

and stand alternately in a row with corolla-lobes; peduncle distinct. Odor, slight; taste, extremely bitter and persisting.

Identification To 2.0 g of pulverized Swertia Herb add 10 mL of ethanol (95), shake for 5 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 2 mg of swertiamarin for thin-layer chromatography in 1 mL of ethanol (95), 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 each of the sample solution and the standard solution on a plate of silica gel with complex fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, 1-propanol and water (6:4:3) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (broad spectrum wavelength): one spot among several spots from the sample solution and a red spot from the standard solution show the same color tone and the same *R_f* value.

Purity Foreign matter—The amount of straw and other foreign matters contained in Swertia Herb does not exceed 1.0%.

Loss on drying Not more than 12.0% (6 hours).

Total ash Not more than 6.5%.

Extract content Dilute ethanol-soluble extract: not less than 20.0%.

Assay Weigh accurately about 1 g of medium powder of Swertia Herb in a glass-stoppered centrifuge tube, add 40 mL of methanol, shake for 15 minutes, centrifuge, and separate the supernatant liquid. To the residue add 40 mL of methanol, and proceed in the same manner. Combine the extracts, and add methanol to make exactly 100 mL. Pipet 5 mL of the solution, add the mobile phase to make exactly 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of Swertiamarin Reference Standard (separately determine the water content), dissolve in methanol to make exactly 20 mL. Pipet 5 mL of the solution, add the mobile phase to make exactly 20 mL, and use this solution as the standard solution. Perform the test with exactly 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 swertiamarin in each solution.

$$\begin{aligned} & \text{Amount (mg) of swertiamarin (C}_{16}\text{H}_{22}\text{O}_{10}) \\ &= \text{amount (mg) of Swertiamarin Reference Standard,} \\ & \quad \text{calculated on the anhydrous basis} \\ & \quad \times \frac{A_T}{A_S} \times 5 \end{aligned}$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 238 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilylated silica gel for liquid chromatography (5 μ m in particle diameter).

Column temperature: A constant temperature of about 50°C.

Mobile phase: A mixture of water and acetonitrile (91:9).

Flow rate: Adjust the flow rate so that the retention time of swertiamarin is about 12 minutes.

System suitability—

System performance: Dissolve 1 mg each of Swertiamarin

Reference Standard and theophylline in the mobile phase to make 10 mL. When the procedure is run with 10 μ L of this solution under the above operating conditions, theophylline and swertiamarin are eluted in this order with the resolution of these peaks being not less than 10.

System repeatability: When the test is repeated 6 times with 10 μ L of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of swertiamarin is not more than 1.5%.

Powdered Swertia Herb

Swertiae Herba Pulverata

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Powdered Swertia Herb is the powder of Swertia Herb.

It contains not less than 2.0% of swertiamarin (C₁₆H₂₂O₁₀: 374.34), calculated on the basis of dried material.

Description Powdered Swertia Herb occurs as a grayish yellow-green to yellow-brown powder. It has a slight odor, and extremely bitter, persistent taste.

Under a microscope, Powdered Swertia Herb reveals xylem tissues with fibers (components of stems and roots); assimilation tissues (components of leaves and calyces); striated epidermis (components of stems and peduncles); tissues of corollas and filaments with spiral vessels; cells of anthers and their inner walls; spherical pollen grains with granular patterns (components of flowers), about 33 μ m in diameter; starch grains are simple grain, about 6 μ m in diameter, and very few.

Identification To 2.0 g of Powdered Swertia Herb add 10 mL of ethanol (95), shake for 5 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 2 mg of swertiamarin for thin-layer chromatography in 1 mL of ethanol (95), 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 each of the sample solution and the standard solution on a plate of silica gel with complex fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, 1-propanol and water (6:4:3) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (broad spectrum wavelength): one spot among several spots from the sample solution and a red spot from the standard solution show the same color tone and *R_f* value.

Purity Foreign matter—Under a microscope, crystals of calcium oxalate, a large quantity of starch grains and groups of stone cells are not observable.

Loss on drying Not more than 12.0% (6 hours).

Total ash Not more than 6.5%.

Acid-insoluble ash Not more than 2.0%.

Extract content Dilute ethanol-soluble extract: not less than 20.0%.

Assay Weigh accurately about 1 g of Powdered Swertia

Herb in a glass-stoppered centrifuge tube, add 40 mL of methanol, shake for 15 minutes, centrifuge, and separate the supernatant liquid. To the residue add 40 mL of methanol, and proceed in the same manner. Combine the extracts, and add methanol to make exactly 100 mL. Pipet 5 mL of the solution, add the mobile phase to make exactly 20 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of Swertiamarin Reference Standard (separately determine the water content), dissolve in methanol to make exactly 20 mL. Pipet 5 mL of the solution, add the mobile phase to make exactly 20 mL, and use this solution as the standard solution. Perform the test with exactly 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 swertiamarin in each solution.

$$\begin{aligned} & \text{Amount (mg) of swertiamarin (C}_{16}\text{H}_{22}\text{O}_{10}) \\ &= \text{amount (mg) of Swertiamarin Reference Standard,} \\ & \quad \text{calculated on the anhydrous basis} \\ & \quad \times \frac{A_T}{A_S} \times 5 \end{aligned}$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 238 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μ m in particle diameter).

Column temperature: A constant temperature of about 50°C.

Mobile phase: A mixture of water and acetonitrile (91:9).

Flow rate: Adjust the flow rate so that the retention time of swertiamarin is about 12 minutes.

System suitability—

System performance: Dissolve 1 mg each of Swertiamarin Reference Standard and theophylline in the mobile phase to make 10 mL. When the procedure is run with 10 μ L of this solution under the above operating conditions, theophylline and swertiamarin are eluted in this order with the resolution of these peaks being not less than 10.

System repeatability: When the test is repeated 6 times with 10 μ L of the standard solution under the above operating conditions, the relative standard deviation of the peak areas of swertiamarin is not more than 1.5%.

Swertia and Sodium Bicarbonate Powder

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Method of preparation

Powdered Swertia Herb	30 g
Sodium Bicarbonate	700 g
Starch, Lactose or their mixture	a sufficient quantity

To make 1000 g

Prepare as directed under Powders, with the above ingredients.

Description Swertia and Sodium Bicarbonate Powder occurs as a light grayish yellow powder, having a bitter taste.

Identification (1) To 10 g of Swertia and Sodium Bicarbonate Powder add 10 mL of ethanol (95), shake for 15 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of swertiamarin for thin-layer chromatography in 1 mL of ethanol (95), and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 30 μ L each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Proceed as directed in the Identification under Swertia Herb.

(2) To 0.5 g of Swertia and Sodium Bicarbonate Powder add 10 mL of water. After stirring, centrifuge the mixture with 500 revolutions per minute. Smear, using a small glass rod, the slide glass with a small amount of the precipitate, add 1 drop of a mixture of water and glycerin (1:1), and put a cover glass on it so that the tissue section spreads evenly without overlapping each other, taking precaution against inclusion of bubbles, and use this as the preparation for microscopic examination. If the precipitate separates into two layers, proceed with the upper layer in the same manner, and use as the preparation for microscopic examination. Heat the preparation for microscopic examination in a short time: the preparation reveals the yellow-green to yellow-brown, approximately spherical pollen grains with granular patterns under a microscope. The pollen grains are about 33 μ m in diameter.

(3) The supernatant liquid obtained in (2) by centrifuging responds to the Qualitative Tests (1) for bicarbonate.

Containers and storage Containers—Well-closed containers.

Talc

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Talc is a native, hydrous magnesium silicate, sometimes containing a small portion of aluminum silicate.

Description Talc occurs as a white to grayish white, fine, crystalline powder. It is odorless and tasteless.

It is unctuous, and adheres readily to the skin.

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

Identification (1) Mix 0.2 g of Talc with 0.9 g of anhydrous sodium carbonate and 1.3 g of potassium carbonate, and heat the mixture in a platinum or nickel crucible until fusion is complete. Cool, and transfer the fused mixture to a beaker with the aid of 50 mL of hot water. Add hydrochloric acid until it ceases to cause effervescence, add 10 mL of hydrochloric acid, and evaporate the mixture on a water bath to dryness. Cool, add 20 mL of water, boil, and filter. Add 10 mL of a solution of methylene blue trihydrate (1 in 10,000) to the residue, and wash with water: the precipitate is blue in color.

(2) Dissolve 2 g of ammonium chloride and 5 mL of ammonia TS in the filtrate obtained in (1), filter if necessary,