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 dr-ing) 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 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 paeonol in each solution.

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

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 μm 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 μL 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 μm 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 ($C_{14}H_{14}N_2.HNO_3$: 273.29), and not less than 0.09 w/v% and not more than 0.11 w/v% of chlorpheniramine maleate ($C_{16}H_{19}ClN_2.C_4H_4O_4$: 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

Dissolve, and mix the above ingredients.

Description Naphazoline and Chlorpheniramine Solution is a clear, colorless liquid.

Identification **(1)** To 20 mL of Naphazoline and Chlorpheniramine Solution add 2 mL of a solution of potassium hydroxide (7 in 10) and 5 mL of pyridine, and heat at 100°C for 5 minutes: a red color is produced (chlorobutanol).

(2) Place 10 mL of Naphazoline and Chlorpheniramine Solution in a glass-stoppered test tube, add 10 mL of ethanol (95), 2 mL of sodium hydroxide TS and 1 mL of a solution of copper (II) chloride dihydrate in ethanol (95) (1 in 10), and shake: a blue color is produced (glycerin).

(3) To 20 mL of Naphazoline and Chlorpheniramine Solution add 5 mL of sodium hydroxide TS, extract with 10 mL of diethyl ether, and separate the diethyl ether layer. Take 5 mL of this solution, distil off the solvent, dissolve the residue in 5 mL of methanol, and use this solution as the sample solution. Dissolve 0.01 g each of naphazoline nitrate and chlorpheniramine maleate in 10 mL and 5 mL of methanol, respectively, and use these solutions as standard solutions (1) and (2). Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solutions on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform, methanol, acetone and ammonia solution (28) (73:15:10:2) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): two spots from the sample solution exhibit the same Rf values as the spots from standard solutions (1) and (2). Spray evenly Dragendorff's TS on the plate: the spots from standard solutions (1) and (2) and the corresponding spot from the sample solutions reveal an orange color.

Assay Pipet 4 mL of Naphazoline and Chlorpheniramine Solution, add exactly 4 mL of the internal standard solution, then add water to make 10 mL, and use this solution as the sample solution. Weigh accurately about 0.05 g of naphazoline nitrate for assay, dried at 105°C for 2 hours, and about 0.1 g of chlorpheniramine maleate for assay, dried at 105°C for 3 hours, dissolve in water to make exactly 100 mL. Pipet 4 mL of this solution, add exactly 4 mL of the internal standard solution, then add water to make 10 mL, and use this solution as the standard solution. Perform the test with 10 μL each of the sample solution and the standard solutions as directed under the Liquid Chromatography according to the following conditions, and calculate the ratios, Q_{Ta} and Q_{Tb}, of the peak height of naphazoline nitrate and chlorpheniramine maleate to that of the internal standard of the sample solution, and the ratios, Q_{Sa} and Q_{Sb}, of the peak height of naphazoline nitrate and chlorpheniramine maleate to that of the internal standard of the standard solution.

Amount (mg) of naphazoline nitrate ($C_{14}H_{14}N_2.HNO_3$)
= amount (mg) of naphazoline nitrate for assay
$$\times \frac{Q_{Ta}}{Q_{Sa}} \times \frac{1}{25}$$

Amount (mg) of chlorpheniramine maleate ($C_{16}H_{19}ClN_2.C_4H_4O_4$)
= amount (mg) of chlorpheniramine maleate for assay
$$\times \frac{Q_{Tb}}{Q_{Sb}} \times \frac{1}{25}$$

Internal standard solution—A solution of ethenzamide in methanol (1 in 1000).

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column, about 4 mm in inside diameter and 25 to 30 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: Room temperature.

Mobile phase: A mixture of acetonitrile and a solution of sodium laurylsulfate (1 in 500) in diluted phosphoric acid (1 in 1000) (1:1).

Flow rate: Adjust the flow rate so that the retention time of chlorpheniramine maleate is about 10 minutes.

Selection of column: Proceed with 10 μL of the standard solution under the above operating conditions. Use a column giving well-resolved peaks of the internal standard, naphazoline nitrate and chlorpheniramine maleate in this order.

Containers and storage Containers—Tight containers.

Storage—Light-resistant.

Nitrogen

窒素

N_2: 28.01

Nitrogen contains not less than 99.5 vol% of N_2.

Description Nitrogen is a colorless gas and is odorless.

Nitrogen (1 mL) dissolves in 65 mL of water and in 9 mL of ethanol (95) at 20°C and at a pressure of 101.3 kPa.

Nitrogen (1000 mL) at 0°C and at a pressure of 101.3 kPa weighs about 1.251 g.

It is inert and does not support combustion.

Identification The flame of a burning wood splinter is extinguished immediately in an atmosphere of Nitrogen.

Purity Carbon dioxide—Maintain the containers of Nitrogen at a temperature between 18°C and 22°C for more than 6 hours before the test, and correct the volume to be at 20°C and 101.3 kPa.

Pass 1000 mL of Nitrogen into 50 mL of barium hydroxide TS in a Nessler tube during 15 minutes through a delivery tube with an orifice approximately 1 mm in diameter, keeping the end of the tube at a distance of 2 mm from the bottom of the Nessler tube: any turbidity produced does not exceed that produced in the following control solution.

Control solution: To 50 mL of barium hydroxide TS in a Nessler tube add 1 mL of a solution of 0.1 g of sodium hydrogen carbonate in 100 mL of freshly boiled and cooled water.

Assay Collect the sample as directed under the Purity. Introduce 1.0 mL of Nitrogen into a gas-measuring tube or syringe for gas chromatography from a metal cylinder with a pressure-reducing valve, through a directly connected polyvinyl chloride tube. Perform the test with this solution as directed under the Gas Chromatography according to the fol-