tartaric Acid in 10 mL of water, and add 2 mL of calcium chloride TS: no turbidity is produced.

(3) Heavy metals—Proceed with 2.0 g of Tartaric Acid according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(4) Calcium—Neutralize a solution of 1.0 g of Tartaric Acid in 10 mL of water with ammonia TS, and add 1 mL of ammonium oxalate TS: no turbidity is produced.

(5) Arsenic—Prepare the test solution with 2.0 g of Tartaric Acid according to Method 1, and perform the test using Apparatus B (not more than 1 ppm).

Loss on drying Not more than 0.5% (3 g, silica gel, 3 hours).

Residue on ignition Not more than 0.05% (1 g).

Assay Weigh accurately about 1.5 g of Tartaric Acid, previously dried, dissolve in 40 mL of water, and titrate with 1 mol/L sodium hydroxide VS (indicator: 2 drops of phenolphthalein TS).

Each mL of 1 mol/L sodium hydroxide VS
= 75.04 mg of $C_4H_6O_6$

Containers and storage Containers—Well-closed containers.

Adsorbed Tetanus Toxoid

沈降破傷風トキソイド

Adsorbed Tetanus Toxoid is a liquid for injection containing tetanus toxoid prepared by treating tetanus toxin with formaldehyde by a method involving no appreciable loss of the immunogenicity and rendered insoluble by the addition of aluminum salt.

It conforms to the requirements of Adsorbed Tetanus Toxoid in the Minimum Requirements for Biological Products.

Description Adsorbed Tetanus Toxoid becomes a uniform white-turbid liquid on shaking.

Freeze-dried Tetanus Antitoxin, Equine

乾燥破傷風ウマ抗毒素

Freeze-dried Tetanus Antitoxin, Equine, is a preparation for injection which is dissolved before use. It contains tetanus antitoxin in immunoglobulin of horse origin.

It conforms to the requirements of Freeze-dried Teta-