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%.

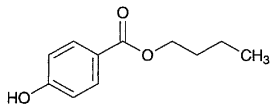
Total ash Not more than 6.5%.

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.