

**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<sup>2</sup>/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*

ブクリヨウ

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*

ブクリヨウ末

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%.