Powdered Peony Root

Paeoniae Radix Pulverata

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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, $5-25~\mu m$ 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 $10 \,\mu\text{L}$ 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 $105\,^{\circ}\text{C}$ 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 Rf 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 μ L each of the sample solution and the standard solution, and perform the test as directed under the Liquid Chro-

matography according to the following conditions. Determine the peak areas, $A_{\rm T}$ and $A_{\rm S}$, of paeoniflorin in each solution.

Amount (mg) of paeoniflorin (C23H28O11)

= amount (mg) of Paeoniflorin Reference Standard, calculated on the anhydrous basis

$$\times \frac{A_{\rm T}}{A_{\rm S}}$$

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 $10 \mu m$ 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 μ L 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