Amount (mg) of berberine [as berberine chloride ($C_{20}H_{18}ClNO_4$)]
= amount (mg) of Berberine Chloride Reference Standard, calculated on the anhydrous basis
$\times \frac{A_T}{A_S}$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 345 nm).

Column: A stainless steel column 4 to 6 mm in inside diameter and 15 to 25 cm in length, packed with octadecylsilanized silica gel (5 to 10 μm in particle diameter).

Column temperature: A constant temperature of about 45°C.

Mobile phase: Dissolve 3.4 g of potassium dihydrogenphosphate and 1.7 g of sodium lauryl sulfate in 1000 mL of a mixture of water and acetonitrile (1:1).

Flow rate: Adjust the flow rate so that the retention time of berberine is about 10 minutes.

Selection of column: Dissolve 1 mg each of Berberine Chloride Reference Standard and palmatine chloride in 10 mL of methanol. Proceed with 20 μL of this solution under the above operating conditions. Use a column giving elution of palmatine and berberine in this order, and clearly dividing each peak.

System repeatability: When the test is repeated 5 times with the standard solution under the above operating conditions, the relative deviation of the peak area of berberine is not more than 1.5%.

Powdered Coptis Rhizome

Coptidis Rhizoma Pulveratum

オウレン末

Powdered Coptis Rhizome is the powder of Coptis Rhizome.

It contains not less than 4.2% of berberine [as berberine chloride ($C_{20}H_{18}ClNO_4$: 371.81)], calculated on the basis of dried material.

Description Powdered Coptis Rhizome occurs as a yellow-brown to grayish yellow-brown powder. It has a slight odor and an extremely bitter, lasting taste, and colors the saliva yellow on chewing.

Under a microscope, almost all elements are yellow in color; it reveals mainly fragments of vessels, tracheids and xylem fibers; parenchyma cells containing starch grains; polygonal cork cells. Usually, round to obtuse polygonal stone cells and their groups, and phloem fibers, 10 - 20 μm in diameter, and fragments of their bundles. Sometimes, polygonal and elongated epidermal cells, originated from the petiole, having characteristically thickened membranes. Starch grains are single grains 1 - 7 μm in diameter.

Identification (1) To 0.5 g of Powdered Coptis Rhizome add 10 mL of water, allow to stand for 10 minutes with occasional shaking, and filter. To 2 to 3 drops of the filtrate add 1 mL of hydrochloric acid and 1 to 2 drops of hydrogen peroxide TS, and shake: a red-purple color develops.

(2) To 0.5 g of Powdered Coptis Rhizome add 20 mL of methanol, shake for 2 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of berberine chloride for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the chromatogram with a mixture of 1-butanol, water and acetic acid (100) (7:2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 365 nm): one spot among the spots from the sample solution and a spot from the standard solution with yellow to yellow-green fluorescence show the same in color tone and *Rf* value.

Purity (1) Phellodendron bark—Under a microscope, crystal cell rows or mucilage masses are not observable. Stir 0.5 g of Powdered Coptis Rhizome with 2 mL of water: the solution does not become gelatinous.

(2) Curcuma—Place Powdered Coptis Rhizome on filter paper, drop diethyl ether on it, and allow to stand. Take the powder off the filter paper, and drip 1 drop of potassium hydroxide TS: no red-purple color develops. Under a microscope, Powdered Coptis Rhizome does not contain gelatinized starch or secretory cells containing yellow-red resin.

Loss on drying Not more than 9.0% (60°C, 8 hours).

Total ash Not more than 4.0%.

Acid-insoluble ash Not more than 1.0%.

Assay Weigh accurately about 0.5 g of Powdered Coptis Rhizome, add 30 mL of a mixture of methanol and dilute hydrochloric acid (100:1), heat under a reflux condenser on a water bath for 30 minutes, cool, and filter. Repeat the above procedure twice with the residue, using 30-mL and 20-mL portions of a mixture of methanol and dilute hydrochloric acid (100:1). To the last residue add 10 mL of methanol, shake well, and filter. Combine the whole filtrates, add methanol to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of Berberine Chloride Reference Standard (separately determine the water content), dissolve in methanol to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 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_T and A_S, of berberine in each solution.

Amount (mg) of berberine [as berberine chloride ($C_{20}H_{18}ClNO_4$)]
= amount (mg) of Berberine Chloride Reference Standard, calculated on the anhydrous basis
$\times \frac{A_T}{A_S}$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 345 nm).

Column: A stainless steel column 4 to 6 mm in inside diameter and 15 to 25 cm in length, packed with octadecylsilanized silica gel (5 to 10 mm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: Dissolve 3.4 g of potassium dihydrogenphosphate and 1.7 g of sodium lauryl sulfate in 1000 mL of a mixture of water and acetonitrile (1:1).

Flow rate: Adjust the flow rate so that the retention time of berberine is about 10 minutes.

Selection of column: Dissolve 0.001 g each of Berberine Chloride Reference Standard and palmatine chloride in 10 mL of methanol. Proceed with 20 mL of this solution under the above operating conditions. Use a column giving elution of palmatine and berberine in this order, and clearly dividing each peak.

System repeatability: When the test is repeated five times with the standard solution under the above operating conditions, the relative deviation of the peak area of berberine is not more than 1.5%.

Corn Oil

Oleum Maydis

トウモロコシ油

Corn Oil is the fixed oil obtained from the embryo of *Zea mays* Linné (*Gramineae*).

Description Corn Oil is a clear, light yellow oil. It is odorless or has a slight odor, and a mild taste.

It is miscible with diethyl ether and with petroleum ether.

It is slightly soluble in ethanol (95), and practically insoluble in water.

At −7°C, it congeals to an unguentary mass.

Specific gravity d_{25}^{25}: 0.915 - 0.921

Acid value Not more than 0.2.

Saponification value 187 - 195

Unsaponifiable matter Not more than 1.5%.

Iodine value 103 - 130

Containers and storage Containers—Tight containers.

Corn Starch

Amylum Maydis

トウモロコシデンプン

Corn Starch consists of starch granules derived from the seeds of *Zea mays* Linné (*Gramineae*).

Description Corn Starch occurs as white to pale yellowish white masses or powder, and is odorless and tasteless.

Under a microscope, Corn Starch appears as spheroidal or polygonal, simple grains of irregular sizes with diameter ranging from 3 to 35 μm, mostly 9 to 18 μm. Hilum is central, often in the shape of a radial cleft; and striation is indistinct.

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

Identification (1) To 1 g of Corn Starch add 50 mL of water, boil, and allow to cool: a turbid, neutral and pasty liquid is formed.

(2) To a portion of Corn Starch add iodine TS: a dark blue-purple color is produced.

Purity Foreign matter—Under a microscope, Corn Starch does not contain starch grains of any other origin. It may contain a minute quantity, if any, of fragments of the tissue of the original plant.

Loss on drying Not more than 15.0% (6 hours).

Total ash Not more than 0.5%.

Cornus Fruit

Corni Fructus

サンシュユ

Cornus Fruit is the sarcocarp of the pseudocarp of *Cornus officinalis* Siebold et Zuccarini (*Cornaceae*).

Description Flattened oblong, 1.5 - 2 cm in length, about 1 cm in width; externally dark red-purple to dark purple, lustrous, and with coarse wrinkles; a crack-like scar formed by removal of true fruit; a scar of calyx at one end, and a scar of peduncle at the other; soft in texture. Odor, slight; taste, acid and slightly sweet.

Identification To 1.0 g of coarse cuttings of Cornus Fruit add 10 mL of ethanol (95), shake for 5 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of loganin for thin-layer chromatography in 2 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 with a mixture of ethyl acetate, water and formic acid (6:1:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat at 90°C for 3 minutes: one of the spots from the sample solution is the same with a red-purple spot from the standard solution in color tone and *R*f value.

Purity Foreign matter—The amount of its peduncles and other foreign matter contained in Cornus Fruit does no exceed 2.0%.

Total ash Not more than 5.0%.

Extract content Dilute ethanol-soluble extract: not less than 35.0%.