2 cm in length, 1 - 2 cm in diameter, with buds and remains of stem at the crown; hard in texture and difficult to break; flank of rhizome sometimes accompanied with stolons having thick and short or thin, long and extremely small, scaly leaves. Under a magnifying glass, the transverse section reveals a thick, light grayish brown cortical layer, and a grayish brown stele. Odor, strong and characteristic; taste, slightly bitter.

Total ash Not more than 10.0%.

Acid-insoluble ash Not more than 5.0%.

Essential oil content Perform the test with 50.0 g of pulverized Japanese Valerian as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added to the sample in the flask: the volume of essential oil is not less than 0.3 mL.

Containers and storage Containers—Tight containers.

Powdered Japanese Valerian

Valerianae Radix Pulverata

カノコソウ末

Powdered Japanese Valerian is the powder of Japanese Valerian.

Description Powdered Japanese Valerian occurs as a dark grayish brown powder. It is somewhat moist to the touch. It has a strong, characteristic odor and a slightly bitter taste.

Under a microscope, Powdered Japanese Valerian reveals starch grains and fragments of parenchyma cells containing them; fragments of pitted vessels, reticulate vessels, ring vessels, and spiral vessels; fragments of exodermis containing oil droplets and composed of cells suberized and divided into daughter cells; fragments of yellow stone cells from the rhizome and the stolon; and very rarely, some fragments of epidermis and phloem fibers. Starch grains, simple grains 10 - 20 μm in diameter and 2- to 4-compound grains; oil droplets stained red with sudan III TS.

Total ash Not more than 10.0%.

Acid-insoluble ash Not more than 5.0%.

Essential oil content Perform the test with 50.0 g of Powdered Japanese Valerian as directed in the Essential oil content under the Crude Drugs, provided that 1 mL of silicon resin is previously added to the sample in the flask: the volume of essential oil is not less than 0.2 mL.

Containers and storage Containers—Tight containers.

Jujube

Zizyphi Fructus

タイソウ

Jujube is the fruit of *Zizyphus jujuba* Miller var. *inermis* Rehder (*Rhamnaceae*).

Description Ellipsoidal or broad ovoid fruit, 2 - 3 cm in length, 1 - 2 cm in diameter; externally reddish brown with coarse wrinkles, or dark grayish red with fine wrinkles, and both lustrous; both ends slightly dented, with a scar of style on one end and a scar of peduncle on the other; epicarp thin and leather; mesocarp thick, dark grayish brown in color, spongy, soft and adhesive; endocarp extremely hard, fusiform, and divided into two loculi; seeds flat and ovoid. Odor, slight and characteristic; taste, sweet.

Purity Rancidity—Jujube has no unpleasant, rancid odor and taste.

Total ash Not more than 3.0%.

Kainic Acid and Santonin Powder

カイニン酸・サントニン散

Kainic Acid and Santonin Powder contains not less than 9.0% and not more than 11.0% of santonin ($C_{15}H_{18}O_3$: 246.30), and not less than 1.80% and not more than 2.20% of kainic acid ($C_{10}H_{15}NO_4.H_2O$: 231.25).

Method of preparation

Santonin	100 g
Kainic Acid	20 g
Starch, Lactose or their mixture	a sufficient quantity
To make	1000 g

Prepare as directed under Powders, with the above ingredients.

Description Kainic Acid and Santonin Powder occurs as a white powder.

Identification (1) Shake 1 g of Kainic Acid and Santonin Powder with 10 mL of chloroform, and filter [use the residue for the test (2)]. Distil off the chloroform of the filtrate, and dissolve the residue in 2 mL of potassium hydroxide-ethanol TS: a red color is produced (santonin).

(2) Shake the residue obtained in (1) with 20 mL of warm water, filter, and to 1 mL of the filtrate add 10 mL of water and 1 mL of ninhydrin-L-ascorbic acid TS. Warm in a water bath between 60°C and 70°C for 5 minutes: a yellow color is produced (kainic acid).

Assay (1) Santonin—Weigh accurately about 0.25 g of Kainic Acid and Santonin Powder, add 20 mL of ethanol (95), shake thoroughly for 5 minutes, and filter. Wash the residue with three 10-mL portions of ethanol (95), and filter. Combine the filtrate and the washings, and add ethanol (95) to make exactly 50 mL. Pipet 2 mL of this solution, add ethanol (95) to make exactly 100 mL, and use this solution as the sample solution. Weigh accurately about 0.025 g of santonin for assay, proceed in the same manner as the sample solution, and use the obtained solution as the standard solution. Determine the absorbances, A_T and A_S, of these solutions at 240 nm as directed under the Ultraviolet-visible Spectrophotometry.

$$\text{Amount (mg) of santonin } (C_{15}H_{18}O_3) = \text{amount (mg) of santonin for assay} \times \frac{A_T}{A_S}$$

(2) Kainic acid—Weigh accurately about 1.25 g of Kainic Acid and Santonin Powder, add 20 mL of diluted pyridine (1 in 10), shake thoroughly for 5 minutes, and filter. Wash the residue with three 10-mL portions of diluted pyridine (1 in 10), and filter. Combine the filtrate and the washings, and add diluted pyridine (1 in 10) to make exactly 50 mL. Pipet 2 mL of this solution, add diluted pyridine (1 in 10) to make exactly 25 mL, and use this solution as the sample solution. Dissolve about 0.025 g of kainic acid for assay, previously dried at 105°C for 4 hours and accurately weighed, in diluted pyridine (1 in 10) to make exactly 50 mL. Pipet 2 mL of this solution, add diluted pyridine (1 in 10) to make exactly 25 mL, and use this solution as the standard solution. Pipet 2 mL each of the sample solution and the standard solution, add 2 mL of ninhydrin-L-ascorbic acid TS, and heat on a water bath for 30 minutes. After cooling immediately, shake vigorously for 2 minutes, add water to make exactly 20 mL, and allow to stand for 15 minutes. Determine the absorbances, A_T and A_S, of these solutions at 425 nm as directed under the Ultraviolet-visible Spectrophotometry, using the solution prepared in the same manner with 2 mL of diluted pyridine (1 in 10) instead of the sample solution as the blank.

$$\text{Amount (mg) of kainic acid } (C_{10}H_{15}NO_4.H_2O) = \text{amount (mg) of kainic acid for assay} \times \frac{A_T}{A_S} \times 1.0845$$

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.

Kaolin

カオリン

Kaolin is a native, hydrous aluminum silicate.

Description Kaolin occurs as white or nearly white, fragmentary masses or powder. It has a slightly clay-like odor.

It is practically insoluble in water, in ethanol (99.5) and in diethyl ether.

It is insoluble in dilute hydrochloric acid and in sodium hydroxide TS.

When moistened with water, it darkens and becomes plastic.

Identification (1) Heat 1 g of Kaolin with 10 mL of water and 5 mL of sulfuric acid in a porcelain dish, and evaporate the mixture nearly to dryness. Cool, add 20 mL of water, boil for 2 to 3 minutes, and filter: the color of the residue is gray.

(2) The filtrate obtained in (1) responds to the Qualitative Tests (1), (2) and (4) for aluminum salt.

Purity (1) Acid or alkali—Add 25 mL of water to 1.0 g of Kaolin, agitate thoroughly, and filter: the pH of the filtrate is between 4.0 and 7.5.

(2) Acid-soluble substances—Add 20 mL of dilute hydrochloric acid to 1.0 g of Kaolin, agitate for 15 minutes, and filter. Evaporate 10 mL of the filtrate to dryness, and heat strongly between 450°C and 550°C to constant mass: the mass of the ignited residue is not more than 0.010 g.

(3) Carbonate—Stir 1.0 g of Kaolin with 5 mL of water, then add 10 mL of diluted sulfuric acid (1 in 2): no effervescence occurs.

(4) Heavy metals—Boil 1.5 g of Kaolin gently with 50 mL of water and 5 mL of hydrochloric acid for 20 minutes with frequent agitation, cool, centrifuge, and separate the supernatant liquid. Wash the precipitate twice with 10 mL of water, centrifuge each time, and combine the supernatant liquid and the washings. Add dropwise ammonia solution (28) to this solution until a slight precipitate occurs, then add dilute hydrochloric acid dropwise while agitating strongly to complete solution. Add 0.45 g of hydroxylammonium chloride, and heat. Cool, add 0.45 g of sodium acetate trihydrate and 6 mL of dilute acetic acid, filter if necessary, and wash with 10 mL of water. Combine the filtrate and the washings, and add water to make 150 mL. Perform the test using 50 mL of this solution as the test solution. To 2.5 mL of Standard Lead Solution add 0.15 g of hydroxylammonium chloride, 0.15 g of sodium acetate trihydrate, 2 mL of acetic acid (31) and water to make 50 mL, and use this solution as the control solution (not more than 50 ppm).

(5) Iron—Add 10 mL of dilute hydrochloric acid to 0.040 g of Kaolin, and heat for 10 minutes with shaking in a water bath. After cooling, add 0.5 g of L-tartaric acid, dissolve with shaking, prepare the test solution with this solution according to Method 2, and perform the test according to Method B. Prepare the control solution with 2.0 mL of Standard Iron Solution (not more than 500 ppm).

(6) Arsenic—Add 5 mL of water and 1 mL of sulfuric acid to 1.0 g of Kaolin, and heat on a sand bath until white fumes begin to evolve. Cool, and add water to make 5 mL. Perform the test using Apparatus B with this solution as the test solution (not more than 2 ppm).

(7) Foreign matter—Place 5 g of Kaolin in a beaker, add 100 mL of water, stir, and decant to leave sand. Repeat this procedure several times with 100-mL portions of water: no sandy residue remains.

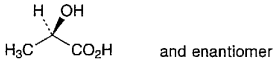
Loss on ignition Not more than 15.0% (1 g, 600°C, 5 hours).

Plasticity Add 7.5 mL of water to 5.0 g of Kaolin, and agitate thoroughly: the resultant mass has no remarkable fluidity.

Containers and storage Containers—Well-closed containers.

Lactic Acid

乳酸



and enantiomer

$C_3H_6O_3$: 90.08

(*RS*)-2-Hydroxypropanoic acid [*50-21-5*]