Atractylodes Lancea Rhizome

Atractylodis Lanceae Rhizoma

ソウジュツ

Atractylodes Lancea Rhizome is the rhizome of *Atractylodes lancea* De Candolle or of *Atractylodes chinensis* Koidzumi (*Compositae*).

Description Irregularly curved, cylindrical rhizome, 3 - 10 cm in length, 1 - 2.5 cm in diameter; externally dark grayish brown to dark yellow-brown; a transverse section nearly orbicular, with light brown to red-brown secretes as fine points. Often white cotton-like crystals produced on its surface. Odor, characteristic; taste, slightly bitter.

Under a microscope, a transverse section usually reveals periderm with stone cells; parenchyma of cortex, usually without any fiber bundle; oil sacs, containing light brown to yellow-brown substances, located at the end region of medullary rays; xylem exhibits vessels surrounded by fiber bundles and arranged radially on the region adjoining the cambium; pith and medullary rays exhibit the same oil sacs as in the cortex; parenchyma cells contain spherocrystals of inulin and fine needle crystals of calcium oxalate.

Purity Atractylodes rhizome—Macerate 0.5 g of pulverized Atractylodes Lancea Rhizome with 5 mL of ethanol (95) by warming in a water bath for 2 minutes, and filter. To 2 mL of the filtrate add 0.5 mL of vanillin-hydrochloric acid TS, and shake immediately: no red to red-purple color develops within 1 minute.

Total ash Not more than 7.0%.

Acid-insoluble ash Not more than 1.5%.

Essential oil content Perform the test with 50.0 g of pulverized Atractylodes Lancea Rhizome as directed in the Essential oil content under the Crude Drugs: the volume of essential oil is not less than 0.7 mL.

Powdered Atractylodes Lancea Rhizome

Atractylodis Lanceae Rhizoma Pulveratum

ソウジュツ末

Powdered Atractylodes Lancea Rhizome is the powder of Aractylodes Lancea Rhizome.

Description Powdered Atractylodes Lancea Rhizome occurs as a yellow-brown powder. It has a characteristic odor, and a slightly bitter taste.

Under a microscope, Powdered Atractylodes Lancea Rhizome reveals mainly parenchyma cells, spherocrystals of inulin, fragments of parenchyma cells containing fine needle crystals of calcium oxalate as their contents; and further fragments of light yellow thick-walled fibers, stone cells and cork cells; a few fragments of reticulate and scalariform vessels, and small yellow-brown secreted masses or oil drops; starch grains absent.

Purity Powdered atractylodes rhizome—To 0.5 g of Powdered Atractylodes Lancea Rhizome add 5 mL of ethanol (95), macerate by warming in a water bath for 2 minutes, and filter. To 2 mL of the filtrate add 0.5 mL of vanillin-hydrochloric acid TS, and shake immediately: no red to red-purple color develops within 1 minute.

Total ash Not more than 7.0%.

Acid-insoluble ash Not more than 1.5%.

Essential oil content Perform the test with 50.0 g of Powdered Atractylodes Lancea Rhizome as directed in the Essential oil content under the Crude Drugs: the volume of essential oil is not less than 0.5 mL.

Containers and storage Containers—Tight containers.

Freeze-dried BCG Vaccine (for Percutaneous Use)

乾燥 BCG ワクチン

Freeze-dried BCG Vaccine (for Percutaneous Use) is a preparation for injection which is dissolved before use. It contains live bacteria derived from a culture of the bacillus of Calmette and Guérin.

It conforms to the requirements of Freeze-dried BCG Vaccine (for Percutaneous Use) in the Minimum Requirements for Biological Products.

Description Freeze-dried BCG Vaccine (for Percutaneous Use) becomes a white to light yellow, turbid liquid on addition of solvent.

Bear Bile

Fel Ursi

ユウタン

Bear Bile is the dried bile of *Ursus arctos* Linné or allied animals (*Ursidae*).

Description Indefinite small masses; externally yellow-brown to dark yellow-brown; easily broken; fractured surface has a glassy luster, and is not wet; usually in a gall sac, occasionally taken out, the gall sac consists of a fibrous and strong membrane, 9 - 15 cm in length and 7 - 9 cm in width; externally dark brown and translucent. Odor, slight and characteristic; taste, extremely bitter.

Identification Warm 0.3 g of pulverized Bear Bile with 50 mL of petroleum ether under a reflux condencer on a water bath for about 1 hour, and filter. To 20 mg of the residue add 0.5 mL of hydrochloric acid, 2 mL of acetic anhydride and 2 mL of chloroform, shake the mixture vigorously for 2 minutes, and filter. To the filtrate add carefully 0.5 mL of sulfuric acid: a red color develops at the zone of contact, then

changes to reddish brown, and the upper layer acquires a somewhat red color. Shake gently to mix the two layers together, and allow to stand: a persistent reddish brown color is produced.

Bearberry Leaf

Uvae Ursi Folium

ウワウルシ

Bearberry Leaf is the leaf of *Arctostaphylos uva-ursi* (Linné) Sprengel (*Ericaceae*).

It contains not less than 7.0% of arbutin.

Description Obovate to spatulate leaves, 1 - 3 cm in length, 0.5 - 1.5 cm in width; upper surface yellow-green to dark green; lower surface light yellow-green; margin entire; apex obtuse or round, sometimes retuse; base cuneate; petiole very short; lamina thick with characteristic reticular vein, and easily broken. Odor, slight; taste, slightly bitter and astringent.

Under a microscope, the transverse section reveals thick cuticula; parenchyma cells of palisade tissue and sponge tissue being similar in form; in the vascular bundle, medullary ray consisting of 2 to 7 rows of one-cell line, appearing as bones of Japanese fan; polygonal solitary crystals and clustered crystals of calcium oxalate present sparsely in cells on both outer and inner sides of the vascular bundle, but no crystals in mesophyll.

Identification **(1)** Macerate 0.5 g of pulverized Bearberry Leaf with 10 mL of boiling water, shake the mixture for a few minutes, allow to cool, and filter. Place 1 drop of the filtrate on filter paper, and add 1 drop of iron (III) chloride TS: a dark purple color appears.

(2) To 0.2 g of pulverized Bearberry Leaf add 10 mL of a mixture of ethanol (95) and water (7:3), shake for 5 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of arbutin for thin-layer chromatography in 1 mL of a mixture of ethanol (95) and water (7:3), and use this solution as the standard solution. Perform the test with the sample solution and the standard solution as directed under the Thin-layer Chromatography. Spot 10 μL each of these solutions on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl formate, formic acid and water (8:1:1) to a distance of about 15 cm, and air-dry the plate. Spray evenly diluted sulfuric acid (1 in 2) upon the plate, and heat at 105°C for 10 minutes: one spot among several spots from the sample solution and that from the standard solution show a yellow-brown to blackish brown color and the same *Rf* value.

Purity **(1)** Twig—The amount of twigs contained in Bearberry Leaf does not exceed 4.5%.

(2) Foreign matter—The amount of foreign matter other than twigs contained in Bearberry Leaf does not exceed 2.0%.

Total ash Not more than 4.0%.

Acid-insoluble ash Not more than 1.5%.

Component determination Weigh accurately about 0.5 g of pulverized Bearberry Leaf in a glass-stoppered centrifuge tube, add 40 mL of water, shake for 30 minutes, centrifuge, and separate the supernatant liquid. To the residue add 40 mL of water, and proceed in the same manner. To the combined extracts add water to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.04 g of arbutin for component determination, previously dried for 12 hours (in vacuum, silica gel), dissolve in water to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions. Determine the peak areas, A_T and A_S, of arbutin in each solution.

$$\text{Amount (mg) of arbutin} = \text{amount (mg) of arbutin for component determination} \times \frac{A_T}{A_S}$$

Operating conditions—

Detector: An ultraviolet spectrophotometer (wavelength: 280 nm).

Column: A stainless steel column 4 - 6 mm in inside diameter and 15 - 25 cm in length, packed with octadecylsilanized silica gel (5 - 10 μm in particle diameter).

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

Mobile phase: A mixture of water, methanol and 0.1 mol/L hydrochloric acid TS (94:5:1).

Flow rate: Adjust the flow rate so that the retention time of arbutin is about 6 minutes.

Selection of column: Dissolve 0.05 g each of arbutin for component determination, hydroquinone and gallic acid in water to make 100 mL. Proceed with 10 μL of this solution under the above operating conditions, and calcutate the resolution. Use a column giving elution of arbutin, hydroquinone and gallic acid in this order, and clearly dividing each peak.

System repeatability: Repeat the test five times with the standard solution under the above operating conditions: the relative standard deviation of the peak area of arbutin is not more than 1.5%.

Beef Tallow

Sevum Bovinum

牛脂

Beef Tallow is a purified fat obtained by wet steam rendering from the fresh fatty tissues of *Bos taurus* Linné var. *domesticus* Gmelin (*Bovidae*).

Description Beef Tallow occurs as a white, uniform mass. It has a characteristic odor and a mild taste.

It is freely soluble in diethyl ether and in petroleum ether, very slightly soluble in ethanol (95), and practically insoluble in water.

It is breakable at a low temperature, but softens above 30°C.

Melting point: 42 - 50°C (Method 2)