all the extracts, add 0.01 mol/L hydrochloric acid TS to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g of emetine hydrochloride for component determination, previously dried in a desiccator (reduced below 0.67 kPa, phosphorus (V) oxide, 50°C) for 5 hours, dissolve in 0.01 mol/L hydrochloric acid TS to make exactly 100 mL, and use this solution as the standard solution. Pipet 10 μL of the sample solution and the standard solution, and perform the test as directed under the Liquid Chromatography according to the following conditions. Determine the peak areas, A_{TE} and A_{TC}, of emetine and cephaeline in the sample solution, and the peak area, A_{SE}, of emetine in the standard solution.

Amount (mg) of total alkaloids (emetine and cephaeline)
= amount (mg) of emetine hydrochloride for component determination
$$\times \frac{A_{TE} + A_{TC} \times 0.971}{A_{SE}} \times 0.868$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength : 283 nm).

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

Column temperature: A constant temperature of about 50°C.

Mobile phase: Dissolve 2.0 g of sodium 1-heptane sulfonate in 500 mL of water, adjust the pH 4.0 with acetic acid (100), and add 500 mL of methanol.

Flow rate: Adjust the flow rate so that the retention time of emetine is about 14 minutes.

Selection of column: Dissolve 1 mg each of emetine hydrochloride for component determination and cephaeline hydrobromide in 10 mL of 0.01 mol/L hydrochloric acid TS. Perform the test with 10 μL of this solution under the above operating conditions. Use a column giving elution of cephaeline and emetine in this order, and clearly dividing each peak.

System repeatability: Repeat the test 6 times with the standard solution under the above operating conditions: the relative standard deviation of the peak area of emetine is not more than 1.5%.

Ipecac Syrup

Syrupus Ipecacuanha

トコンシロップ

Ipecac Syrup is a syrup containing not less than 0.12 g and not more than 0.15 g of the total alkaloids (emetine and cephaeline) per 100 mL.

Method of preparation Take coarse powder of Ipecac, prepare the fluidextract as directed under Fluidextracts using a mixture of Ethanol and Purified Water (3:1), and evaporate the mixture under reduced pressure or add a suitable amount of Ethanol or Purifiect Water if necessary to get a solution containing 1.7 to 2.1 g of the total alkaloids (emetine and cephaeline) per 100 mL. 70 mL of To this solution add 100 mL of Glycerin and Simple Syrup to make 1000 mL, as directed under Syrups.

Description Ipecac Syrup is a yellow-brown, viscous liquid. It has a sweet taste and a bitter aftertaste.

Identification Take 2 mL of Ipecac Syrup into an evaporating dish, mix with 1 mL of hydrochloric acid, and add small pieces of chlorinated lime: circumference of it turns orange.

Purity Ethanol—Take exactly 5 mL of Ipecac Syrup, add 5 mL of the internal standard solution and water to make 50 mL, and use this solution as the sample solution. Separately, pipet 5 mL of ethanol (99.5), and add water to make exactly 100 mL. To exactly 5 mL of this solution add exactly 5 mL of the internal standard solution and water to make 50 mL, and use this solution as the standard solution. Perform the test with 2 μL each of the sample solution and the standard solution as directed under the Gas Chromatography according to the following conditions, and determine the rate of peak height of ethanol to that of the internal standard, Q_T and Q_S: Q_T is not larger than Q_S.

Internal standard solution—A solution of acetonitrile (5 in 100).

Operating conditions—

Detector: A hydrogen flame-ionization detector.

Column: A glass-column about 3 mm in inside diameter and about 1.5 m in length, packed with ethylvinylbenzene-divinylbenzene porous co-polymer for gas chromatography (150 to 180 μm in particle diameter).

Column temperature: A constant temperature of between 105°C and 115°C.

Carrier gas: Nitrogen

Flow rate: Adjust the flow rate so that the retention time of ethanol is 5 to 10 minutes.

Selection of column: Proceed with 2 μL of the standard solution under the above operating conditions. Use a column giving elution of ethanol and the internal standard in this order, and clearly dividing each peak.

Component determination Take exactly 5 mL of Ipecac Syrup, add 0.01 mol/L hydrochloric acid TS to make exactly 50 mL, and use the solution as the sample solution. Separately, weigh accurately about 0.01 g of emetine hydrochloride for component determination, previously dried in a desiccator (reduced pressure under 0.67 kPa, phosphorus (V) oxide, 50°C) for 5 hours, dissolve in 0.01 mol/L hydrochloric acid TS to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 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_{TE} and A_{TC}, of emetine and cephaeline in the sample solution, and the peak area, A_{SE}, of emetine in the standard solution.

Amount (mg) of total alkaloids (emetine and cephaeline)
= amount (mg) of emetine hydrochloride for component determination
$$\times \frac{A_{TE} + A_{TC} \times 0.971}{A_{SE}} \times \frac{1}{2} \times 0.868$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 283 nm).

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

Column temperature: A constant temperature of about 50°C.

Mobile phase: Dissolve 2.0 g of sodium l-heptane sulfonate in 500 mL of water, adjust the pH to 4.0 with acetic acid (100), and add 500 mL of methanol.

Flow rate: Adjust the flow rate so that the retention time of emetine is about 14 minutes.

Selection of column: Dissolve 1 mg each of emetine hydrochloride for component determination and cephaeline hydrobromide in 10 mL of 0.01 mol/L hydrochloric acid TS. Perform the test with 10 μL of this solution under the above operating conditions. Use a column giving elution of cephaeline and emetine in this order, and clearly dividing each peak.

System repeatability: When the test is repeated 6 times with the standard solution under the above operating conditions, the relative standard deviation of the peak area of emetine is not more than 1.5%.

Microbial limit Proceed with Ipecac Syrup as directed under the Microbial Limit Test: the total viable aerobic microbial count is not more than 1000 per mL, and the total count of fungi and yeast is not more than 100 per mL. *Salmonella*, *Escherichia coli*, *Pseudomonas aeruginosa* and *Staphylococcus aureus* should not be observed.

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Japanese Angelica Root

Angelicae Radix

トウキ

Japanese Angelica Root is the root of *Angelica acutiloba* Kitagawa or *Angelica acutiloba* Kitagawa var. *sugiyamae* Hikino (*Umbelliferae*), usually after being passed through hot water.

Description Thick and short main root, with numerous branched roots, nearly fusiform; 10 - 25 cm in length; externally dark brown to red-brown, with longitudinal wrinkles and horizontal protrusions composed of numerous scars of fine rootlets; fractured surface is dark brown to yellow-brown in color, and smooth; and with a little remains of leaf sheath at the crown. Odor, characteristic; taste, slightly sweet, followed by slight pungency.

Under a microscope, a transverse section reveals 4 to 10 layers of cork, with several layers of collenchyma inside of the layer; the cortex exhibits many oil canals surrounded by secretory cells and often large hollows appear; boundary of phloem and xylem is distinct; in the xylem, numerous vessels radiate alternately with medullary rays; vessels in the outer part of the xylem are singly or in several groups, and disposed rather densely in a cuneiform pattern, but vessels in the region of the center are scattered very sparsely; starch grains are simple grains, not more than 20 μm in diameter, and rarely 2- to 5-compound grains, up to 25 μm in diameter; starch grains often gelatinized.

Purity (1) Leaf sheath—The amount of leaf sheath contained in Japanese Angelica Root does not exceed 3.0%.
(2) Foreign matter—The amount of foreign matter other than leaf sheath contained in Japanese Angelica Root does not exceed 1.0%.

Total ash Not more than 7.0%.

Acid-insoluble ash Not more than 1.0%.

Extract content Dilute ethanol-soluble extract: not less than 35.0%.

Powdered Japanese Angelica Root

Angelicae Radix Pulverata

トウキ末

Powdered Japanese Angelica Root is the powder of Japanese Angelica Root.

Description Powdered Japanese Angelica Root occurs as a light grayish brown powder. It has a characteristic odor and a slight, sweet taste with a slightly pungent aftertaste.

Under a microscope, Powdered Japanese Angelica Root reveals starch grains or masses of gelatinized starch, and fragments of parenchyma containing them; fragments of light yellow-brown cork tissue; fragments of rather thick-walled collenchyma and phloem tissue; fragments of resin duct surrounded by secretory cells; fragments, 20 - 60 μm in diameter, of scalariform and reticulate vessels with simple perforation; starch grains composed of simple grains not more than 20 μm in diameter, and rarely 2- to 3-compound grains.

Purity Foreign matter—Under a microscope, Powdered Japanese Angelica Root does not show remarkably lignified sclerenchymatous cells.

Total ash Not more than 7.0%.

Acid-insoluble ash Not more than 1.0%.

Extract content Dilute ethanol-soluble extract: not less than 35.0%.

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Japanese Encephalitis Vaccine

日本脳炎ワクチン

Japanese Encephalitis Vaccine is a liquid for injection containing inactivated Japanese encephalitis virus.

It conforms to the requirements of Japanese Encephalitis Vaccine in the Minimum Requirements for Biological Products.

Description Japanese Encephalitis Vaccine is a clear or a slightly whitish turbid and colorless liquid.