acetate VS (indicator: 0.025 g of eriochrome black T-sodium chloride indicator). Perform a blank determination.

Each mL of 0.02 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 5.041 mg of $Ca(H_2PO_4)_2.H_2O$

Containers and storage Containers—Tight containers.

Calcium Stearate

ステアリン酸カルシウム

Calcium Stearate mainly consists of calcium salts of stearic acid ($C_{18}H_{36}O_2$) and palmitic acid ($C_{16}H_{32}O_2$).

Calcium Stearate, when dried, contains not less than 6.4% and not more than 7.1% of calcium (Ca: 40.08).

Description Calcium Stearate occurs as a white, light, bulky powder. It feels smooth when touched, and is adhesive to the skin. It is odorless or has a faint, characteristic odor.

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

Identification (1) Shake vigorously 3 g of Calcium Stearate with 20 mL of diluted hydrochloric acid (1 in 2) and 30 mL of diethyl ether for 3 minutes, and allow to stand: the separated aqueous layer responds to the Qualitative Tests (1), (2) and (4) for calcium salt.

(2) Wash the diethyl ether layer obtained in (1) with 20 mL and 10 mL of dilute hydrochloric acid and 20 mL of water successively, and evaporate the diethyl ether on a water bath: the residue melts at a temperature not below 54°C (Method 2).

Purity (1) Heavy metals—Heat gently 1.0 g of Calcium Stearate with caution at the beginning, and heat further, gradually raising the temperature, to incineration. After cooling, add 2 mL of hydrochloric acid, evaporate on a water bath to dryness, warm the residue with 20 mL of water and 2 mL of dilute acetic acid for 2 minutes, cool, filter, and wash the residue with 15 mL of water. Combine the filtrate and the washings, add water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution by evaporating 2 mL of hydrochloric acid on a water bath to dryness and by adding 2 mL of dilute acetic acid, 2.0 mL of Standard Lead Solution and water to make 50 mL (not more than 20 ppm).

(2) Arsenic—To 1.0 g of Calcium Stearate add 5 mL of diluted hydrochloric acid (1 in 2) and 20 mL of chloroform, shake vigorously for 3 minutes, allow to stand, and separate the water layer. Perform the test using Apparatus B with this water layer as the test solution (not more than 2 ppm).

Loss on drying Not more than 4.0% (1 g, 105°C, 3 hours).

Assay Weigh accurately about 0.5 g of Calcium Stearate, previously dried, heat gently with caution at first, and then ignite gradually to ash. Cool, add 10 mL of dilute hydrochloric acid to the residue, warm for 10 minutes on a water bath, and transfer the contents to a flask with the aid of 10-mL, 10-mL, and 5-mL portions of hot water. Add sodium hydroxide TS until the solution becomes slightly turbid, and then add 25 mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS, 10 mL of ammonia-ammonium chloride buffer solution, pH 10.7, 4 drops of eriochrome black T TS and 5 drops of methyl yellow TS, and titrate rapidly the excess disodium dihydrogen ethylenediamine tetraacetate with 0.05 mol/L magnesium chloride VS, until the green color of the solution disappears and a red color develops. Perform a blank determination.

Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 2.0039 mg of Ca

Containers and storage Containers—Well-closed containers.

Calumba

Calumbae Radix

コロンボ

Calumba is the cross-sectioned root of *Jateorhiza columba* Miers (*Menispermaceae*).

Description Disk-like slices, 0.5 – 2 cm in thickness, 3 – 8 cm in diameter; mostly with concave center and slightly waved; side surface grayish brown in color, with irregular wrinkles; cut surface light yellow and powdery, with pale and dark radiating stripes; cortex rather yellowish; cambium and its neighborhood light grayish brown, warty protrusions in the center; hard in texture, but brittle. Odor characteristic; taste, bitter.

Identification To 3 g of pulverized Calumba add 30 mL of water, allow to stand for 5 minutes with occasional shaking, and filter. To 2 mL of the filtrate add gently 1 mL of sulfuric acid, and, after cooling, add carefully chlorine TS to make two layers: a light red to red color develops at the zone of contact.

Total ash Not more than 7.5%.

Powdered Calumba

Calumbae Radix Pulverata

コロンボ末

Powdered Calumba is the powder of Calumba.

Description Powdered Calumba occurs as a grayish yellow powder, and has a characteristic odor and a bitter taste.

Under a microscope, Powdered Calumba reveals numerous starch grains, fragments of parenchyma cells containing them; fragments of cork cells, stone cells, fibers, substitute fibers, vessels, tracheids, and also solitary crystals of calcium oxalate; starch grains consisting of solitary grains or 2- to 3-compound grains; hilum, unevenly scattered, usually 25 – 50 μm, but up to 90 μm in diameter.

Identification To 3 g of Powdered Calumba add 30 mL of water, allow to stand for 5 minutes with occasional shaking.

and filter. To 2 mL of the filtrate add gently 1 mL of sulfuric acid, and after cooling, add carefully chlorine TS to make two layers: a light red to red color develops at the zone of contact.

Total ash Not more than 7.5%.

Camellia Oil

Oleum Camelliae

ツバキ油

Camellia Oil is the fixed oil obtained from the peeled seeds of *Camellia japonica* Linné (*Theaceae*).

Description Camellia Oil is a colorless or pale yellow, clear oil.

It is nearly odorless and tasteless.

It is miscible with diethyl ether and with petroleum ether.

It is slighthy soluble in ethanol (95).

It congeals partly at −10°C, and completely at −15°C.

Specific gravity d_{25}^{25}: 0.910 - 0.914

Identification To 2 mL of Camellia Oil add dropwise 10 mL of a mixture of fuming nitric acid, sulfuric acid, and water (1:1:1), previously cooled to room temperature: a bluish green color develops at the zone of contact.

Acid value Not more than 2.8.

Saponification value 188 - 194

Unsaponifiable matters Not more than 1.0%.

Iodine value 78 - 83

Containers and storage Containers—Tight containers.

Capsicum

Capsici Fructus

トウガラシ

Capsicum is the fruit of *Capsicum annuum* Linné (*Solanaceae*).

Capsicum contains not less than 0.10% of total capsaicins (capsaicin and dihydrocapsaicin), calculated on the basis of dried material.

Description Elongated conical to fusiform fruit, often bent, 3 - 10 cm in length, about 0.8 cm in width; outer surface lustrous and dark red to dark yellow-red; interior of pericarp hollow and usually divided into two loculi, containing numerous seeds nearly circular and compressed, light yellow-red, about 0.5 cm in diameter; usually with remains of calyx and peduncle. Odor, slight and characteristic; taste, hot and acrid.

Identification To 2.0 g of pulverized Capsicum add 5 mL of ethanol (95), warm on a water bath for 5 minutes, cool, centrifuge, and use the supernatant liquid as the sample solution. Separately, dissolve 1 mg of capsaicin 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 10 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of diethyl ether and methanol (19:1) to a distance of about 12 cm, and air-dry the plate. Spray evenly 2,6-dibromo-*N*-chloro-1,4-benzoquinone monoimine TS on the plate, and allow to stand in ammonia gas: a spot from the sample solution and a blue spot from the standard solution show the same color tone and the same *Rf* value.

Purity Foreign matter—The amount of foreign matter contained in Capsicum does not exceed 1.0%.

Loss on drying Not more than 14.0% (6 hours).

Total ash Not more than 8.0%.

Acid-insoluble ash Not more than 1.2%.

Extract content Ether-soluble extract: not less than 9.0%.

Component determination Weigh accurately about 0.5 g of medium powder of Capsicum in a glass-stoppered centrifuge tube, add 30 mL of methanol, shake for 15 minutes, centrifuge, and separate the supernatant liquid. To the residue add 10 mL of methanol, shake for 5 minutes, centrifuge, and separate the supernatant liquid. Repeat this procedure again, combine the extracts, add methanol to make exactly 50 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, and 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
$$\times \frac{A_{TC} + A_{TD}}{A_S} \times 0.08$$

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