10) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 10 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 magnolol in each solution.

Amount (mg) of magnolol
= amount (mg) of magnolol for component determination
$\times \frac{A_T}{A_S}$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 289 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 20°C.

Mobile phase: A mixture of water, acetonitrile and acetic acid (100) (50:50:1).

Flow rate: Adjust the flow rate so that the retention time of magnolol is about 14 minutes.

Selection of column: Dissolve 1 mg each of magnolol for component determination and honokiol in 10 mL of diluted methanol (7 in 10). Proceed with 10 μL of this solution under the above operating conditions. Use a column giving elution of honokiol and magnolol in this order with the resolution between these peaks being not less than 5.

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 magnolol is not more than 1.5%.

Powdered Magnolia Bark

Magnoliae Cortex Pulveratus

コウボク末

Powdered Magnolia Bark is the powder of Magnolia Bark.

It contains not less than 0.8% of magnolol.

Description Powdered Magnolia Bark occurs as a yellow-brown powder, and has a slight odor and a bitter taste.

Under a microscope, Powdered Magnolia Bark reveals starch grains and parenchyma cells containing them; stone cells of various sizes or its groups; fibers 12 to 25 μm in diameter; yellowish red-brown cork tissue; oil cells containing a yellow-brown to red-brown substance. Simple starch grains about 10 μm in diameter and 2- to 4-compound starch grains.

Identification To 1.0 g of Powdered Magnolia Bark add 10 mL of methanol, stir for 10 minutes, centrifuge, and perform the test with the supernatant liquid as the sample solution as directed under the Thin-layer Chromatography. Spot 20 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (4:2:1) to a distance of about 10 cm, and air-dry the plate, and spray evenly with Dragendorff's TS on the plate: the yellow spot is observed at the *Rf* value of near 0.3.

Total ash Not more than 6.0%.

Extract content Dilute ethanol-soluble extract: not less than 12.0%.

Component determination Weigh accurately about 0.5 g of Powdered Magnolia Bark, add 40 mL of diluted methanol (7 in 10), heat under a reflux condenser on a water bath for 20 minutes, cool, and filter. Repeat the above procedure with the residue, using 40 mL of diluted methanol (7 in 10). Combine the whole filtrates, add diluted methanol (7 in 10) to make exactly 100 mL, and use this solution as the sample solution. Separately, dry magnolol for component determination in a desiccator (silica gel) for 1 hour on more. Weigh accurately about 0.01 g of it, dissolve in diluted methanol (7 in 10) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 10 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 magnolol in each solution.

Amount (mg) of magnolol
= amount (mg) of magnolol for component determination
$\times \frac{A_T}{A_S}$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 289 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 20°C.

Mobile phase: A mixture of water, acetonitrile and acetic acid (100) (50:50:1).

Flow rate: Adjust the flow rate so that the retention time of magnolol ia about 14 minutes.

Selection of column: Dissolve 1 mg each of magnolol for component determination and honokiol in 10 mL of diluted methanol (7 in 10). Proceed with 10 μL of this solution under the above operating conditions. Use a column giving elution of honokiol and magnolol in this order with the resolution between these peaks being not less than 5.

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 magnolol is not more than 1.5%.

Containers and storage Containers—Tight containers.

Mallotus Bark

Malloti Cortex

アカメガシワ

Mallotus Bark is the bark of *Mallotus japonica*

Mueller Arg. (*Euphorbiaceae*).

Description Mallotus Bark is flat or semitubular pieces of bark, 1 to 3 mm in thickness; externally green-gray to brown-gray brow in color, with a vertically striped shape gathering numerous lenticels; internal surface light yellowish brown to grayish brown in color, and smooth with numerous fine striped lines; easy to break; slightly fibrous at fracture surface.

Mallotus Bark has slightly a odor, a bitter taste and slightly astringent.

Identification To 0.5 g pulverized Mallotus Bark add 10 mL of methanol, warm on a water bath for 5 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of bergenin 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 with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (95) and water (100:17:13) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): a principal spot with a dark blue color which appears at Rf of about 0.5 from the sample solution is the same as the spot from the standard solution in color and the Rf.

Loss on drying Not more than 13.0% (6 hours).

Total ash Not more than 12.0%.

Acid-insoluble ash Not more than 2.5%.

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

Freeze-dried Mamushi Antivenom, Equine

乾燥まむしウマ抗毒素

Freeze-dried Mamushi Antivenom, Equine, is a preparation for injection which is dissolved before use. It contains *Agkistrodon Halys* antivenom in immunoglobulin of horse origin.

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

Description Freeze-dried Mamushi Antivenom, Equine, becomes a colorless or light yellow-brown, clear liquid, or a slightly white-turbid liquid on addition of solvent.

Freeze-dried Live Attenuated Measles Vaccine

乾燥弱毒生麻しんワクチン

Freeze-dried Live Attenuated Measles Vaccine is a preparation for injection which is dissolved before use. It contains live attenuated measles virus.

It conforms to the requirements of Freeze-dried Live Attenuated Measles Vaccine in the Minimum Requirements for Biological Products.

Description Freeze-dried Live Attenuated Measles Vaccine becomes a colorless, yellowish or reddish clear liquid on addition of solvent.

Medicinal Carbon

薬用炭

Description Medicinal Carbon occurs as a black, odorless and tasteless powder.

Identification Place 0.5 g of Medicinal Carbon in a test tube, and heat by direct application of flame with the aid of a current of air: it burns without any flame. Pass the evolved gas through calcium hydroxide TS: a white turbidity is produced.

Purity **(1)** Acid or alkali—Boil 3.0 g of Medicinal Carbon with 60 mL of water for 5 minutes, allow to cool, dilute to 60 mL with water, and filter: the filtrate is colorless and neutral.

(2) Chloride—Take 4.0 mL of the filtrate obtained in (1) in a Nessler tube, add 6 mL of dilute nitric acid and sufficient water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.80 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.142%).

(3) Sulfate—Take 5 mL of the filtrate obtained in (1) in a Nessler tube, add 1 mL of dilute hydrochloric acid and sufficient water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 1.0 mL of 0.005 mol/L sulfuric acid VS (not more than 0.192%).

(4) Sulfide—Boil 0.5 g of Medicinal Carbon with a mixture of 15 mL of dilute hydrochloric acid and 10 mL of water: lead (II) acetate paper does not become brown when held in the evolved gas within 5 minutes.

(5) Cyanogen compounds—Place a mixture of 5 g of Medicinal Carbon, 2 g of L-tartaric acid and 50 mL of water in a distilling flask connected to a condenser provided with a tightly fitting adapter, the end of which dips below the surface of a mixture of 2 mL of sodium hydroxide TS and 10 mL of water, contained in a small flask surrounded by ice. Heat the mixture in the distilling flask to boiling, and distil to 25 mL. Dilute the distillate with water to 50 mL. To 25 mL of the diluted distillate add 1 mL of a solution of iron (II) sulfate heptahydrate (1 in 20), heat the mixture almost to boil-