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%.

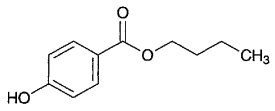
Total ash Not more than 6.5%.

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.

Melting point 69 - 72°C

Purity (1) Chloride—Heat 2.0 g of Butyl Parahydroxybenzoate with 50 mL of water, allow to stand in ice water for 1 hour with occasional shaking, then add water to make 100 mL, and filter. Perform the test with 25 mL of the filtrate. Prepare the control solution with 0.50 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.035%).

(2) Sulfate—Perform the test with 40 mL of the filtrate obtained in Purity (1). Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.024%).

(3) Heavy metals—Dissolve 1.0 g of Butyl Parahydroxybenzoate in 25 mL of acetone, add 2 mL of dilute acetic acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution as follows: to 2.0 mL of Standard Lead Solution add 25 mL of acetone, 2 mL of dilute acetic acid, and water to make 50 mL (not more than 20 ppm).

(4) Parahydroxybenzoic acid and salicylic acid—Dissolve 0.50 g of Butyl Parahydroxybenzoate in 30 mL of diethyl ether, shake with 20 mL of a solution of sodium hydrogen carbonate (1 in 100), wash the separated aqueous layer with two 20-mL portions of diethyl ether, shake the aqueous layer with 5 mL of dilute sulfuric acid and 30 mL of diethyl ether, and allow to stand. Shake gently the separated diethyl ether layer with 10 mL of water, remove the aqueous layer after allowing the mixture to stand, filter the diethyl ether, wash the vessel and the filter paper with a small amount of diethyl ether, evaporate the diethyl ether from the combined filtrate and washings on a water bath, and dry the residue in a desiccator (silica gel) to constant mass: the mass of the residue is not more than 5.0 mg. Warm the residue with 5 mL of water, filter, and to the filtrate add 2 to 3 drops of dilute iron (III) chloride TS: no purple color develops.

(5) Readily carbonizable substances—Perform the test with 0.50 g of Butyl Parahydroxybenzoate. The solution has no more color than Matching Fluid D.

Loss on drying Not more than 0.5% (2 g, silica gel, 3 hours).

Residue on ignition Not more than 0.10% (1 g).

Assay Weigh accurately about 2 g of Butyl Parahydroxybenzoate, previously dried, add exactly 40 mL of 1 mol/L sodium hydroxide VS, and boil for 30 minutes. Cool, and titrate the excess sodium hydroxide with 0.5 mol/L sulfuric acid VS until the solution shows the same color as that of phosphate buffer solution, pH 6.5, to which the same indicator has been added (indicator: 5 drops of bromothymol blue TS). Perform a blank determination.

Each mL of 1 mol/L sodium hydroxide VS
= 194.23 mg of $C_{11}H_{14}O_3$

Containers and storage Containers—Well-closed containers.

Cacao Butter

Oleum Cacao

カカオ脂

Cacao Butter is the fat obtained from the seed of *Theobroma cacao* Linné (*Sterculiaceae*).

Description Cacao Butter occurs as a yellowish white, hard, brittle mass. It has a slight, chocolate-like odor, and has no odor of rancidity.

It is freely soluble in diethyl ether and in petroleum ether, soluble in boiling ethanol (99.5), and very slightly soluble in ethanol (95).

Congealing point of the fatty acids: 45 - 50°C

Melting point 31–35°C (Cram the sample into a capillary tube without melting the sample, then follow Method 2).

Specific gravity d_{20}^{40}: 0.895 - 0.904

Acid value Not more than 3.0.

Saponification value 188 - 195

Iodine value 35 - 43

Containers and storage Containers—Well-closed containers.

Calcium Hydroxide

Slaked Lime

水酸化カルシウム

$Ca(OH)_2$: 74.09

Calcium Hydroxide contains not less than 90.0% of $Ca(OH)_2$.

Description Calcium Hydroxide occurs as a white powder. It has a slightly bitter taste.

It is slightly soluble in water, very slightly soluble in boiling water, and practically insoluble in ethanol (95) and in diethyl ether.

It dissolves in dilute acetic acid, in dilute hydrochloric acid and in dilute nitric acid.

It absorbs carbon dioxide from air.

Identification (1) Mix Calcium Hydroxide with 3 to 4 times its mass of water: the mixture is slushy and is alkaline.

(2) Dissolve 1 g of Calcium Hydroxide in 30 mL of dilute acetic acid, and boil. After cooling, neutralize with ammonia TS: the solution responds to the Qualitative tests (2) and (3) for calcium salt.

Purity (1) Acid-insoluble substances—To 5 g of Calcium Hydroxide add 100 mL of water, add hydrochloric acid dropwise with strring until the solution becomes acidic, and further add 1 mL of hydrochloric acid. Boil this solution for 5 minutes, cool, and filter through a tared glass filter (G4). Wash the residue with boiling water until the last washing ex-