Each mL of 0.5 mol/L potassium hydroxide-ethanol VS = 106.12 mg of $C_{14}H_{12}O_2$

Containers and storage Containers—Tight containers. Storage—Light-resistant.

Bitter Cardamon

Alpiniae Fructus

ヤクチ

Bitter Cardamon is the fruit of *Alpinia oxyphylla* Miquer (*Zingiberaceae*).

Description Spherical to fusiform fruit, with both ends somewhat pointed; 1 - 2 cm in length, 0.7 - 1 cm in width; externally brown to dark brown, with numerous longitudinal, knob-like protruding lines; pericarp 0.3 - 0.5 mm in thickness, closely adhering to the seed mass, and difficult to separate; inside divided vertically into three loculi by thin membranes, each loculus containing 5 to 8 seeds adhering by aril; seeds irregularly polygonal, about 3.5 mm in diameter, brown to dark brown in color, and hard in texture. Odor, characteristic; taste, slightly bitter.

Total ash Not more than 10.0%.

Acid-insoluble ash Not more than 2.5%.

Essential oil content Perform the test with 50.0 g of pulverized Bitter Cardamon as directed in the Essential oil content under Crude Drugs: the volume of essential oil is not less than 0.4 mL.

Bitter Orange Peel

Aurantii Pericarpium

トウヒ

Bitter Orange Peel is the pericarp of the ripe fruit of *Citrus aurantium* Linné or *Citrus aurantium* Linné var. *daidai* Makino (*Rutaceae*).

Description Usually quartered sections of a sphere, sometimes warped or flattened, 4 - 8 cm in length, 2.5 - 4.5 cm in width and 0.5 - 0.8 cm in thickness; the outer surface is dark red-brown to grayish yellow-brown, with numerous small dents associated with oil sacs; the inner surface is white to light grayish yellow-red, with irregular indented reticulation left by vascular bundles; light and brittle in texture. Odor, characteristic aroma; taste, bitter, somewhat mucilaginous and slightly pungent.

Identification To 1.0 g of pulverized Bitter Orange Peel add 10 mL of ethanol (95), allow to stand for 30 minutes with occasional shaking, filter, and use the filtrate as the sample solution. Separately, dissolve 10 mg of naringin for thin-layer chromatography in 10 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 ethyl acetate, ethanol (99.5) and water (8:2:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly dilute 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 grayish green spot from the standard solution show the same color tone and the same *R*f value.

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

Total ash Not more than 5.5%.

Acid-insoluble ash Not more than 0.5%.

Essential oil content Perform the test with 50 g of pulverized Bitter Orange Peel as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added to the test sample in the flask: the volume of essential oil is not less than 0.2 mL.

Bitter Tincture

Tinctura Amara

苦味チンキ

Method of preparation

Bitter Orange Peel, in coarse powder	50 g
Swertia Herb, in coarse powder	5 g
Zanthoxylum Fruit, in coarse powder	5 g
70 vol% Ethanol	a sufficient quantity
	To make 1000 mL

Prepare as directed under Tinctures, with the above ingredients. An appropriate quantity of Ethanol and Purified Water may be used in place of 70 vol% Ethanol.

Description Bitter Tincture is a yellow-brown liquid. It has a characteristic aroma and a bitter taste.

Specific gravity d_{20}^{20}: about 0.90

Identification **(1)** To 1 mL of Bitter Tincture add 5 mL of methanol, then add 0.1 g of magnesium in ribbon form and 1 mL of hydrochloric acid, and allow to stand: the solution is red-purple in color.

(2) Use Bitter Tincture as the sample solution. Separately, to 5.0 g of pulverized Bitter Orange Peel add 100 mL of diluted ethanol (7 in 10), stopper the vessel tightly, shake for 30 minutes, filter, and use the filtrate as the standard solution (1). Proceed with 0.5 g each of pulverized Swertia Herb and Zanthoxylum Fruit in the same manner, and use the solutions so obtained as the standard solution (2) and the standard solution (3). Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the standard solutions (1), (2) and (3) on the plate of silica gel with complex fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (95) and water (8:2:1) to a distance of about 10 cm, and air-dry the plate. Examine the plate under ultraviolet light (broad spectrum wavelength): three of the several spots from the sample solution show the same color tone and *R*f value as those of the upper spot of the two bright blue to purple spots among the several spots from the standard solu-

tion (1), appearing close to each other at an *R*f value of about 0.4, and a bright red spot from the standard solution (2), appearing at an *R*f value of about 0.35, and a bright grayish red to red spot from the standard solution (3), appearing at an *R*f value of about 0.7.

Alcohol number Not less than 6.9 (Method 2).

Containers and storage Containers—Tight containers.

Freeze-dried Botulism Antitoxin, Equine

乾燥ボツリヌスウマ抗毒素

Freeze-dried Botulism Antitoxin, Equine, is a preparation for injection which is dissolved before use. It contains botulism antitoxin type A, botulism antitoxin type B, botulism antitoxin type E and botulism antitoxin type F in immunoglobulin of horse origin.

It may contain one, two or three of these four antitoxins.

It conforms to the requirements of Freeze-dried Botulism Antitoxin, Equine, in the Minimum Requirements for Biological Products.

Description Freeze-dried Botulism Antitoxin, Equine, becomes a colorless or yellow-brown, clear liquid or a slightly white-turbid liquid on the addition of solvent.

Bupleurum Root

Bupleuri Radix

サイコ

Bupleurum Root is the root of *Bupleurum falcatum* Linné (*Umbelliferae*).

Description Single or branched root of long cone or column shape, 10 – 20 cm in length, 0.5 – 1.5 cm in diameter; occasionally with remains of stem on the crown; externally light brown to brown and sometimes with deep wrinkles; easily broken, and fractured surface somewhat fibrous; odor, characteristic, and taste, slightly bitter.

Under a microscope, a transverse section reveals the thickness of cortex reaching ⅓ – ½ of the radius, tangentially extended clefts in cortex; and cortex scattered with a good many intercellular schizogenous oil canals 15 – 35 μm in diameter; in xylem, vessels lined radially or stepwise, and fiber groups scattered; in the pith at the crown, the same oil canals as in the cortex; parenchyma cells containing starch grains and oil droplets. Starch grains composed of simple grains, 2 – 10 μm in diameter, or compound grains.

Identification **(1)** Shake vigorously 0.5 g of pulverized Bupleurum Root with 10 mL of water: lasting fine foam is produced.

(2) To 2.0 g of pulverized Bupleurum Root add 10 mL of methanol, boil gently under a reflux condenser on a water bath for 15 minutes, cool, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of saikosaponin a 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 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 chloroform, methanol and water (30:10:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly a mixture of sulfuric acid and ethanol (95) (1:1) on the plate, and warm at 50°C for 5 minutes: one spot among the several spots from the sample solution and the blue spot from the standard solution show the same *R*f value, and the color tone is blue to blue-purple.

Purity **(1)** Stem and leaf—The amount of the stems and leaves contained in Bupleurum Root does not exceed 10.0%.

(2) Foreign matter—The amount of foreign matter other than stems and leaves contained in Bupleurum Root does not exceed 1.0%.

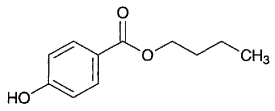
Total ash Not more than 6.5%.

Acid-insoluble ash Not more than 2.0%.

Extract content Dilute ethanol-soluble extract: not less than 11.0%.

Butyl Parahydroxybenzoate

パラオキシ安息香酸ブチル



$C_{11}H_{14}O_3$: 194.23
Butyl 4-hydroxybenzoate [*94-26-8*]

Butyl Parahydroxybenzoate, when dried, contains not less than 99.0% of $C_{11}H_{14}O_3$.

Description Butyl Parahydroxybenzoate occurs as colorless crystals or white, crystalline powder. It is odorless and tasteless. It numbs the tongue.

It is freely soluble in ethanol (95), in acetone and in diethyl ether, slightly soluble in hot water, and practically insoluble in water.

Identification **(1)** Dissolve 0.25 g of Butyl Parahydroxybenzoate in 5 mL of dilute ethanol, and add 1 drop of iron (III) chloride TS: a red-purple color develops.

(2) Boil 0.5 g of Butyl Parahydroxybenzoate with 10 mL of sodium hydroxide TS for about 30 minutes, allowing the solution to evaporate to about 5 mL. After cooling, acidify with dilute sulfuric acid, collet the precipitate formed, wash thoroughly with a small amount of water, and dry in a desiccator (silica gel): the precipitate melts between 213°C and 217°C.

(3) To 0.05 g of Butyl Parahydroxybenzoate add 2 drops of acetic acid (31) and 5 drops of sulfuric acid, and heat the mixture for 5 minutes: the odor of butyl acetate is perceptible.