Powdered Peony Root

Paeoniae Radix Pulverata

シャクヤク末

Powdered Peony Root is the powder of Peony Root. It contains not less than 2.0% of paeoniflorin, calculated on the dried basis.

Description Powdered Peony Root occurs as a light grayish brown powder, and has a characteristic odor and a slightly sweet taste at first, followed by an astringency and a slight bitterness.

Under a microscope, Powdered Peony Root reveals starch grains and fragments of parenchyma cells containing them; fragments of cork cells, vessels, tracheids and xylem fibers; rosette aggregates of calcium oxalate, and fragments of rows of crystal cells containing them. Starch grains consist of simple grains, 5 - 25 μm in diameter, occasionaly 2- to 3-compound grains.

Identification (1) Shake 0.5 g of Powdered Peony Root with 30 mL of ethanol (95) for 15 minutes, and filter. To 3 mL of the filtrate add 1 drop of iron (III) chloride TS, and mix: a blue-purple to blue-green color is produced, and thereafter it changes to dark blue-purple to dark green.

(2) To 2 g of Powdered Peony Root add 10 mL of methanol, warm on a water bath for 5 minutes, cool, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of paeoniflorin 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 acetone, ethyl acetate and acetic acid (100) (10:10:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat at 105°C for 5 minutes: one spot among the spots from the sample solution and the purple spot from the standard solution show the same in color tone and *R*f value.

Purity Foreign matter—Under a microscope, Powdered Peony Root does not show groups of light yellow stone cells and fibers.

Total ash Not more than 6.5%.

Acid-insoluble ash Not more than 0.5%.

Loss on drying Not less than 14.0% (6 hours).

Assay Weigh accurately about 0.5 g of Powdered Peony Root, add 50 mL of diluted methanol (1 in 2), heat under a reflux condenser on a water bath for 30 minutes, cool, and filter. To the residue add 50 mL of diluted methanol (1 in 2), and proceed in the same manner. Combine the filtrates, add diluted methanol (1 in 2) to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of Paeoniflorin Reference Standard, dissolve in diluted methanol (1 in 2) to make exactly 100 mL, and use this solution as the standard solution. Pipet 20 μL each of the sample solution and the standard solution, and perform the test as directed under the Liquid Chromatography according to the following conditions. Determine the peak areas, A_T and A_S, of paeoniflorin in each solution.

Amount (mg) of paeoniflorin ($C_{23}H_{28}O_{11}$)
= amount (mg) of Paeoniflorin Reference Standard, calculated on the anhydrous basis
$\times \frac{A_T}{A_S}$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 230 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 for liquid chromatography (5 to 10 μm in diameter).

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

Mobile phase: A mixture of water and acetonitrile (4:1).

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

Selection of column: Dissolve 1 mg each of Paeoniflorin Reference Standard and *p*-hydroxyacetophenone in diluted methanol (1 in 2) to make 10 mL. Perform the test with 20 μL of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of paeoniflorin and *p*-hydroxyacetophenone in this order with the resolution between these peaks being not less than 3.0.

System repeatability: When the test is repeated 5 times with the standard solution under the above operating conditions, the relative standard deviation of the peak area of paeoniflorin is not more than 1.5%.

Perilla Herb

Perillae Herba

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Perilla Herb is the leaf and twig of *Perilla frutescens* Britton var. *acuta* Kudo or *Perilla frutescens* Britton var. *crispa* Decaisne (*Labiatae*).

Description Usually, contracted and wrinkled leaves, often with thin stems. Both surfaces of the leaf are brownish purple, or the upper surface is grayish green to brownish green, and the lower surface is brownish purple in color. When smoothed by immersion in water, the lamina is ovate to obcordate, 5 - 12 cm in length, 5 - 8 cm in width; the apex, acuminate; the margin, serrate; the base, broadly cuneate; petiole, 3 - 5 cm in length; cross sections of stem and petiole, square. Under a magnifying glass, hairs are observed on both surfaces of the leaf, but abundantly on the vein and sparsely on other parts; small glandular hairs are observed on the lower surface. Odor, characteristic; taste slightly bitter.

Identification To 0.3 mL of the mixture of essential oil and xylene, obtained in Essential oil content, add 1 mL of acetic anhydride, shake, and add 1 drop of sulfuric acid: a red-purple to dark red-purple color develops.

Purity (1) Stem—The amount of its stems, which are not

less than 3 mm in diameter, contained in Perilla Herb does not exceed 3.0%.

(2) Foreign matter—The amount of foreign matter other than the stems contained in Perilla Herb does not exceed 1.0%.

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

Total ash Not more than 16.0%.

Acid-insoluble ash Not more than 2.5%.

Essential oil content Perform the test with 50.0 g of pulverized Perilla Herb as directed in Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added to the sample in the flask: the volume of essential oil is not less than 0.2 mL.

Adsorbed Purified Pertussis Vaccine

沈降精製百日せきワクチン

Adsorbed Purified Pertussis Vaccine is a liquid for injection prepared by adding an aluminum salt to a liquid containing the protective antigen of *Bordetella pertussis* to make the antigen insoluble.

It conforms to the requirements of Adsorbed Purified Pertussis Vaccine in the Minimum Requirements for Biological Products.

Description Adsorbed Purified Pertussis Vaccine forms a homogeneous, white turbidity on shaking.

Adsorbed Diphtheria-Purified Pertussis-Tetanus Combined Vaccine

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Adsorbed Diphtheria-Purified Pertussis-Tetanus Combined Vaccine is a liquid for injection consisting of a liquid containing the protective antigen of *Bordetella pertussis*, Diphtheria Toxoid and a liquid containing tetanus toxoid obtained by detoxifying the tetanus toxin with formaldehyde solution without impairing its immunogenicity, to which aluminum is added to make the antigen and the toxoids insoluble.

It conforms to the requirements of Adsorbed Diphtheria-Purified Pertussis-Tetanus Combined Vaccine in the Minimum Requirements for Biological Products.

Description Adsorbed Diphtheria-Purified Pertussis-Tetanus Combined Vaccine becomes a homogeneous, white turbid liquid on shaking.

Hydrophilic Petrolatum

親水ワセリン

Method of preparation

White Beeswax	80 g
Stearyl Alcohol or Cetanol	30 g
Cholesterol	30 g
White Petrolatum	a sufficient quantity
	To make 1000 g

Melt and mix Stearyl Alcohol or Cetanol, White Beeswax and White Petrolatum on a water bath. Add Cholesterol, and melt completely by stirring. Stop warming, and stir until the mixture congeals.

Description Hydrophilic Petrolatum is white in color. It has a slight, characteristic odor.

When mixed with an equal volume of water, it retains the consistency of ointment.

Containers and storage Containers—Tight containers.

White Petrolatum

白色ワセリン

White Petrolatum is a decolorized and purified mixture of hydrocarbons obtained from petroleum.

Description White Petrolatum is a white to pale yellow, homogeneous, unctuous mass. It is odorless and tasteless.

It is practically insoluble in water, in ethanol (95) and in ethanol (99.5).

It dissolves in diethyl ether making a clear liquid or producing slight insoluble substances.

It becomes a clear liquid when warmed.

Melting point 38 - 60°C (Method 3).

Purity (1) Color—Melt White Petrolatum by warming, and pour 5 mL of it into a test tube, and keep the content in a liquid condition: the liquid has no more color than the following control solution, when observed transversely from side against a white background.

Control solution: Add 3.4 mL of water to 1.6 mL of Ferric Chloride Colorimetric Stock Solution.

(2) Acid or alkali—To 35.0 g of White Petrolatum add 100 mL of hot water, shake vigorously for 5 minutes, and then draw off the aqueous layer. Treat the White Petrolatum layer in the same manner using two 50-mL portions of hot water. To the combined aqueous layer add 1 drop of phenolphthalein TS, and boil: no red color is produced. Further add 2 drops of methyl orange TS: no red color is produced.

(3) Heavy metals—Proceed with 1.0 g of White Petrolatum according to Method 2, and perform the test. Prepare the control solution with 3.0 mL of Standard Lead Solution (not more than 30 ppm).

(4) Arsenic—Prepare the test solution with 1.0 g of