

**Loss on drying** Not more than 14.0% (6 hours).

**Total ash** Not more than 3.5%.

## Plantago Herb

*Plantaginis Herba*

シャゼンソウ

Plantago Herb is the entire plant of *Plantago asiatica* Linné (*Plantaginaceae*), collected during the flowering season.

**Description** Usually wrinkled and contracted leaf and spike, grayish green to dark yellow-green in color; when soaked in water and smoothed out, the lamina is ovate to orbicular-ovate, 4–15 cm in length, 3–8 cm in width; apex acute, and base sharply narrowed; margin slightly wavy, with distinct parallel veins; glabrous or nearly glabrous; petiole is rather longer than the lamina, and its base is slightly expanded with thin-walled leaf-sheath; scape is 10–50 cm in length, one-third to one-half of the upper part forming the spike, with dense florets; the lower part of inflorescence often shows pyxidial; roots usually removed, but, if any, fine roots are closely packed. Odor, slight; tasteless.

**Identification** To 2.0 g of pulverized Plantago Herb add 10 mL of methanol, warm on a water bath for 3 minutes, cool, filter, and use the filtrate as the sample solution. Perform the test with this solution as directed under the Thin-layer Chromatography. Spot 10  $\mu$ L of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (7:2:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly iron (III) chloride TS on the plate: a dark blue spot appears at the *R<sub>f</sub>* value about 0.5.

**Total ash** Not more than 15.0%.

**Acid-insoluble ash** Not more than 4.0%.

**Extract content** Dilute ethanol-soluble extract: not less than 14.0%.

## Plantago Seed

*Plantaginis Semen*

シャゼンシ

Plantago Seed is the seed of *Plantago asiatica* Linné (*Plantaginaceae*).

**Description** Flattened ellipsoidal seed, 2–2.5 mm in length, 0.7–1 mm in width, 0.3–0.5 mm in thickness; externally brown to yellow-brown and lustrous. Under a magnifying glass, the surface of the seed is practically smooth, with the dorsal side protruding like a bow, and with the ventral side somewhat dented; micropyle and raphe not observable. 100 seeds weigh about 0.05 g. Odorless; taste, slightly bitter and mucous.

Under a microscope, a transverse section reveals a seed coat consisting of three layers of epidermis composed of cells containing mucilage, a vegetative layer, and a pigment layer of approximately equidiameter cells; in the interior, endosperm thicker than seed coat, enclosing two cotyledons.

**Identification (1)** To 1 g of Plantago Seed add 2 mL of warm water, and allow the mixture to stand for 10 minutes: the seed coat swells to discharge mucilage.

**(2)** Boil gently 1 g of Plantago Seed with 10 mL of dilute hydrochloric acid for 2 minutes, and filter. Neutralize the filtrate with sodium hydroxide TS, to 3 mL of this solution add 1 mL of Fehling's TS, and warm the mixture: a red precipitate is produced.

**Purity** Foreign matter—The amount of foreign matter contained in Plantago Seed does not exceed 2.0%.

**Total ash** Not more than 5.5%.

**Acid-insoluble ash** Not more than 2.0%.

## Platycodon Fluidextract

キキヨウ流エキス

**Method of preparation** Take coarse powder of platycodon, and prepare the fluidextract as directed under Fluidextracts using 25 vol% ethanol. An appropriate quantity of Ethanol and Purified Water may be used in place of 25 vol% ethanol.

**Description** Platycodon Fluidextract is a red-brown liquid. It is miscible with water, producing slight turbidity. It has a mild taste at first, followed by an acrid and bitter taste.

**Identification (1)** Shake vigorously 0.5 mL of Platycodon Fluidextract with 10 mL of water: a lasting fine foam is produced.

**(2)** Dissolve 1 drop of Platycodon Fluidextract in 2 mL of acetic anhydride, and add gently 0.5 mL of sulfuric acid: a red to red-brown color develops at the zone of contact.

**Purity** Starch—Mix 1 mL of Platycodon Fluidextract with 4 mL of water, and add 1 drop of dilute iodine TS: no purple or blue color develops.

**Content of the active principle** Transfer 5 mL of Platycodon Fluidextract, accurately measured, to a tared beaker, evaporate to dryness on a water bath, and dry at 105°C for 5 hours: the mass of the residue is not less than 0.50 g.

**Containers and storage** Containers—Tight containers.

Storage—Light-resistant.

## Platycodon Root

*Platycodi Radix*

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Platycodon Root is the root of *Platycodon grandiflorum* A. De Candolle (*Campanulaceae*).

**Description** Irregular, somewhat thin and long fusiform to conical root, often branched; externally grayish brown, light brown or white; main root 10–15 cm in length, 1–3 cm in diameter; the upper end, with dented scars of removed stems; the neighborhood, with fine lateral wrinkles and longitudinal furrows and also slightly constricted; the greater part of the root, except the crown, covered with coarse longitudinal wrinkles, lateral furrows and lenticel-like lateral lines; hard in texture, but brittle; fractured surface not fibrous, often with cracks. Under a magnifying glass, a transverse section reveals cambium and its neighborhood often brown in color; cortex slightly thinner than xylem, almost white and with scattered cracks; xylem white to light brown in color, and the tissue slightly denser than cortex. Odor, slight; tasteless at first, later acrid and bitter.

**Identification** (1) Boil 0.5 g of pulverized Platycodon Root with 10 mL of water for a while, allow to cool, and shake the mixture vigorously: a lasting fine foam is produced.

(2) Warm 0.2 g of pulverized Platycodon Root with 2 mL of acetic anhydride on a water bath for 2 minutes, and filter. To 1 mL of the filtrate add carefully 0.5 mL of sulfuric acid to make two layers: a red to red-brown color develops at the zone of contact, and the upper layer acquires a blue-green to green color.

**Total ash** Not more than 4.0%.

**Extract content** Dilute ethanol-soluble extract: not less than 25.0%.

## Powdered Platycodon Root

### *Platycodi Radix Pulverata*

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Powdered Platycodon Root is the powder of Platycodon Root.

**Description** Powdered Platycodon Root occurs as a light grayish yellow to light grayish brown powder. It has a slight odor, and is tasteless at first, later acrid and bitter.

Under a microscope, Powdered Platycodon Root reveals numerous fragments of colorless parenchyma cells; fragments of reticulate vessels and scalariform vessels; fragments of sieve tubes and lactiferous tubes; fragments of cork layer are sometimes observed. Usually, starch grains are not observed, but very rarely simple grain.

**Identification** (1) Boil 0.5 g of Powdered Platycodon Root with 10 mL of water for a while, allow to cool, and shake the mixture vigorously: a lasting fine foam is produced.

(2) Warm 0.2 g of Powdered Platycodon Root with 2 mL of acetic anhydride on a water bath for 2 minutes, and filter. To 1 mL of the filtrate add carefully 0.5 mL of sulfuric acid to make two layers: a red to red-brown color develops at the zone of contact, and the upper layer acquires a blue-green to green color.

**Purity** Foreign matter—Under a microscope, Powdered Platycodon Root does not show fibers, stone cells or other

foreign matter.

**Total ash** Not more than 4.0%.

**Acid-insoluble ash** Not more than 1.0%.

**Extract content** Dilute ethanol-soluble extract: not less than 25.0%.

## Live Oral Poliomyelitis Vaccine

経口生ポリオワクチン

Live Oral Poliomyelitis Vaccine contains live attenuated poliovirus of type I, II and III.

Monovalent or bivalent product may be prepared, if necessary.

Live Oral Poliomyelitis Vaccine conforms to the requirements of Live Oral Poliomyelitis Vaccine in the Minimum Requirements for Biological Products.

**Description** Live Oral Poliomyelitis Vaccine is a light yellow-red to light red, clear liquid.

## Polygala Root

### *Polygalae Radix*

オンジ

Polygala Root is the root of *Polygala tenuifolia* Willdenow (*Polygalaceae*).

**Description** Thin, long and bent, cylindrical or tubular root; main root, 10–20 cm in length, 0.2–1 cm in diameter, sometimes with one to several lateral roots; externally light grayish brown, with coarse longitudinal wrinkles, and with deep lateral furrows cracked to some degree here and there; brittle, and fractured surface not fibrous; margin of the transverse section irregularly undulate; cortex, comparatively thick, with large cracks here and there; xylem usually round to elliptical, light brown in color, and often tears in a wedge-like shape. Odor, slight; taste, slightly acrid.

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

(2) To 0.5 g of pulverized 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.

**Purity** (1) Stem—The amount of the stems contained in Polygala Root does not exceed 10.0%.

(2) Foreign matter—The amount of foreign matter other than the stems contained in Polygala Root does not exceed 1.0%.

**Total ash** Not more than 6.0%.