

under Crude Drugs: the volume of essential oil is not less than 0.4 mL.

Containers and storage Containers—Tight containers.

Anemarrhena Rhizome

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チモ

Anemarrhena Rhizome is the rhizome of *Anemarrhena asphodeloides* Bunge (*Liliaceae*).

Description Rather flat and cord-like rhizome, 3–15 cm in length, 0.5–1.5 cm in diameter, slightly bent and branched; externally yellow-brown to brown; on the upper surface, a longitudinal furrow and hair-like remains or scars of leaf sheath forming fine ring-nodes; on the lower surface, scars of root appearing as numerous round spot-like hollows; light and easily broken. Under a magnifying glass, a light yellow-brown transverse section reveals an extremely narrow cortex; stele porous, with many irregularly scattered vascular bundles. Odor, slight; taste, slightly sweet and mucous, followed by bitterness.

Identification (1) Shake vigorously 0.5 g of pulverized Anemarrhena Rhizome with 10 mL of water in a test tube: a lasting fine foam is produced. Filter the mixture, and to 2 mL of the filtrate add 1 drop of iron (III) chloride TS: a dark green precipitate is produced.

(2) Warm 0.5 g of pulverized Anemarrhena Rhizome with 2 mL of acetic anhydride on a water bath for 2 minutes while shaking, then filter, and to the filtrate add carefully 1 mL of sulfuric acid to make two layers: a red-brown color develops at the zone of contact.

Purity Foreign matter—The amount of fiber, originating from the dead leaves, and other foreign matter contained in Anemarrhena Rhizome does not exceed 3.0%.

Total ash Not more than 7.0%.

Acid-insoluble ash Not more than 2.5%.

Angelica Dahurica Root

ビャクシ

Angelica Dahurica Root is the root of *Angelica dahurica* Bentham et Hooker (*Umbelliferae*).

Description Main root from which many long roots are branched out and nearly fusiform and conical in whole shape, 10–25 cm in length; externally grayish brown to dark brown, with longitudinal wrinkles, and with numerous scars of rootlets laterally elongated and protruded. A few remains of leaf sheath at the crown and ring-nodes closely protruded near the crown. In a transverse section, the outer region is grayish white in color, and the central region is sometimes

dark brown in color. Odor, characteristic; taste, slightly bitter.

Identification To 0.2 g of pulverized Angelica Dahurica Root add 5 mL of ethanol (95), allow to stand for 5 minutes with shaking, and filter. Examine the filtrate under ultraviolet light (main wavelength: 365 nm): a blue to blue-purple fluorescence develops.

Purity (1) Leaf sheath—The amount of leaf sheath contained in Angelica Dahurica Root does not exceed 3.0%.

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

Total ash Not more than 7.0%.

Acid-insoluble ash Not more than 2.0%.

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

Dental Antiformin

Dental Sodium Hypochlorite Solution

歯科用アンチホルミン

Dental Antiformin contains not less than 3.0 w/v% and not more than 6.0 w/v% of sodium hypochlorite (NaClO: 74.44).

Description Dental Antiformin is a slightly light yellow-green, clear liquid. It has a slight odor of chlorine.

It gradually changes by light.

Identification (1) Dental Antiformin changes red litmus paper to blue, and then decolorizes it.

(2) To Dental Antiformin add dilute hydrochloric acid: it evolves the odor of chlorine, and the gas changes potassium iodide starch paper moistened with water to blue.

(3) Dental Antiformin responds to the Qualitative Tests (1) for sodium salt.

Assay Measure exactly 3 mL of Dental Antiformin in a glass-stoppered flask, add 50 mL of water, 2 g of potassium iodide and 10 mL of acetic acid (31), and titrate the liberated iodine with 0.1 mol/L sodium thiosulfate VS (indicator: 3 mL of starch TS).

Each mL of 0.1 mol/L sodium thiosulfate VS
= 3.7221 mg of NaClO

Containers and storage Containers—Tight containers.
Storage—Light-resistant, and not exceeding 10°C.

Apricot Kernel

Armeniaca Semen

キョウニン

Apricot Kernel is the seed of *Prunus armeniaca*

Linné or *Prunus armeniaca* Linné var. *ansu* Maximowicz (*Rosaceae*).

Description Flattened, somewhat asymmetric ovoid seed, 1.1 – 1.8 cm in length, 0.8 – 1.3 cm in width, 0.4 – 0.7 cm in thickness; sharp at one end and rounded at the other end where chalaza situated; seed coat brown and its surface being powdery with rubbing easily detachable stone cells of epidermis; numerous vascular bundles running from chalaza throughout the seed coat, appearing as thin vertical furrows; seed coat and thin semitransparent white albumen easily separate from cotyledon when soaked in boiling water; cotyledon, white in color. Almost odorless; taste, bitter and oily.

Under a microscope, surface of epidermis reveals stone cells on veins protruded by vascular bundles, forming angular circle to ellipse and approximately uniform in shape, with uniformly thickened walls, and 60 – 90 μm in diameter; in lateral view, stone cell appearing obtusely triangular and its wall extremely thickened at the apex.

Identification To 1.0 g of ground Apricot Kernel add 10 mL of methanol, immediately heat under a reflux condenser on a water bath for 10 minutes, cool, filter, and use the filtrate as the sample solution. Separately, dissolve 2 mg of amygdalin for thin-layer chromatography in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, methanol and water (7:3:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly dilute sulfuric acid upon the plate, and heat at 105°C for 10 minutes: one spot among the spots from the sample solution and a brown to dark green spot from the standard solution show the same color tone and the same *R_f* value.

Purity (1) Rancidity—Grind Apricot Kernel with hot water: no unpleasant odor of rancid oil is perceptible.

(2) Foreign matter—Apricot Kernel does not contain fragments of endocarp and other foreign matter.

Apricot Kernel Water

キョウニン水

Apricot Kernel Water contains not less than 0.09 w/v% and not more than 0.11 w/v% of hydrogen cyanide (HCN: 27.03).

Method of preparation Prepare by one of the following methods.

(1) To Apricot Kernels, previously crushed and pressed to remove as much fixed oils as possible, add a suitable amount of Water or Purified Water, and carry out steam distillation. Determine the amount of hydrogen cyanide in the distillate by the method as directed in the Assay, and carry on the distillation until the content of hydrogen cyanide in the distillate is about 0.14 w/v%. To the distillate add Ethanol in about $\frac{1}{3}$ of the volume of the distillate, and dilute with a mixture of Purified Water and Ethanol (3:1) until the

content of hydrogen cyanide meets the specification.

(2) Dissolve 7.5 mL of freshly prepared mandelonitrile in 1000 mL of a mixture of Purified Water and Ethanol (3:1), mix well, and filter. Determine the amount of hydrogen cyanide in the solution as directed in the Assay, and, if the amount is more than that specified above, dilute the solution to the specified concentration by the addition of the mixture of Purified Water and Ethanol (3:1).

Description Apricot Kernel Water is a clear, colorless or pale yellow liquid. It has an odor of benzaldehyde and a characteristic taste.

pH: 3.5 – 5.0

Identification To 2 mL of Apricot Kernel Water add 1 mL of ammonia TS, and allow to stand for 10 minutes: a slight turbidity is produced. Allow to stand for 20 minutes: the turbidity is intensified.

Specific gravity d_{20}^{20} : 0.968 – 0.978

Purity (1) Sulfate—Add a few drops of 0.1 mol/L sodium hydroxide VS to 5.0 mL of Apricot Kernel Water to make slightly alkaline, evaporate on a water bath to dryness, and ignite between 450°C and 550°C. Dissolve the residue in 1.0 mL of dilute hydrochloric acid, and add water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.50 mL of 0.005 mol/L sulfuric acid VS (not more than 0.005%).

(2) Heavy metals—Evaporate 50 mL of Apricot Kernel Water on a water bath to dryness, ignite between 450°C and 550°C, dissolve the residue in 5 mL of dilute acetic acid with warming, add water to make exactly 50 mL, and filter. Remove the first 10 mL of the filtrate, dilute the subsequent 20 mL to 50 mL with water, and perform the test using this solution as the test solution. Prepare the control solution as follows: to 2.0 mL of Standard Lead Solution add 2 mL of dilute acetic acid and water to make 50 mL (not more than 1 ppm).

(3) Free hydrogen cyanide—To 10 mL of Apricot Kernel Water add 0.8 mL of 0.1 mol/L silver nitrate VS and 2 to 3 drops of nitric acid at 15°C, filter, and add 0.1 mol/L silver nitrate VS to the filtrate: no change occurs.

(4) Residue on evaporation—Evaporate 5.0 mL of Apricot Kernel Water to dryness, and dry the residue at 105°C for 1 hour: the mass of the residue is not more than 1.0 mg.

Assay Measure exactly 25 mL of Apricot Kernel Water, add 100 mL of water, 2 mL of potassium iodide TS and 1 mL of ammonia TS, and titrate with 0.1 mol/L silver nitrate VS until a yellow turbidity persists.

Each mL of 0.1 mol/L silver nitrate VS
= 5.405 mg of HCN

Containers and storage Containers—Tight containers.

Storage—Light-resistant.