the Nessler tube, stopper, and allow to stand for 2 days: no precipitate is produced.

(2) Chloride—To 10.0 g of White Soft Sugar add water to make 100 mL, and use this solution as the sample solution. To 20 mL of the sample solution add 6 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 0.30 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.005%).

(3) Sulfate—To 40 mL of the sample solution obtained in (2) add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Propare the control solution with 0.50 mL of 0.005 mol/L sulfuric acid VS (not more than 0.006%).

(4) Calcium—To 10 mL of the sample solution obtained in (2) add 1 mL of ammonium oxalate TS: this solution shows immediately no change.

(5) Heavy metals—Proceed with 5.0 g of White Soft Sugar according to Method 1, and perform the test. Prepare the control solution with 2.5 mL of Standard Lead Solution (not more than 5 ppm).

(6) Arsenic—Prepare the test solution with 1.0 g of White Soft Sugar according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

(7) Invert sugar—Dissolve 5.0 g of White Soft Sugar in water to make 100 mL, filter if necessary, and use this solution as the sample solution. Separately place 100 mL of alkaline copper (II) sulfate solution in a 300-mL beaker, cover the beaker with a watch glass, and boil. Immediately add 50.0 mL of the sample solution, boil the mixture exactly for 5 minutes, add at once 50 mL of freshly boiled and cooled water, dip it in a water bath of a temperature below 10°C for 5 minutes, and collect the precipitate in a tared glass filter (G4). Wash the residue on the filter with water until the last washing is neutral, then wash with 10 mL of ethanol (95), add 10 mL of diethyl ether, and dry at 105°C for 30 minutes: the mass of the residual precipitate is not more than 0.120 g.

Loss on drying Not more than 1.30% (15 g, 105°C, 2 hours).

Residue on ignition Not more than 0.10% (2 g).

Containers and storage Containers—Well-closed containers.

Sulfur and Camphor Lotion

イオウ・カンフルローション

Method of preparation

Sulfur	60 g
d-Camphor or *dl*-Camphor	5 g
Hydroxypropylcellulose	4 g
Calcium Hydroxide	1 g
Ethanol	4 mL
Water or Purified Water	a sufficient quantity
	To make 1000 mL

Dissolve Hydroxypropylcellulose in 200 mL of Water or Purified Water. Add this solution in small portions to the triturate of Sulfur with the Ethanol solution of *d*-Camphor or *dl*-Camphor, and triturate again the mixture. Separately, dissolve Calcium Hydroxide in 500 mL of Water or Purified Water, stopper tightly, shake, and allow to stand. Add 300 mL of this supernatant liquid to the above mixture, then add Water or Purified Water to make 1000 mL, and shake thoroughly.

Description Sulfur and Camphor Lotion is a light yellow suspension.

A part of the components separates out on standing.

Identification **(1)** To 5 mL of well shaken Sulfur and Camphor Lotion add 25 mL of water, and centrifuge [use this supernatant liquid for test (3)]. To 0.02 g of the precipitate add 2 mL of pyridine and 0.2 mL of sodium hydrogen carbonate TS, and boil: a blue color develops (sulfur).

(2) To 10 mL of well shaken Sulfur and Comphor Lotion add 5 mL of diethyl ether, and mix. Separate the diethyl ether layer, and filter through a pledget of cotton. Wash the cotton with a small portion of diethyl ether, combine the washings with the filtrate, and distil cautiously on a water bath to remove the diethyl ether. Dissolve the residue in 1 mL of methanol, add 1 mL of 2,4-dinitrophenylhydrazine TS, and heat for about 2 minutes on a water bath. Cool, dilute with water to make about 5 mL, and allow to stand. Filter the produced precipitate through a glass filter (G4), and wash the residue on the filter with water until the last washing is colorless. Dissolve the residue in 10 mL of ethanol (95), add 5 mL of sodium hydroxide TS, and allow to stand for 2 minutes: a red color develops (*d*-camphor or *dl*-camphor).

(3) The supernatant liquid obtained in (1) responds to the Qualitative Tests (2) and (3) for calcium salt.

Containers and storage Containers—Tight containers.

Sulfur, Salicylic Acid and Thianthol Ointment

イオウ・サリチル酸・チアントール軟膏

Method of preparation

Sulfur	100 g
Salicylic Acid, finely powdered	30 g
Thianthol	100 mL
Zinc Oxide, very finely powdered	100 g
Simple Ointment or a suitable ointment base	a sufficient quantity
	To make 1000 g

Prepare as directed under Ointments, with above ingredients.

Description Sulfur, Salicylic Acid and Thianthol Ointment is light yellow in color.

Identification **(1)** Stir well 0.5 g of Sulfur, Salicylic Acid and Thianthol Ointment with 10 mL of water while heating, cool, and filter. To 1 mL of the filtrate add 5 mL of iron (III) nitrate TS: a purple color is produced (salicylic acid).

(2) Shake 1 g of Sulfur, Salicylic Acid and Thianthol Ointment with 20 mL of diethyl ether, remove the super-

natant liquid and floating materials. Wash the residue with 10 mL of diethyl ether, and remove the diethyl ether by suction. To the residue add 2 mL of pyridine and 0.2 mL of sodium hydrogen carbonate TS, and boil: a light blue to blue color is produced (sulfur).

(3) To 1 g of Sulfur, Salicylic Acid and Thianthol Ointment add 15 mL of ethanol (95), stir well while warming on a water bath, cool, and filter. Use the filtrate as the sample solution. Dissolve 0.01 g each of salicylic acid and thianthol in 5 mL of ethanol (95), and use these solutions as the standard solution (1) and standard solution (2). Perform the test with these solutions as directed under Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solutions on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform, acetone and acetic acid (100) (45:5:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots of each component obtained from the sample solution and the standard solutions (1) and (2) show the same *Rf* value. Spray iron (III) chloride TS upon the plate evenly: the spot from the standard solution (1) and that from the corresponding sample solution reveal a purple color.

Containers and storage Containers—Tight containers.

Sweet Hydrangea Leaf

Hydrangeae Dulcis Folium

アマチャ

Sweet Hydrangea Leaf is the leaf and twig of *Hydrangea macrophylla* Seringe var. *thunbergii* Makino (*Saxifragaceae*).

Description Usually wrinkled and contracted leaf, dark green to dark yellow-green in color. When soaked in water and smoothed out, it is lanceolate to acuminately ovate, about 12 cm in length, about 5 cm in width; margin serrated, base slightly wedged; coarse hair on both surfaces, especially on the veins; lateral veins not reaching the margin but curving upwards and connecting with each other; petiole short and less than one-fifth of the length of lamina. Odor, slight; taste, characteristically sweet.

Identification Mix 0.5 g of pulverized Sweet Hydrangea Leaf with 8 mL of a mixture of diethyl ether and petroleum ether (1:1), shake well, filter, and evaporate the filtrate to dryness. Dissolve the residue in 1 mL of dilute ethanol, and add 1 drop of dilute iron (III) chloride TS: a red-purple color develops, which disappears on the addition of 2 to 3 drops of dilute sulfuric acid.

Purity (1) Stem—The amount of stems contained in Sweet Hydrangea Leaf does not exceed 3.0%.

(2) Foreign matter—The amount of foreign matter other than stems contained in Sweet Hydrangea Leaf does not exceed 1.0%.

Loss on drying Not more than 13.0% (6 hours).

Total ash Not more than 12.0%.

Acid-insoluble ash Not more than 2.5%.

Powdered Sweet Hydrangea Leaf

Hydrangeae Dulcis Folium Pulveratum

アマチャ末

Powdered Sweet Hydrangea Leaf is the powder of Sweet Hydrangea Leaf.

Description Powdered Sweet Hydrangea Leaf occurs as a dark yellow-green powder, and has a faint odor and a characteristic, sweet taste.

Under a microscope, Powdered Sweet Hydrangea Leaf reveals fragments of epidermis with wavy lateral membrane; stomata with two subsidiary cells; unicellular and thin-walled hair with numerous protrusions of the surface, 150 – 300 μm in length; fragments of palisade tissue and spongy tissue; fragments of vascular bundle and mucilage cells containing raphides of calcium oxalate 50 – 70 μm in length.

Identification Mix 0.5 g of Powdered Sweet Hydrangea Leaf with 8 mL of a mixture of diethyl ether and petroleum ether (1:1), shake well, filter, and evaporate the filtrate to dryness. Dissolve the residue in 1 mL of dilute ethanol, and add 1 drop of dilute iron (III) chloride TS: a red-purple color develops, which disappears on the addition of 2 to 3 drops of dilute sulfuric acid.

Purity Foreign matter—Under a microscope, Powdered Sweet Hydrangea Leaf does not show stone cells, a large quantity of fibers or starch grains.

Loss on drying Not more than 12.0% (6 hours).

Total ash Not more than 12.0%.

Acid-insoluble ash Not more than 2.5%.

Swertia Herb

Swertiae Herba

センブリ

Swertia Herb is the whole herb of *Swertia japonica* Makino (*Gentianaceae*) collected during the blooming season.

It contains not less than 2.0% of swertiamarin ($C_{16}H_{22}O_{10}$: 374.34), calculated on the basis of dried material.

Description Herb, 20 cm in length, having flowers, opposite leaves, stems, and, usually, with short, lignified roots; stems square, about 0.2 cm in diameter, often with branches; the leaves and stems dark green to dark purple or yellow-brown in color; the flowers white to whitish, and the roots yellow-brown. When smoothed by immersing in water, leaves, linear or narrow lanceolate, 1 – 4 cm in length, 0.1 – 0.5 cm in width, entire, and sessile; corolla split deeply as five lobes; the lobes narrow, elongated ellipse shape, and under a magnifying glass, with two elliptical nectaries juxtaposed at the base of the inner surface; the margin of lobe resembles eyelashes; the five stamens grow on the tube of the corolla