

Description Tubular to semi-tubular bark, about 0.5 cm in thickness, 5–8 cm in length, 0.8–1.5 cm in diameter; externally dark brown to purplish brown, with small and transversely elongated ellipsoidal scars of lateral roots, and with longitudinal wrinkles; internally, light grayish brown to purplish brown and smooth; fractured surface coarse; white crystals often attached on the internal and fractured surfaces. Odor, characteristic; taste, slightly pungent and bitter.

Identification To 2.0 g of pulverized Moutan Bark add 10 mL of hexane, shake for 3 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of paeonol for thin-layer chromatography in 10 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 μ L 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 hexane and ethyl acetate (1:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): a spot among several spots from the sample solution is similar with the spot from the standard solution in color tone and R_f value.

Purity (1) Xylem—The amount of the xylem contained in Moutan Bark does not exceed 5.0%.

(2) Foreign matter—The amount of foreign matter other than xylem contained in Moutan Bark does not exceed 1.0%.

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 1.0%.

Component determination Weigh accurately about 0.3 g of pulverized Moutan Bark, add 40 mL of methanol, heat under a reflux condenser on a water bath for 30 minutes, cool, and filter. Repeat the above procedure with the residue, using 40 mL of methanol. Combine the whole filtrates, add methanol to make exactly 100 mL, then pipet 10 mL of this solution, add methanol to make exactly 25 mL, and use this solution as the sample solution. Separately, dry paeonol for component determination in a desiccator (calcium chloride for drying) for more than 1 hour. Weigh accurately about 0.01 g of it, dissolve in methanol to make exactly 100 mL, then pipet 10 mL of this solution, add methanol to make exactly 50 mL, and use this solution as the standard solution. Perform the test with 10 μ L 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 paeonol in each solution.

$$\begin{aligned} & \text{Amount (mg) of paeonol} \\ &= \text{amount (mg) of paeonol} \\ & \quad \text{for component determination} \\ & \quad \times \frac{A_T}{A_S} \times \frac{1}{2} \end{aligned}$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 274 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 μ m in particle diameter).

Column temperature: A constant temperature of about 20°C.

Mobile phase: A mixture of water, acetonitrile, and acetic acid (100) (65:35:2).

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

Selection of column: Dissolve 0.001 g of paeonol for component determination and 0.005 g of butyl parahydroxybenzoate in 25 mL of methanol. Proceed with 10 μ L of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of paeonol and butyl parahydroxybenzoate in this order, with the resolution between these peaks being not less than 2.

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 paeonol is not more than 1.5%.

Powdered Moutan Bark

Moutan Cortex Pulveratus

ポタンピ末

Powdered Moutan Bark is the powder of Moutan Bark.

It contains not less than 0.7% of paeonol.

Description Powdered Moutan Bark occurs as a light grayish yellow-brown powder. It has a characteristic odor and a slight, pungent and bitter taste.

Under a microscope, Powdered Moutan Bark reveals starch grains and fragments of parenchyma containing them; fragments of cork tissue containing tannin; fragments of somewhat thick-walled collenchyma, medullary rays, and phloem parenchyma; rosette aggregates of calcium oxalate and also fragments of parenchyma cells containing them. Starch grains are simple or 2- to 10-compound grains, 10–25 μ m in diameter; rosette aggregates are 20–30 μ m in diameter.

Identification To 2.0 g of Powdered Moutan Bark add 10 mL of hexane, shake for 3 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of paeonol for thin-layer chromatography in 10 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 μ L 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 hexane and ethyl acetate (1:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): a spot among several spots from the sample solution is similar with the spot from the standard solution in color tone and R_f value.

Purity Foreign matter—Under a microscope, usually vessels and other thick-walled cells are not observable.

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 1.0%.

Component determination Weigh accurately about 0.5 g of Powdered Moutan Bark, add 40 mL of methanol, heat under a reflux condenser on a water bath for 30 minutes, cool, and filter. Repeat the above procedure with the residue, using 40 mL of methanol. Combine the whole filtrates, add methanol

to make exactly 100 mL, then pipet 10 mL of this solution, add methanol to make exactly 25 mL, and use this solution as the sample solution. Separately, dry paeonol for component determination in a desiccator (calcium chloride for drying) for more than 1 hour. Weigh accurately about 0.01 g of it, dissolve in methanol to make exactly 100 mL, then pipet 10 mL of this solution, add methanol to make exactly 50 mL, and use this solution as the standard solution. Perform the test with 10 μ L 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 paeonol in each solution.

$$\begin{aligned} & \text{Amount (mg) of paeonol} \\ &= \text{amount (mg) of paeonol} \\ & \quad \text{for component determination} \\ & \quad \times \frac{A_T}{A_S} \times \frac{1}{2} \end{aligned}$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 274 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 μ m in particle diameter).

Column temperature: A constant temperature of about 20°C.

Mobile phase: A mixture of water, acetonitrile, and acetic acid (100) (65:35:2).

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

Selection of column: Dissolve 0.001 g of paeonol for component determination and 0.005 g of butyl parahydroxybenzoate in 25 mL of methanol. Proceed with 10 μ L of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of paeonol and butyl parahydroxybenzoate in this order, with the resolution between these peaks being not less than 2.

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 paeonol is not more than 1.5%.

Containers and storage Containers—Tight containers.

Mulberry Bark

Mori Cortex

ソウハクヒ

Mulberry Bark is the root bark of *Morus alba* Linné (*Moraceae*).

Description Tubular, semi-tubular or cord-like bark, 1–6 mm thick, often in fine lateral cuttings; externally, white to yellow-brown; in the case of the bark with periderm, its periderm is yellow-brown in color, easy to peel, with numerous longitudinal, fine wrinkles and numerous red-purple lenticels laterally elongated; inner surface, dark yellow-brown in color and flat; cross section, white to light brown in color, and fibrous. Odor, slight; taste, slight.

Under a microscope, a transverse section of bark with

periderm reveals 5 to 12 layers of cork cells in the outer portion; phloem fibers or their bundles scattered in the cortex, arranged alternately and stepwise with phloem parenchyma; lactiferous tubes; solitary crystals of calcium oxalate; starch grains as spheroidal or ellipsoidal, simple or compound grains, simple grain 1–7 μ m in diameter.

Identification Boil 1 g of pulverized Mulberry Bark with 20 mL of hexane under a reflux condenser on a water bath for 15 minutes, and filter. Evaporate the filtrate to dryness, dissolve the residue in 10 mL of chloroform, mix 0.5 mL of the solution with 0.5 mL of acetic anhydride in a test tube, and add carefully 0.5 mL of sulfuric acid to make two layers: a red-brown color develops at the zone of contact.

Purity Foreign matter—The amount of the root xylem and other foreign matter contained in Mulberry Bark does not exceed 1.0%.

Total ash Not more than 11.0%.

Acid-insoluble ash Not more than 1.0%.

Freeze-dried Live Attenuated Mumps Vaccine

乾燥弱毒生おたふくかぜワクチン

Freeze-dried Live Attenuated mumps Vaccine is a dried preparation containing live attenuated mumps virus.

It conforms to the requirements of Freeze-dried Live Attenuated Mumps Vaccine in the Minimum Requirements of Biologic Products.

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

Naphazoline and Chlorpheniramine Solution

ナファゾリン・クロルフェニラミン液

Naphazoline and Chlorpheniramine Solution contains not less than 0.045 w/v% and not more than 0.055 w/v% of naphazoline nitrate ($C_{14}H_{14}N_2 \cdot HNO_3$: 273.29), and not less than 0.09 w/v% and not more than 0.11 w/v% of chlorpheniramine maleate ($C_{16}H_{19}ClN_2 \cdot C_4H_4O_4$: 390.86).

Method of preparation

Naphazoline Nitrate	0.5 g
Chlorpheniramine Maleate	1 g
Chlorobutanol	2 g
Glycerin	50 mL
Purified Water	a sufficient quantity
To make 1000 mL	