

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 Atractylodes 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 condenser 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