

Cod Liver Oil

肝油

Cod Liver Oil is the fatty oils obtained from fresh livers and pyloric appendages of *Gadus macrocephalus* Tilesius or *Theragra chalcogramma* Pallas (*Gadidae*).

Cod Liver Oil contains not less than 2000 Vitamin A Units and not more than 5000 Vitamin A Units per g.

Description Cod Liver Oil is a yellow to orange oily liquid. It has a characteristic, slightly fishy odor and a mild taste.

It is miscible with chloroform, with diethyl ether and with petroleum ether.

It is slightly soluble in ethanol (95).

Its decomposition is accelerated by air or by light.

Identification Dissolve 0.1 g of Cod Liver Oil in 10 mL of chloroform, and to 1 mL of this solution add 3 mL of antimony (III) chloride TS: a blue color develops immediately, but the color fades rapidly.

Specific gravity d_{20}^{20} : 0.918 – 0.928

Acid value Not more than 1.7.

Saponification value 180 – 192

Unsaponifiable matter Not more than 3.0%.

Iodine value 130 – 170

Purity Rancidity—No unpleasant odor of rancid oil is perceptible on warming Cod Liver Oil.

Assay Proceed with about 0.5 g of Cod Liver Oil, accurately weighed, as directed in Method 2 under the Vitamin A Determination, and perform the test.

Containers and storage Containers—Tight containers.

Storage—Light-resistant, and almost well-filled, or under nitrogen atmosphere.

Coix Seed

Coicis Semen

ヨクイニン

Coix Seed is the seed of *Coix lachryma-jobi* Linné var. *ma-yuen* Stapf (*Gramineae*), from which the seed coat has been removed.

Description Ovoid or broad ovoid seed, about 6 mm in length, and about 5 mm in width; with a slightly hollowed apex and base; dorsal side distended; ventral side longitudinally and deeply furrowed in the center; dorsal side mostly white in color and powdery; in the furrow on the ventral surface, attached brown, membranous pericarp and seed coat. Under a magnifying glass, the cross section reveals light yellow scutellum in the hollow of the ventral side. Hard in texture; odor, slight; taste, slightly sweet; adheres to the teeth on chewing.

Identification To a cross-section of Coix Seed add iodine

TS dropwise: a dark red-brown color develops in the endosperm, and a dark gray color develops in the scutellum.

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

Total ash Not more than 3.0%.

Powdered Coix Seed

Coicis Semen Pulveratum

ヨクイニン末

Powdered Coix Seed is the powder of Coix Seed.

Description Powdered Coix Seed occurs as a brownish, grayish white to grayish yellow-white powder, and has a slight odor and a slightly sweet taste.

Under a microscope, Powdered Coix Seed reveals starch grains, and fragments of endosperm containing them; fragments of tissue accompanied with epidermal cells of pericarp composed of yellowish and oblong cells, and fragments of parenchyma cells containing fixed oil, aleuron grains and starch grains; a very few fragments of spiral vessels. Starch grains are simple and 2-compound grains, simple grain nearly equidiameter to obtuse polygon, 10 – 20 μm in diameter, and have a stellate cleft-like hilum in the center. Spherical starch grains, coexisting with aleuron grains, are spherical simple grains, 3 – 7 μm in diameter.

Identification Place a small amount of Powdered Coix Seed on a slide glass, add dropwise iodine TS, and examine under a microscope: nearly equidiameter and obtuse polygonal simple starch grains, usually 10 – 15 μm in diameter, and compound starch grains have a reddish brown color. Small spheroidal starch grains, coexisting with fixed oil and with aleuron grains in parenchymatous cells, have a blue-purple color.

Purity Foreign matter—Under a microscope, Powdered Coix Seed reveals no fragments of tissue having silicified cell wall, no stone cells, no fragments of other thick-walled and lignified cells, no fragments of reticulate, scalariform and pitted vessels, no fragments of fibers and hairs, and no large starch grains, more than 10 μm in diameter, appearing blue-purple upon addition of iodine TS.

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

Total ash Not more than 3.0%.

Containers and storage Containers—Tight containers.

Condurango

Condurango Cortex

コンズランゴ

Condurango is the bark of the trunk of *Marsdenia cundurango* Reichenbach fil. (*Asclepiadaceae*).

Description Tubular or semi-tubular pieces of bark, 0.1 –

0.6 cm in thickness, 4–15 cm in length; outer surface grayish brown to dark brown, nearly smooth and with numerous lenticels, or more or less scaly and rough; inner surface light grayish brown and longitudinally striate; fractured surface fibrous on the outer region and generally granular in the inner region. Odor, slight; taste, bitter.

Under a microscope, a transverse section reveals a cork layer composed of several layers of thin-walled cells; primary cortex with numerous stone cell groups; secondary cortex with phloem fiber bundles scattered inside the starch sheath consisting of one-cellular layer; articulate latex tubes scattered in both cortices; parenchyma cells containing starch grains or rosette aggregates of calcium oxalate; starch grain 3–20 μm in diameter.

Identification Digest 1 g of pulverized Condurango in 5 mL of water, and filter: the clear filtrate becomes turbid on heating, but becomes clear again upon cooling.

Purity Foreign matter—The xylem and other foreign matter contained in Condurango do not exceed 2.0%.

Total ash Not more than 12.0%.

Condurango Fluidextract

コンズランゴ流エキス

Method of preparation Take medium powder of Condurango, and prepare the fluidextract as directed under Fluidextracts using a suitable quantity of a mixture of Purified Water, Ethanol and Glycerin (5:3:2) as the first solvent, and a suitable quantity of a mixture of Purified Water and Ethanol (3:1) as the second solvent.

Description Condurango Fluidextract is a brown liquid. It has a characteristic odor and a bitter taste.

Identification Mix 1 mL of Condurango Fluidextract with 5 mL of water, filter, if necessary, and heat the clear solution: turbidity is produced. However, it becomes almost clear upon cooling.

Containers and storage Containers—Tight containers.

Coptis Rhizome

Coptidis Rhizoma

オウレン

Coptis Rhizome is the rhizome of *Coptis japonica* Makino, *Coptis chinensis* Franchet, *Coptis deltoidea* C.Y. Cheng et Hsiao or *Coptis teeta* Wallich (*Ranunculaceae*), from which the roots have been removed practically.

It contains not less than 4.2% of berberine [as berberine chloride ($\text{C}_{20}\text{H}_{18}\text{ClNO}_4$: 371.81)], calculated on the basis of dried material.

Description Irregular, cylindrical rhizome, 2 to 4 cm, rarely up to 10 cm in length, 0.2–0.7 cm in diameter, slightly

curved and often branched; externally grayish yellow-brown, with ring nodes, and with numerous remains of rootlets; generally remains of petiole at one end; fractured surface rather fibrous; cork layer light grayish brown, cortex and pith are yellow-brown to reddish yellow-brown, xylem is yellow to reddish yellow in color. Odor, slight; taste, extremely bitter and lasting; it colors the saliva yellow on chewing.

Under a microscope, a transverse section of Coptis Rhizome reveals a cork layer composed of thin-walled cork cells; cortex parenchyma usually exhibiting groups of stone cells near the cork layer and yellow phloem fibers near the cambium; xylem consisting chiefly of vessels, tracheae and wood fibers; medullary ray distinct; pith large; in pith, stone cells or stone cells with thick and lignified cells are sometimes recognized; parenchyma cells contain minute starch grains.

Identification (1) To 0.5 g of pulverized 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 pulverized 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 color tone and the same R_f value.

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 pulverized 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.