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.