Description Capsicum Tincture is a yellow-red liquid. It has a burning, pungent taste.

Specific gravity d_{20}^{20}: about 0.82

Identification Proceed as directed in the Identification under Capsicum, using Capsicum Tincture as the sample solution. Spot 20 μL each of the sample solution and the standard solution.

Alcohol number Not less than 9.7 (Method 2).

Component determination Pipet 2 mL of Capsicum Tincture, add methanol to make exactly 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of capsaicin for component determination, previously dried in a desiccator (in vacuum, phosphorus (v) oxide, 40°C) for 5 hours, dissolve in methanol to make exactly 50 mL. Pipet 2 mL of this solution, add methanol to make exactly 25 mL, and use this solution as the standard solution. Perform the test with exactly 20 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_{TC} and A_{TD}, of capsaicin and dihydrocapsaicin (the relative retention time to capsaicin is about 1.3) in the sample solution, and the peak area, A_S, of capsaicin in the standard solution.

Amount (mg) of total capsaicins
= amount (mg) of capsaicin for component determination
$$\times \frac{A_{TC} + A_{TD}}{A_S} \times 0.032$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 281 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 25 cm in length, packed with phenylated silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 30°C.

Mobile phase: A mixture of diluted phosphoric acid (1 in 1000) and acetonitrile (3:2).

Flow rate: Adjust the flow rate so that the retention time of capsaicin is about 20 minutes.

System suitability—

System performance: Dissolve 1 mg each of capsaicin for component determination and 4-hydroxy-3-methoxybenzyl nonylic acid amide in methanol to make 50 mL. When the procedure is run with 20 μL of this solution under the above operating conditions, 4-hydroxy-3-methoxybenzyl nonylic acid amide and capsaicin are eluted in this order with the resolution between these peaks being not less than 1.5.

System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of capsaicin is not more than 1.5%.

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Capsicum and Salicylic Acid Spirit

トウガラシ・サリチル酸精

Method of preparation

Capsicum Tincture	40 mL
Salicylic Acid	50 g
Liquefied Phenol	20 mL
Castor Oil	100 mL
Aromatic substance	a suitable quantity
Ethanol	a sufficient quantity
	To make 1000 mL

Prepare as directed under Medicated Spirits, with the above ingredients.

Description Capsicum and Salicylic Acid Spirit is a light brown-yellow liquid.

Specific gravity d_{20}^{20}: about 0.84

Identification **(1)** Shake 10 mL of Capsicum and Salicylic Acid Spirit with 15 mL of sodium hydrogen carbonate TS and 10 mL of diethyl ether, and separate the water layer. To 1 mL of the solution add hydrochloric acid-potassium chloride buffer solution, pH 2.0, to make 200 mL, and to 5 mL of this solution add 5 mL of a solution of iron (III) nitrate enneahydrate (1 in 200): a red-purple color is produced (salicylic acid).

(2) To 0.5 mL of Capsicum and Salicylic Acid Spirit add 20 mL of water and 5 mL of dilute hydrochloric acid, extract with 20 mL of diethyl ether, wash the diethyl ether extract with two 5-mL portions of sodium hydrogen carbonate TS, and then extract with 20 mL of dilute sodium hydroxide TS. To 1 mL of the extract add 1 mL of sodium nitrite TS and 1 mL of dilute hydrochloric acid, shake, and allow to stand for 10 minutes. Add 3 mL of sodium hydroxide TS: a yellow color is produced (phenol).

(3) To 0.2 mL of Capsicum and Salicylic Acid Spirit add 5 mL of dilute hydrochloric acid, extract with 5 mL of chloroform, and use the extract as the sample solution. Dissolve 0.01 g of salicylic acid and 0.02 g of phenol in 5 mL and 25 mL of chloroform, respectively, and use both solutions as standard solution (1) and standard solution (2). Perform the test with the sample solution and standard solution (1) and standard solution (2) as directed under Thin-layer Chromatography. Spot 5 μL each of these 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): two spots from the sample solution exhibit the same *Rf* values as those from standard solution (1) and standard solution (2). Spray evenly iron (III) chloride TS upon the plate: the spot from standard solution (1) and the corresponding spot from the sample solution reveal a purple color.

Alcohol number Not less than 8.1 (Method 2). Prepare the sample solution as follows: Pipet 5 mL of Capsicum and Salicylic Acid Spirit at 15 ± 2°C into a glass-stoppered, conical flask containing exactly 45 mL of water while shaking vigorously, allow to stand, and filter the lower layer. Discard the first 15 mL of the filtrate. Pipet 25 mL of the subsequent

filtrate, add exactly 10 mL of the internal standard solution, and add water to make exactly 100 mL.

Containers and storage Containers—Tight containers.

Capsules

カプセル

Capsules are made of gelatin or a suitable material, and their shape is a pair of cylinders with one end closed which can be overlapped on each other.

Method of preparation Dissolve Gelatin or the like in water by warming, add Glycerin or D-Sorbitol, emulsifier, preservatives, coloring substances and so forth, if necessary, to make a thick gluey solution, and form into capsules while warm.

Capsules may be coated with a lubricant, if necessary.

Description Capsules are odorless and elastic.

Purity Odor, solubility, and acidity or alkalinity—Place, without overlapping of the parts, 1 piece (1 pair) of Capsules in a 100-mL conical flask, add 50 mL of water, and shake often, keeping the temperature at 37 ± 2°C.Perform this test 5 times: they all dissolve within 10 minutes. All these solutions are odorless, and neutral or slightly acidic.

Containers and storage Containers—Well-closed containers.

Cardamon

Cardamomi Fructus

ショウズク

Cardamon is the fruit of *Elettaria cardamomum* Maton (*Zingiberaceae*). The capsules are removed from the seeds before use.

Description Nearly ellipsoidal, 1 - 2 cm in length, 0.5 - 1 cm in diameter; externally, light yellow with three blunt ridges and many longitudinal lines; 0.1 - 0.2-cm beak at one end; pericarp thin, light and fibrous; interior longitudinally divided into three loculi by thin membranes, each loculus containing 3 to 7 seeds joining by aril; seed irregularly angular ovoid, 0.3 - 0.4 cm in length, dark brown to blackish brown; the dorsal side convex, the ventral side longitudinally grooved; external surface coarsely tuberculated. Seed has a characteristic aroma, and pungent, slightly bitter taste; pericarp, odorless and tasteless.

Total ash Not more than 6.0% (seed).

Acid-insoluble ash Not more than 4.0% (seed).

Essential oil content Perform the test with 30.0 g of the pulverized seeds of Cardamon as directed in the Essential oil content under the Crude Drugs: the volume of essential oil is not less than 1.0 mL.

Carmellose

Carboxymethylcellulose
CMC

カルメロース

Carmellose is a polycarboxymethylether of cellulose.

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

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

It swells with water to form suspension.

It becomes viscid in sodium hydroxide TS.

The pH of a suspension, obtained by shaking 1 g of Carmellose with 100 mL of water, is between 3.5 and 5.0.

It is hygroscopic.

Identification (1) Shake well 0.1 g of Carmellose with 10 mL of water, add 2 mL of sodium hydroxide TS, shake, and allow to stand for 10 minutes. Use this solution as the sample solution. To 1 mL of the sample solution add water to make 5 mL. To 1 drop of this solution add 0.5 mL of concentrated disodium chlomotropate TS, and heat in a water bath for 10 minutes: a red-purple color develops.

(2) Shake 5 mL of the sample solution obtained in (1) with 10 mL of acetone: a white, flocculent precipitate is produced.

(3) Shake 5 mL of the sample solution obtained in (1) with 1 mL of iron (III) chloride TS: a brown, flocculent precipitate is produced.

Purity (1) Chloride—Shake well 0.8 g of Carmellose with 50 mL of water, dissolve in 10 mL of sodium hydroxide TS, and add water to make 100 mL. Heat 20 mL of this solution with 10 mL of dilute nitric acid on a water bath until a flocculent precipitate is produced, cool, centrifuge, and take out the supernatant liquid. Wash the precipitate with three 10-mL portions of water by centrifuging each time, combine the supernatant liquid and the washings, and add water to make 100 mL. Take 25 mL of this solution, and 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 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.360%).

(2) Sulfate—Shake well 0.40 g of Carmellose with 25 mL of water, dissolve in 5 mL of sodium hydroxide TS, and add 20 mL of water. Heat this solution with 2.5 mL of hydrochloric acid in a water bath until a flocculent precipitate is produced. Cool, centrifuge, and take out the supernatant liquid. Wash the precipitate with three 10-mL portions of water by centrifuging each time, combine the supernatant liquid and the washings, and add water to make 100 mL. Filter this solution, discard 5 mL of the first filtrate, take 25 mL of the subsequent filtrate, and add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 1.5 mL of 0.005 mol/L sulfuric acid VS (not more than 0.720%).

(3) Silicate—Weigh accurately about 1 g of Carmellose, ignite in a platinum dish, add 20 mL of dilute hydrochloric