

10 mL of methanol, boil gently for 2 minutes, and filter. To 5 mL of the filtrate add 0.1 g of magnesium in ribbon form and 1 mL of hydrochloric acid, and allow to stand: a red-purple color develops.

**Total ash** Not more than 7.0%.

## Human Normal Immunoglobulin

人免疫グロブリン

Human Normal Immunoglobulin is a liquid for injection containing immunoglobulin G in serum globulins of humans.

It conforms to the requirements of Human Normal Immunoglobulin in the Minimum Requirements for Biological Products.

**Description** Human Normal Immunoglobulin is a clear, colorless or yellow-brown liquid.

## Imperata Rhizome

*Imperatae Rhizoma*

ボウコン

Imperata Rhizome is the rhizome of *Imperata cylindrica* Beauvois (*Gramineae*), from which rootlets and scale leaves have been removed.

**Description** Long and thin cylindrical rhizome, 0.3–0.5 cm in diameter; sometimes branched; externally yellowish white, with slight longitudinal wrinkles, and with nodes at 2–3-cm intervals; difficult to break; fractured surface fibrous. Cross section irregularly round; thickness of cortex is slightly smaller than the diameter of the stele; pith often forms a hollow. Under a magnifying glass, a transverse section reveals cortex, yellowish white, and with scattered brown spots; stele, yellow-brown in color. Odorless, and tasteless at first, but later slightly sweet.

**Identification** To 1 g of pulverized Imperata Rhizome add 20 mL of hexane, allow the mixture to stand for 30 minutes with occasional shaking, and filter. Evaporate the filtrate to dryness, dissolve the residue in 5 mL of chloroform, place 0.5 mL of this solution in a test tube, and, after mixing with 0.5 mL of acetic anhydride by shaking, add carefully 0.5 mL of sulfuric acid to make two layers: a red-brown color develops at the zone of contact, and the upper layer acquires a blue-green to blue-purple color.

**Purity** (1) Rootlet and scaly leaf—The amount of the rootlets and scaly leaves contained in Imperata Rhizome does not exceed 3.0%.

(2) Foreign matter—The amount of foreign matter other than rootlets and scaly leaves contained in Imperata Rhizome does not exceed 1.0%.

**Total ash** Not more than 5.0%.

**Acid-insoluble ash** Not more than 1.5%.

## Influenza HA Vaccine

インフルエンザ HA ワクチン

Influenza HA Vaccine is a liquid for injection containing hemagglutinin of influenza virus.

It conforms to the requirements of Influenza HA Vaccine in the Minimum Requirements for Biological Products.

**Description** Influenza HA Vaccine is a clear liquid or a slightly whitish turbid liquid.

## Iodine Tincture

ヨードチンキ

Iodine Tincture contains not less than 5.7 w/v% and not more than 6.3 w/v% of iodine (I: 126.90), and not less than 3.8 w/v% and not more than 4.2 w/v% of potassium iodide (KI: 166.00).

### Method of preparation

Iodine	60 g
Potassium Iodide	40 g
70 vol% Ethanol	a sufficient quantity

To make 1000 mL

Prepare as directed under Tinctures, with the above ingredients. It may be prepared with an appropriate quantity of Ethanol or Ethanol for Disinfectant and Purified Water in place of 70 vol% Ethanol.

**Description** Iodine Tincture is a dark red-brown liquid, and has a characteristic odor.

Specific gravity  $d_{20}^{20}$ : about 0.97

**Identification** (1) To a mixture of 1 mL of starch TS and 9 mL of water add 1 drop of Iodine Tincture: a dark blue-purple color develops.

(2) Evaporate 3 mL of Iodine Tincture to dryness on a water bath, and heat gently over a free flame: a white residue is formed which responds to the Qualitative Tests for potassium salt and iodide.

**Alcohol number** Not less than 6.6 (Method 2). Perform the pretreatment (ii) in the Method 1.

**Assay** (1) Iodine—Pipet 5 mL of Iodine Tincture, add 0.5 g of potassium iodide, 20 mL of water and 1 mL of dilute hydrochloric acid, and titrate with 0.1 mol/L sodium thiosulfate VS (indicator: 2 mL of starch TS).

Each mL of 0.1 mol/L sodium thiosulfate VS  
= 12.690 mg of I

(2) Potassium iodide—Pipet 5 mL of Iodine Tincture into an iodine flask, add 20 mL of water, 50 mL of hydrochloric acid and 5 mL of chloroform. Cool to room temperature, and titrate with 0.05 mol/L potassium iodate VS until the red-purple color disappears from the chloroform layer, with agitating the mixture vigorously and con-