with the resolution between these peaks being not less than 5.

System repeatability: When the test is repeated 6 times with the solution for system suitability test under the above operating conditions, the relative standard deviation of the peak areas of methyl palmitate and methyl stearate are not more than 6.0%, respectively, and the relative standard deviation of the ratios of the peak area of methyl palmitate to methyl stearate is not more than 1.0%.

Loss on drying Not more than 6.0% (2 g, 105°C, constant mass).

Microbial limit Proceed with Magnesium Stearate as directed under the Microbial Limit Test: the total viable aerobic microbial count is not more than 1000 per g, and the total count of fungi and yeasts is not more than 500 per g. *Salmonella* and *Escherichia coli* should not be observed.

Assay Transfer about 0.5 g of previously dried Magnesium Stearate, accurately weighed, to a 250-mL flask, add 50 mL of a mixture of 1-butanol and ethanol (99.5) (1:1), 5 mL of ammonia solution (28), 3 mL of ammonium chloride buffer solution, pH 10, 30.0 mL of 0.1 mol/L disodium dihydrogen ethylenediamine tetraacetate VS, and 1 to 2 drops of eriochrome black T TS, and mix. Heat at 45°C to 50°C to make the solution clear, and after cooling, titrate the excess disodium dihydrogen ethylenediamine tetraacetate with 0.1 mol/L zinc sulfate VS until the solution changes from blue to purple in color. Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 2.4305 mg of Mg

Containers and storage Containers—Tight containers.

Magnesium Sulfate Mixture

硫酸マグネシウム水

Magnesium Sulfate Mixture contains not less than 13.5 w/v% and not more than 16.5 w/v% of magnesium sulfate ($MgSO_4.7H_2O$: 246.47).

Method of preparation

Magnesium Sulfate	150 g
Bitter Tincture	20 mL
Dilute Hydrochloric Acid	5 mL
Purified Water	a sufficient quantity
	To make 1000 mL

Prepare before use, with the above ingredients.

Description Magnesium Sulfate Mixture is a light yellowish clear liquid. It has a bitter and acid taste.

Identification (1) Magnesium Sulfate Mixture responds to the Qualitative Tests for magnesium salt.

(2) Magnesium Sulfate Mixture responds to the Qualitative Tests (2) for chloride.

Assay Pipet 10 mL of Magnesium Sulfate Mixture, and add water to make exactly 100 mL. Pipet 10 mL of this solution, add 50 mL of water and 5 mL of pH 10.7 ammonia-ammonium chloride buffer solution, and titrate with 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS (indicator: 0.04 g of eriochrome black T-sodium chloride indicator).

Each mL of 0.05 mol/L disodium dihydrogen ethylenediamine tetraacetate VS
= 12.324 mg of $MgSO_4.7H_2O$

Containers and storage Containers—Tight containers.

Magnolia Bark

コウボク

Magnolia Bark is the bark of the trunk of *Magnolia obovata* Thunberg, *Magnolia officinalis* Rehder et Wilson, *Magnolia officinalis* Rehder et Wilson var. *biloba* Rehder et Wilson (*Magnoliaceae*).

It contains not less than 0.8% of magnolol.

Description Plate-like or semi-tubular bark, 2 - 7 mm in thickness; externally grayish white to grayish brown, and rough, sometimes cork layer removed, and externally red-brown; internally light brown to dark purplish brown; cut surface extremely fibrous, and light red-brown to purplish brown. Odor, slight; taste, bitter.

Under a microscope, a transverse section reveals a thick cork layer or several thin cork layers, and internally adjoining the circular tissue of stone cells of approximately equal diameter; primary cortex thin; fiber groups scattered in the pericycle; phloem fibers lined stepwise between medullary rays in the secondary cortex, and then these tissues show a latticework; oil cells scattered in the primary and secondary cortex, but sometimes observed in the narrow medullary rays.

Identification To 1.0 g of pulverized Magnolia Bark add 10 mL of methanol, stir for 10 minutes, centrifuge, and use the supernatant liquid as the sample solution. Perform the test with this 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 distance of about 10 cm, and air-dry the plate, spray evenly the plate with Dragendorff's TS, the spot with yellow shows in the range of 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 pulverized 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 or 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 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*