

## 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