Powdered Polygala Root

Polygalae Radix Pulverata

オンジ末

Powdered Polygala Root is the powder of Polygala Root.

Description Powdered Polygala Root occurs as a light grayish yellow-brown powder. It has a slight odor and a slightly acrid taste.

Under a microscope, Powdered Polygala Root reveals fragments of cork layers, pitted vessels, reticulate vessels and tracheids; fragments of xylem fibers and xylem parenchyma cells with a small number of simple pits; fragments of parenchyma cells containing substances such as oil droplets, rosette aggregates and solitary crystals of calcium oxalate. Oil drop-like contents stained red with sudan III TS.

Identification (1) Shake vigorously 0.5 g of Powdered Polygala Root with 10 mL of water: a lasting fine foam is produced.

(2) To 0.5 g of Powdered Polygala Root add 2 mL of acetic anhydride. After shaking well, allow to stand for 2 minutes, and filter. To the filtrate add carefully 1 mL of sulfuric acid to make two layers: a red-brown color develops at the zone of contact, and changes to dark green later.

Purity Foreign matter—Under a microscope, Powdered Polygala Root does not show stone cells or starch grains.

Total ash Not more than 6.0%.

Polyoxyl 40 Stearate

ステアリン酸ポリオキシル 40

Polyoxyl 40 Stearate is the monostearate of condensation polymers of ethylene oxide represented by the formula $H(OCH_2CH_2)_nOOCC_{17}H_{35}$, in which n is approximately 40.

Description Polyoxyl 40 Stearate occurs as a white to light yellow, waxy solid or powder. It is odorless or has a faint fat-like odor.

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

Congealing point 39.0 - 44.0°C

Congealing point of the fatty acid Not below 53°C.

Acid value Not more than 1.

Saponification value 25 - 35

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Polyoxyl 40 Stearate in 20 mL of water: the solution is clear and colorless.

(2) Heavy metals—Proceed with 2.0 g of Polyoxyl 40 Stearate according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(3) Arsenic—Prepare the test solution with 0.67 g of Polyoxyl 40 Stearate, according to Method 3, and perform the test using Apparatus B (not more than 3 ppm).

Residue on ignition Not more than 0.10% (1 g)

Containers and storage Containers—Tight containers.

Polyporus Sclerotium

Polyporus

チョレイ

Polyporus Sclerotium is the sclerotium of *Polyporus umbellatus* Fries (*Polyporaceae*).

Description Irregularly shaped mass, usually 5 - 15 cm in length; externally blackish brown to grayish brown, with numerous dents and coarse wrinkles; breakable; fractured surface rather soft and cork-like, and almost white to light brown in color, and a white speckled pattern on the inner region; light in texture. Odorless and tasteless.

Identification Warm, while shaking, 0.5 g of pulverized Polyporus Sclerotium with 5 mL of acetone on a water bath for 2 minutes, filter, and evaporate the filtrate to dryness. Dissolve the residue in 5 drops of acetic anhydride, and add 1 drop of sulfuric acid: a red-purple color develops, and immediately changes to dark green.

Total ash Not more than 16.0%.

Acid-insoluble ash Not more than 4.0%.

Powdered Polyporus Sclerotium

Polyporus Pulveratus

チョレイ末

Powdered Polyporus Sclerotium is the powder of the Polyporus Sclerotium.

Description Powdered Polyporus Sclerotium occurs as a light grayish brown to light brown powder.

It has a slight odor, and a slightly bitter and acrid taste, is gritty between the teeth on chewing.

Under a microscope, Powdered Polyporus Sclerotium reveals hypha, 1 to 2 μm, rarely up to 13 μm in diameter, and colorless transparent; granule strongly refracting light; and a few mucilage plates; sometimes fragments of false tissue consisting of them; somewhat brown false tissues; and solitary crystal. Solitary crystal is 10 to 40 μm in diameter, sometimes 100 μm in diameter.

Identification Warm, while shaking, 0.5 g of Powdered Polyporus Sclerotium with 5 mL of acetone on a water bath for 2 minutes, filter and evaporate the filtrate to dryness. Dissolve the residue in 5 drops of acetic anhydride, and add 1 drop of sulfuric acid: a red-purple color develops, and immediately changes to dark green.

Total ash Not more than 16.0%.

Acid-insoluble ash Not more than 4.0%.

Containers and storage Containers—Tight containers.

Polysorbate 80

ポリソルベート 80

Polysorbate 80 is a polyoxyethylene ether of anhydrous sorbitol, partially esterified with oleic acid.

Description Polysorbate 80 is a colorless or orange-yellow, viscous liquid, having a faint, characteristic odor and a warm, slightly bitter taste.

It is miscible with methanol, with ethanol (95), with warm ethanol (95), with pyridine and with chloroform.

It is freely soluble in water and slightly soluble in diethyl ether.

The pH of a solution of Polysorbate 80 (1 in 20) is between 5.5 and 7.5.

Identification (1) To 5 mL of a solution of Polysorbate 80 (1 in 20) add 5 mL of sodium hydroxide TS, boil for 5 minutes, cool, and acidify with dilute hydrochloric acid: the solution is opalescent.

(2) To 5 mL of a solution of polysorbate 80 (1 in 20) add 2 to 3 drops of bromine TS: the color of the test solution is discharged.

(3) Mix 6 mL of Polysorbate 80 with 4 mL of water at an ordinary, or lower than ordinary, temperature: a jelly-like mass is produced.

(4) To 10 mL of a solution of Polysorbate 80 (1 in 20) add 5 mL of ammonium thiocyanate-cobaltous nitrate TS, shake well, add 5 mL of chloroform, shake, and allow to stand: a blue color develops in the chloroform layer.

Viscosity 345 - 445 mm^2/s (Method 1, 25°C).

Specific gravity d_{20}^{20}: 1.065 - 1.095

Acid value Not more than 2.0.

Saponification value 45 - 55

Iodine value 19 - 24 Use chloroform instead of cyclohexane, and titrate without using an indicator, until the yellow color of iodine disappears.

Purity (1) Heavy metals—Proceed with 1.0 g of Polysorbate 80 according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(2) Arsenic—Prepare the test solution with 1.0 g of Polysorbate 80 according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

Water Not more than 3.0% (1 g, back titration).

Residue on ignition Not more than 0.15% (2 g).

Containers and storage Containers—Tight containers.

Poria Sclerotium

Poria

ブクリョウ

Poria Sclerotium is the sclerotium of *Poria cocos* Wolf (*Polyporaceae*), from which usually the external layer has been mostly removed.

Description Mass, about 10 - 30 cm in diameter, up to 0.1 - 2 kg in mass; usually it appears as broken or chipped pieces; white or slightly reddish white; sclerotium with remaining outer layer is dark brown to dark red-brown in color, coarse, which fissures; hard in texture, but brittle. Almost odorless, tasteless, and slightly mucous.

Identification (1) Warm 1 g of pulverized Poria Sclerotium with 5 mL of acetone on a water bath for 2 minutes with shaking, and filter. Evaporate the filtrate to dryness, dissolve the residue in 0.5 mL of acetic anhydride, and add 1 drop of sulfuric acid: a light red color develops, which changes immediately to dark green.

(2) To a section or powder of Poria Sclerotium add 1 drop of iodine TS: a deep red-brown color is produced.

Total ash Not more than 1.0%.

Powdered Poria Sclerotium

Poria Pulveratum

ブクリョウ末

Powdered Poria Sclerotium is the powder of Poria Sclerotium.

Description Powdered Poria Sclerotium occurs as a white to grayish white powder. It is almost odorless and tasteless, but is slightly mucous.

Under a microscope, Powdered Poria Sclerotium reveals colorless and transparent hyphae strongly refracting light, and fragments of false tissue consisting of granules and mucilage plates. Thin hyphae, 2 - 4 μm in diameter; thick ones, usually 10 - 20 μm, up to 39 μm.

Identification (1) Warm 1 g of Powdered Poria Sclerotium with 5 mL of acetone on a water bath for 2 minutes with shaking, and filter. Evaporate the filtrate to dryness, dissolve the residue in 0.5 mL of acetic anhydride, and add 1 drop of sulfuric acid: a light red color develops, which changes immediately to dark green.

(2) To Powdered Poria Sclerotium add 1 drop of iodine TS: a deep red-brown color is produced.

Purity Foreign matter—Under a microscope, Powdered Poria Sclerotium does not show starch grains.

Total ash Not more than 1.0%.