事　務　連　絡
令和４年11月２日

公益社団法人日本医師会　御中

厚生労働省医薬・生活衛生局医薬品審査管理課

日本薬局方外生薬規格2022の英文版について

標記につきまして、別添写しのとおり各都道府県衛生主管部（局）薬務主管課宛通知しましたので、了知願います。

写

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令和４年11月２日

各都道府県衛生主管部（局）薬務主管課　御中

厚生労働省医薬・生活衛生局医薬品審査管理課

日本薬局方外生薬規格2022の英文版について

日本薬局方に収載されていない生薬については、令和４年３月８日付け薬生薬審発0308第１号厚生労働省医薬・生活衛生局医薬品審査管理課長通知「日本薬局方外生薬規格2022について」において示してきたところですが、別添のとおり、当該規格の英文版を作成しましたので、貴管下関係業者に対し周知方お願いします。

Non-JPS 2022

The Japanese standards for non-Pharmacopoeial crude drugs 2022

Official from March 8, 2022

English Version

GENERAL PROVISIONS

1. The official name of this standard is 日本薬局方外生薬規格 2022, and the abbreviation is 局外生規 2022.
2. The English name of this standard is The Japanese standards for non-Pharmacopoeial crude drugs 2022, and may be abbreviated as Non-JP crude drug standards 2022 or Non-JPS 2022.
3. Among drugs, the non-Pharmacopoeial crude drugs are those specified in the monographs. The title names and the commonly used names adopted in the monographs should be used as official names.
4. These standards have been established for determination of the nature, method of preparation, description, quality and storage of drugs specified in the monographs, and, unless otherwise specified in General Provisions and/or the monographs, the provisions of General Notices, General Rules for Crude Drugs, General Rules for Preparations and General Tests in the latest version of the Japanese Pharmacopoeia shall be applied.
5. Drugs are to be tested according to the provisions given in General Provisions and the monographs, and those in General Notices, General Rules for Crude Drugs, General Rules for Preparations, and General Tests in the latest version of the Japanese Pharmacopoeia for their conformity to these standards.
6. When and if any discrepancy arises between the Japanese Pharmacopeia and non-JP crude drug standards 2022 according to the revision of the Japanese Pharmacopoeia, the former is authentic.
7. The term "JP" or "Non-JPS" stated in the monographs indicates the latest version of the Japanese Pharmacopoeia or The Japanese standards for non-Pharmacopoeial crude drugs, respectively.

MONOGRAPH

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Reagents, Test Solutions

アカメガシワエキス
Mallotus Bark Extract

Mallotus Bark Extract contains not less than 12.0% and not more than 18.0% of bergenin.

Method of preparation Pulverize Mallotus Bark in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP. 1.0 g of Mallotus Bark Extract is equivalent to about 8 g of Mallotus Bark in JP.

Description Mallotus Bark Extract is brown powder; Odor and taste, slightly characteristic. It dissolves in water with a slight turbidity.

Identification To 0.1 g of Mallotus Bark Extract add 10 mL of methanol, shake, filter, and use the filtrate as the sample solution. Then, proceed as directed in the Identification under Mallotus Bark in JP.

Purity **Heavy metals** 〈*1.07*〉 —Prepare the test solution with 0.6 g of Mallotus Bark Extract as directed in the Extract (4) under General Rules for Preparations in JP, and perform the test (not more than 50 ppm).

Loss on drying 〈*2.41*〉 Not more than 8.0% (1 g, 105°C, 4 hours).

Total ash 〈*5.01*〉 Not more than 10.0% (1 g).

Assay Weigh accurately about 0.1 g of Mallotus Bark Extract, add 100 mL of a mixture of water and acetonitrile (9:1), shake for 30 minutes, filter, and use the filtrate as the sample solution. Separately, weigh accurately about 10 mg of bergenin for assay, dissolve in a mixture of water and acetonitrile (9:1) to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 10 µL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉 according to the following conditions, and determine the peak areas, A_T and A_S, of bergenin in each solution.

Amount (mg) of bergenin
$= M_S \times A_T / A_S \times 2$

M_S: Amount (mg) of bergenin for assay taken

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 272 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 µm in particle diameter).

Column temperature: A constant temperature of about 30°C.

Mobile phase: A mixture of water and acetonitrile (9:1).

Flow rate: Adjust so that the retention time of bergenin is about 9 minutes.

System suitability—

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of bergenin are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of bergenin is not more than 1.5%.

Containers and storage Containers—Tight containers.

Bergenin for assay $C_{14}H_{16}O_9$ Use bergenin for thin-layer chromatography in JP meeting the following additional specifications.

Optical rotation 〈*2.24*〉 $E_{1\%}^{1cm}$ (275 nm): 240 - 255 (2 mg, methanol, 100 mL). Separately determine the water 〈*2.48*〉 (5 mg, coulometric titration), and calculate on the anhydrous basis.

Purity Related substances—Dissolve 5 mg of bergenin for assay in 10 mL of the mobile phase in the Assay under Mallotus Bark Extract in Non-JPS, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add the mobile phase in the Assay under Mallotus Bark Extract in Non-JPS to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉 according to the following conditions. Determine each peak area by the automatic integration method: the total area of the peaks other than bergenin obtained from the sample solution is not larger than the peak area of bergenin obtained from the standard solution.

Operating conditions

Detector, column, column temperature, mobile phase and flow rate: Proceed as directed in the operating conditions in the Assay under Mallotus Bark Extract in Non-JPS.

Time span of measurement: About 3 times as long as the retention time of bergenin.

System suitability

Test for required detectability: Pipet 1 mL of the standard solution, and add the mobile phase in the Assay under Mallotus Bark Extract in Non-JPS to make exactly 20 mL. Confirm that the peak area of bergenin obtained from 10 μL of this solution is equivalent to 3.5 to 6.5% of that obtained from the standard solution.

System performance and system repeatability: Proceed as directed in the system suitability in the Assay under Mallotus Bark Extract in Non-JPS.

アキョウ

Donkey Glue

ASINI CORII COLLAS

Donkey Glue is the dry concentrated heat-extract prepared by boiling the hairless hide, bone, tendon and ligament of *Equus asinus* Linné (*Equidae*) with water and excluding fat.

Description Yellow-brown to black-brown plates; it is brittle.

Odorless or odor slight; tasteless.

Identification To 5 mL of a solution of Donkey Glue (1 in 5000) add 1 drop of tannic acid TS: a turbidity is formed.

Purity **(1)** Heavy metals 〈*1.07*〉 —Proceed with 0.5 g of Donkey Glue according to Method 2, and perform the test. Prepare the control solution with 2.5 mL of Standard Lead Solution (not more than 50 ppm).

(2) Arsenic 〈*1.11*〉 —Place 15.0 g of Donkey Glue in a flask, add 60 mL of diluted hydrochloric acid (1 in 5), and dissolve by heating. Add 15 mL of bromine TS, heat until the excess of bromine is expelled, neutralize with ammonia TS, add 1.5 g of disodium hydrogen phosphate dodecahydrate, and allow to cool. To this solution add 30 mL of magnesia TS, allow to stand for 1 hour, and collect the precipitates. Wash the precipitates with five 10-mL portions of diluted ammonia TS (1 in 4), and dissolve in diluted hydrochloric acid (1 in 4) to make exactly 50 mL. Perform the test with 5 mL of this solution: the solution has no more color than the following color standard.

Color Standard: Proceed with 15 mL of Standard Arsenic Solution, instead of Donkey Glue, in the same manner (not more than 1 ppm).

Loss on drying 〈*5.01*〉 Not more than 15.0% (6 hours).

Acid-insoluble ash 〈*5.01*〉 Not more than 0.5%.

Containers and storage Containers—Well-closed containers.

アルニカ

Arnica Flower

ARNICAE FLOS

Arnica Flower is the capitulum of *Arnica montana* Linné (*Compositae*).

Arnica Flower is restricted to the use for the Preparations for Cutaneous Application under General Rules for Preparations in JP.

Description Capitulum, 15 - 30 mm in diameter, 15 - 20 mm in height; consists of tubular florets, ligulate florets, and involucre; sometimes having peduncle 20 - 30 mm in length; tubular florets and ligulate florets yellow to vivid yellow; involucre consisting of 2 rows of involucral scales; involucral scale, lanceolate, covered with short hairs, grayish green to dark brown; achenes with pappus are usually mixed; achenes, narrow obovate, 5 - 8 mm in height.

Odor, characteristically aromatic.

Identification Use the sample solution obtained in the Purity (2) as the sample solution. Separately, dissolve 1 mg of chlorogenic acid for thin-layer chromatography in 10 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography ⟨*2.03*⟩. Spot 20 μL each of the sample solution and standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, water, formic acid and methanol (8:2:1:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly NP TS on the plate, air-dry and then spray PEG TS. Examine under ultraviolet light (main wavelength: 365 nm): one spot among several spots obtained from the sample solution and a spot obtained from the standard solution show the same color tone and the same R_f value.

Purity **(1)** Foreign matter ⟨*5.01*⟩ —The stem and other foreign matter contained in Arnica Flower do not exceed 5.0%.

(2) Capitulum of *Heterotheca* species—To 1 g of Arnica Flower add 20 mL of methanol, warm on a boiling water bath for 3 minutes. After cooling, filter and use the filtrate as sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography ⟨*2.03*⟩. Spot 20 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, water, formic acid and methanol (8:2:1:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly NP TS on the plate, air-dry and then spray PEG TS. Examine under ultraviolet light (main wavelength: 365 nm): a yellow-orange fluorescent spot at an R_f value of about 0.4 does not appear (rutin).

Loss on drying ⟨*5.01*⟩ Not more than 11.0% (2 hours).

Total ash ⟨*5.01*⟩ Not more than 10.0%.

Extract content ⟨*5.01*⟩ Dilute ethanol-soluble extract: not less than 15.0%.

Containers and storage Containers—Well-closed containers.

2-Aminoethyl diphenylborinate $C_{14}H_{16}BNO$ A white to brown crystal, crystalline powder or powder. Freely soluble in methanol, soluble in ethanol (99.5), and very slightly soluble in water. Melting point: about 193°C.

Identification Determine the infrared absorption spectrum of 2-aminoethyl diphenylborinate as directed in the potassium bromide disk method under Infrared Spectrophotometry ⟨*2.25*⟩ : it exhibits absorptions at the wave numbers of about 3290 cm^{-1}, 1611 cm^{-1}, 1062 cm^{-1}.

NP TS Dissolve 0.5 g of 2-aminoethyl diphenylborinate in methanol to make 100 mL.

PEG TS Dissolve 5 g of macrogol 4000 in JP in ethanol (99.5) to make 100 mL.

イカリソウエキス

Epimedium Herb Extract

Epimedium Herb Extract is used as the manufacturing material for single crude drug extract preparation.

Epimedium Herb Extract contains not less than 1.3% of icariin.

Method of preparation Pulverize Epimedium Herb in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP to prepare a dry extract.

Description Epimedium Herb Extract is light brown to dark brown powder; Odor, characteristic; taste, astringent and bitter.

It dissolves in water with a slight turbidity.

Identification To 0.4 g of Epimedium Herb Extract add 10 mL of methanol, shake for 10 minutes, centrifuge, and use the supernatant liquid as the sample solution. Separately, dissolve 0.5 mg of magnoflorine 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 Thin-layer Chromatography 〈*2.03*〉. Spot 20 μL of the sample solution and 10 μL of the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (4:2:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly Dragendorff's TS on the plate: one spot among several spots obtained from the sample solution and a spot obtained from the standard solution show the same color tone and the same R_f value.

Purity **(1)** Heavy metals 〈*1.07*〉—Prepare the test solution with 1.0 g of Epimedium Herb Extract as directed in the Extracts **(4)** under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

(2) Arsenic 〈*1.11*〉—Prepare the test solution with 0.67 g of Epimedium Herb Extract according to Method 3, and perform the test (not more than 3 ppm).

Loss on drying 〈*2.41*〉 Not more than 11.0% (1 g, 105°C, 5 hours).

Total ash 〈*5.01*〉 Not more than 23.0% (1 g).

Assay Weigh accurately about 0.1 g of Epimedium Herb Extract, add 60 mL of diluted methanol (7 in 10), treat with ultrasonic waves for 30 minutes, and filter. Repeat the procedure with the residue using 30 mL of diluted methanol (7 in 10), combine the extracts, add diluted methanol (7 in 10) to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 4 mg of icariin for assay, and dissolve in methanol to make exactly 50 mL. Pipet 10 mL of this solution, add methanol to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉, and determine the peak areas, A_T and A_S, of icariin in each solution.

Amount (mg) of icariin
$= M_S \times A_T / A_S \times 2/5$

M_S: Amount (mg) of icariin for assay taken

Operating conditions—

Detector: An ultraviolet absorptionphotometer (wavelength: 270 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: A mixture of water and acetonitrile (73:27).

Flow rate: Adjust so that the retention time of icariin is about 9 minutes.

System suitability—

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of icariin are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of icariin is not more than 1.5%.

Containers and storage Containers—Tight containers.

Icariin for assay $C_{33}H_{40}O_{15}$ Use icariin for thin-layer chromatography in JP meeting the following additional specifications.

Optical rotation ⟨*2.24*⟩ $E_{1\%}^{1cm}$ (270 nm): 374 - 413 (2 mg, methanol, 200 mL). Separately determine the water ⟨*2.48*⟩ (5 mg, coulometric titration), and calculate on the anhydrous basis.

Purity Related substances—Dissolve 1 mg of icariin for assay in 1 mL of methanol, add the mobile phase to make exactly 10 mL, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add the mobile phase to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography ⟨*2.01*⟩ according to the following conditions. Determine each peak area by the automatic integration method: the total area of the peaks other than icariin obtained from the sample solution is not larger than the peak area of icariin obtained from the standard solution.

Operating conditions

Detector, column, column temperature, mobile phase and flow rate: Proceed as

directed in the operating conditions in the Assay under Epimedium Herb Extract in Non-JPS.

Time span of measurement: About 3 times as long as the retention time of icariin beginning after the solvent peak.

System suitability

Test for required detectability: Pipet 1 mL of the standard solution, and add the mobile phase to make exactly 20 mL. Confirm that the peak area of icariin obtained from 10 µL of this solution is equivalent to 3.5 to 6.5% of that obtained from the standard solution.

System performance: When the procedure is run with 10 µL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of icariin are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 µL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of icariin is not more than 1.5%.

ウバイ

Processed Mume

MUME FRUCTUS

Processed Mume is the smoked immature fruit of *Prunus mume* Siebold et Zuccarini (*Rosaceae*).

Description Globose to semiglobose, 1.5 - 2.5 cm in diameter; externally blackish brown to black, without luster, with dispersed wrinkles; endocarp extremely hard, wrapping up a seed.

Odor, slight and characteristic; taste very acid.

Identification To 1 g of finely cut Processed Mume add 2 mL of acetic anhydride, shake for 5 minutes, and filter. To 1 mL of the filtrate add gently 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 dark green-brown color.

Loss on drying 〈*5.01*〉 Not more than 19.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 5.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 25.0%.

Containers and storage Containers—Well-closed containers.

ウラジロガシ

Quercus Salicina Leaf

QUERCUS SALICINAE FOLIUM

Quercus Salicina Leaf is the leaf of *Quercus salicina* Blume (*Fagaceae*), often with the stem.

Description Lanceolate or oblong-lanceolate, 5 - 15 cm in length, 1 - 5 cm in width, apex acuminate or tail-like acute, broadly cuneate base, with short petiole, somewhat serrated upwards. Thin coriaceus, upper surface light grayish yellow-brown to light green, with lustrous, lower surface white to light grayish green with wax secreted. Stem cylindrical, 0.1 - 1 cm in diameter, grayish white to grayish brown or light red-brown to light green-purple, nearly glabrous.

Practically odorless; tasteless at first, followed by a slight bitterness.

Identification **(1)** To 13 g of pulverized Quercus Salicina Leaf add 50 mL of water, and heat under a reflux condenser on a water bath at 80° C for 3 hours. After cooling, filter the liquid by suction, and use the filtrate as the test solution. To 5 mL of the test solution add 5 mL of water, shake, add 10 mL of hexane, shake, and centrifuge. Transfer the water layer to a separator, add 5 mL of ethyl acetate, shake, centrifuge if necessary, then separate ethyl acetate layer, add 5 mL of water, and wash by shaking. Evaporate ethyl acetate under low pressure (in vacuo), dissolve the residue in 10 mL of ethanol (95), and use this solution as the sample solution.

(i) To 1 mL of the sample solution add 1 drop of iron (III) chloride TS: a green to blue-green color is produced.

(ii) To 1 mL of the sample solution add 3 drops of a solution of aluminum chloride (1 in 100): the solution shows a light yellow to yellow-green color. Examine under the ultraviolet light (main wavelength: 365 nm), and observe under scattered light: the solution shows a blue-white fluorescence.

(2) To 5 mL of the test solution obtained in **(1)** add carefully 0.5 mL of sulfuric acid, and boil under a reflux condenser for 30 minutes. After cooling, centrifuge, take the supernatant liquid, transfer to a separator, add 10 mL of diethyl ether, and shake. Take the water layer, add 0.1 g of activated charcoal, heat under a reflux condenser on a water bath for 10 minutes, and filter. If any colors appear on the filtrate, add activated charcoal again, and repeat the procedure. Take 1 mL of the filtrate, add 2 drops of a solution of 1-naphthol in ethanol (95) (3 in 20) and 0.5 mL of sulfuric acid: a dark purple to dark red-purple color develops.

Loss on drying 〈*5.01*〉 Not more than 11.5% (6 hours).

Total ash 〈*5.01*〉 Not more than 6.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 14%.

Containers and storage Containers—Well-closed containers.

ウラジロガシエキス

Quercus Salicina Extract

Quercus Salicina Extract contains not less than 2.3 - 3.6% of ellagic acid.

Method of preparation Pulverize Quercus Salicina Leaf in Non-JPS to suitable sizes and extract it with Water, Purified Water or Purified Water in Containers (JP grade) as directed under Extracts in General Rules for Preparations in JP.

Description Quercus Salicina Extract is brown to blackish brown powder; Odor, characteristic; taste, astringent and bitter. It dissolves in water with a slight turbidity.

Identification **(1)** To 1 g of Quercus Salicina Extract add 30 mL of water, shake, add 30 mL of hexane, shake, and centrifuge. Then, proceed as directed in the Identification **(1)** under Quercus Salicina Leaf in Non-JPS.

(2) To 1 g of Quercus Salicina Extract add 20 mL of dilute sulfuric acid, and boil under a reflux condenser for 30 minutes. Then, proceed as directed in the Identification **(2)** under Quercus Salicina Leaf in Non-JPS.

Purity Heavy metals 〈*1.07*〉 —Prepare the test solution with 1.0 g of Quercus Salicina Extract as directed in the Extracts **(4)** under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

Loss on drying 〈*2.41*〉 Not more than 8.0% (1 g, 105°C, 3 hours).

Total ash 〈*5.01*〉 Not more than 10.0% (1 g, platinum crucible).

Assay Weigh accurately about 0.1 g of Quercus Salicina Extract, add 50 mL of dilute hydrochloric acid, shake well, and disperse using ultrasonic waves if necessary. Heat under a reflux condenser on a water bath for 4 hours with occasional shaking, cool quickly, and add methanol to make exactly 200 mL. Filter this solution through a membrane filter with a pore size not exceeding 0.45 μm, discard the first 10 mL of the filtrate, and use the subsequent filtrate as the sample solution. Separately, weigh accurately about 20 mg of ellagic acid for assay (separately dry at 105°C for 4 hours, and determine the loss on drying), and dissolve in methanol to make exactly 100 mL. Pipet 2 mL of this solution, add a mixture of methanol and water (18:7) to make exactly 20 mL, and use this solution as the standard solution. Perform the test with exactly 7 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉 according to the following conditions, and determine the peak areas, A_T and A_S, of ellagic acid in each solution.

Amount (mg) of ellagic acid
$= M_S \times A_T / A_S \times 1/5$

M_S: Amount (mg) of ellagic acid for assay taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 270 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 10 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (3 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase A: Diluted phosphoric acid (1 in 1000).

Mobile phase B: Methanol.

Flowing of mobile phase: Control the gradient by mixing the mobile phases A and B as directed in the following table.

Time after injection of sample (min)	Mobile phase A (vol%)	Mobile phase B (vol%)
0 - 7	98	2
7 - 8	98 → 60	2 → 40
8 - 17	60	40
17 - 20	60 → 98	40 → 2
20 - 30	98	2

Flow rate: 1.0 mL per minute.

System suitability—

System performance: When the procedure is run with 7 μL of the standard solution according to the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of ellagic acid are not less than 4000 and not more than 2.0, respectively.

System repeatability: When the test is repeated 6 times with 7 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of ellagic acid is not more than 2.0%.

Containers and storage Containers—Tight containers.

Ellagic acid for assay $C_{14}H_6O_8$ A light yellow or light grayish yellow to yellowish dark red crystals or powder. Slightly soluble in tetrahydrofuran, very slightly soluble in methanol or ethanol (99.5), and practically insoluble in water.

Identification Determine the infrared absorption spectrum of Ellagic acid for assay, previously dried at 105°C for 4 hours, as directed in the potassium bromide disk method under Infrared Spectrophotometry ⟨*2.25*⟩ : it exhibits absorptions at the wave numbers of about 1725 cm^{-1}, 1615 cm^{-1}, 1323 cm^{-1}, 1111 $cm^{-1}$and 760 cm^{-1}.

Purity Related substances—To 4 mg of Ellagic acid for assay add 5 mL of tetrahydrofuran, dissolve using ultrasonication if necessary, add diluted methanol (1 in 2) to make 10 mL, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add a mixture of tetrahydrofuran and diluted methanol (1 in 2) (1:1)

to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 5 μL of the sample solution and standard solution as directed in Liquid Chromatography 〈*2.01*〉 according to the following conditions. Determine each peak area by the automatic integration method: the total area of the peaks other than ellagic acid and the solvent obtained from the sample solution is not larger than the peak area of ellagic acid obtained from the standard solution.

Operating conditions

Detector: An ultraviolet absorption photometer (wavelength: 255 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: A mixture of diluted phosphoric acid (1 in 1000) and methanol (17:8).

Flow rate: Adjust so that the retention time of ellagic acid is about 19 minutes.

Time span of measurement: About 2 times as long as the retention time of ellagic acid, beginning after the solvent peak.

System suitability

System performance: When the procedure is run with 5 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of ellagic acid are not less than 5000 and not more than 1.5, respectively.

エンメイソウ
Isodon Herb
ISODONIS HERBA

Isodon Herb is the terrestrial part of *Isodon japonicus* H. Hara (*Plectranthus japonicus* Koidzumi, *Rabdosia japonica* H. Hara) or *Isodon trichocarpus* Kudô (*Plectranthus trichocarpus* Maximowicz, *Rabdosia trichocarpa* H. Hara) (*Labiatae*).

Description Stem with opposite leaves; stem prismatic square, light brown to greenish brown, pilose; leaves oblong-ovate to broadly ovoid, acute at apex, shallowly cordate or broadly cuneate at base; 6 - 15 cm in length, 3.5 - 10 cm in width, margin serrate, petiole 2 - 4 cm in length; upper surface of leaves light yellow-brown to greenish brown, lower surface light greenish yellow, both surfaces pilose.

Odor, slight; taste, extremely bitter.

Identification To 1 g of pulverized Isodon Herb add 20 mL of water, heat on a water bath for 5 minutes, and filter after cooling. To 2 mL of the filtrate add 2 to 3 drops of 2,4-dinitrophenylhydrazine TS, and warm on a water bath: a yellow-red precipitate is formed.

Total ash 〈*5.01*〉 Not more than 9.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 9.0%.

Containers and storage Containers—Well-closed containers.

エンメイソウ末

Powdered Isodon Herb

ISODONIS HERBA PULVERATA

Powdered Isodon Herb is the powder of Isodon Herb in Non-JPS.

Description Powdered Isodon Herb occurs as a light green-brown to brown powder. Odor and taste are as directed in the Description under Isodon Herb in Non-JPS.

Under a microscope 〈*5.01*〉, Powdered Isodon Herb reveals fragments of fibers, ring vessels, reticulate vessels and pitted vessels; glandular scales, multicellular hairs, fragments of epidermal cells and stone cells; numerous fine protrusions on the surface of multicellular hairs.

Identification Proceed as directed in the Identification under Isodon Herb in Non-JPS.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Isodon Herb in Non-JPS.

Acid-insoluble ash 〈*5.01*〉 Proceed as directed in the Acid-insoluble ash under Isodon Herb in Non-JPS.

Extract content 〈*5.01*〉 Proceed as directed in the Extract content under Isodon Herb in Non-JPS.

Containers and storage Containers—Tight containers.

オンジエキス

Polygala Root Extract

Polygala Root Extract is used as the manufacturing material for single crude drug extract preparation.

Polygala Root Extract contains not less than 0.20% of 3,6'-di-*O*-sinapoylsucrose.

Method of preparation Pulverize Polygala Root in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP to prepare a dry extract. Or, prepare a dry extract by adding dextrin in JP to the above extractive as directed under Extracts in General Rules for Preparations in JP.

Description Polygala Root Extract is light yellow-white to yellow-brown powder; Odor, characteristic; taste, slightly sweet and acid at first, followed by a slight numbness of the tongue and residual acridity.

It dissolves in water with a slight turbidity.

Identification To 1.0 g of Polygala Root Extract add 10 mL of a solution of sodium hydroxide (1 in 10), and heat under a reflux condenser for 20 minutes. After cooling, add 10 mL of dilute hydrochloric acid and shake. After cooling, add 10 mL of 1-butanol, shake for 10 minutes, centrifuge, and use the 1-butanol layer as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, methanol, water and acetic acid (100) (20:4:2:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat at 105°C for 10 minutes: a red-brown to light brown spot appears at an R_f value of about 0.35 (tenuifolin).

Purity **(1)** Heavy metals 〈*1.07*〉 —Prepare the test solution with 1.0 g of Polygala Root Extract as directed in the Extract **(4)** under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

(2) Arsenic 〈*1.11*〉 —Prepare the test solution with 0.67 g of Polygala Root Extract according to Method 3, and perform the test (not more than 3 ppm).

Loss on drying 〈*2.41*〉 Not more than 8.0% (1 g, 105°C, 5 hours).

Total ash 〈*5.01*〉 Not more than 6.0%, calculated on the dried basis.

Assay Conduct this procedure without exposure to light, using light-resistant vessels. Weigh accurately about 0.5 g of Polygala Root Extract, add 25 mL of methanol, shake for 15 minutes, centrifuge and use the supernatant liquid as the sample solution. Separately, weigh accurately about 5 mg of 3,6'-di-*O*-sinapoylsucrose for assay (separately determine the water 〈*2.48*〉 by coulometric titration, using 5 mg), dissolve in methanol to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution

as directed under Liquid Chromatography 〈*2.01*〉, and determine the peak areas, A_T and A_S, of 3,6'-di-*O*-sinapoylsucrose in each solution.

Amount (mg) of 3,6'-di-*O*-sinapoylsucrose
$= M_S \times A_T / A_S \times 1/2$

M_S: Amount (mg) of 3,6'-di-*O*-sinapoylsucrose for assay taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorptionphotometer (wavelength: 330 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 30°C.

Mobile phase: A mixture of water, acetonitrile and phosphoric acid (800:200:1).

Flow rate: 1.0 mL per minute.

System suitability—

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of 3,6'-di-*O*-sinapoylsucrose are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of 3,6'-di-*O*-sinapoylsucrose is not more than 1.5%.

Containers and storage Containers—Tight containers.

3,6'-Di-*O*-sinapoylsucrose for assay $C_{34}H_{42}O_{19}$ A yellow crystalline powder or powder. Freely soluble in methanol, soluble in ethanol (99.5), and very slightly soluble in water.

Identification — Determine the infrared absorption spectrum of 3,6'-di-*O*-sinapoylsucrose for assay as directed in the potassium bromide disk method under Infrared Spectrophotometry 〈*2.25*〉: it exhibits absorptions at the wave numbers of about 2940 cm^{-1}, 1702 cm^{-1}, 1603 cm^{-1}, 1286 cm^{-1}.

Purity Related substances—Conduct this procedure without exposure to light, using light-resistant vessels. Dissolve 5 mg of 3,6'-di-*O*-sinapoylsucrose for assay in 50 mL of methanol and use this solution as the sample solution. Pipet 5 mL of the sample solution, add methanol to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉 according to the following conditions. Determine each peak area by the automatic integration method: the total

area of the peaks other than 3,6'-di-*O*-sinapoylsucrose obtained from the sample solution is not larger than the peak area of 3,6'-di-*O*-sinapoylsucrose obtained from the standard solution.

Operating conditions

Detector: An ultraviolet absorptionphotometer (wavelength: 330 nm).

Column, column temperature, mobile phase and flow rate: Proceed as directed in the operating conditions in the Assay under Polygala Root Extract in Non-JPS.

Time span of measurement: About 3 times as long as the retention time of 3,6'-di-*O*-sinapoylsucrose beginning after the solvent peak.

System suitability

Test for required detectability: Pipet 1 mL of the standard solution, and add methanol to make exactly 100 mL. Confirm that the peak area of 3,6'-di-*O*-sinapoylsucrose obtained from 10 µL of this solution is equivalent to 0.7 to 1.3% of that obtained from the standard solution.

System performance: When the procedure is run with 10 µL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of 3,6'-di-*O*-sinapoylsucrose are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 µL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of 3,6'-di-*O*-sinapoylsucrose is not more than 1.5%.

カイカ

Sophora Japonica Flower

SOPHORAE FLOS

Sophora Japonica Flower is the flower bud of *Sophora japonica* Linné (*Leguminosae*).

Description Nearly ellipsoidal, 3 - 10 mm in length; consists of yellow-green to yellow-brown calyx and light yellow to light brown corolla; calyx 3 - 4 mm in length, shallowly 5-lobed; corolla with 5 petals; under a magnifying glass, stamens 10 in number and filaments combined with each other at the basal parts; pistil single and short.

Practically odorless and tasteless.

Identification To 0.1 g of pulverized Sophora Japonica Flower add 25 mL of methanol, shake for 3 minutes, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, water and formic acid (4:1:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat at 105°C for 5 minutes: a yellow to yellow-brown spot is observed at an R_f value of about 0.5 (Rutin).

Loss on drying 〈*5.01*〉 Not more than 12.5% (6 hours).

Acid-insoluble ash 〈*5.01*〉 Not more than 1.5%.

Containers and storage Containers—Well-closed containers.

ガイハク

Allium Chinense Bulb

ALLII CHINENSE BULBUS

Allium Chinense Bulb is the bulb of *Allium chinense* G. Don (*Liliaceae*).

Description Slightly flat and oblong-ovoid, 1 - 3 cm in length, 0.3 - 1.2 cm in diameter, usually cut. externally light yellow-brown to yellow-brown, usually several lines of vascular bundles longitudinally in parallel are seen through parenchyma; slightly soft in texture; section is composed of 2 or 3 layers of scaly leaf.

Odor, garlic-like; taste, characteristic.

Identification To 4 g of pulverized Allium Chinense Bulb add 20 mL of hexane, treat with ultrasonic waves for 20 minutes, and filter. Evaporate the filtrate to dryness under low pressure (in vacuo). Dissolve the residue in 1 mL of hexane and use this solution as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (10:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly vanillin-sulfuric acid-ethanol TS for spraying on the plate, and heat at 105°C for 5 minutes: a purple to blue-purple spot is observed at an R_f value of about 0.3 and about 0.7, respectively.

Purity **(1)** Heavy metals 〈*1.07*〉 —Proceed with 3.0 g of pulverized Allium Chinense Bulb according to Method 3, and perform the test. Prepare the control solution with 3.0 mL of Standard Lead Solution (not more than 10 ppm).

(2) Arsenic 〈*1.11*〉 —Prepare the test solution with 0.40 g of pulverized Allium Chinense Bulb according to Method 4, and perform the test (not more than 5 ppm).

Loss on drying 〈*5.01*〉 Not more than 13.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 4.0%.

Containers and storage Containers—Tight containers.

カシ

Myrobalan Fruit

CHEBULAE FRUCTUS

Myrobalan Fruit is the fruit of *Terminalia chebula* Retzius (*Combretaceae*).

Description Nearly long ovoid to ovoid, 2.5 - 3.5 cm in length, 1.5 - 2.5 cm in diameter; externally yellow-brown to brown, slightly glossy; 5 longitudinal ridges; irregularly arranged wrinkles between ridges; small disc-like scar of fruit stalk on the base; hard in texture; in transverse section, sarcocarp 2 - 5 mm in thickness, dark brown, endocarp about 5 mm in thickness, yellow-brown, extremely hard in texture, with brown suture; 1 seed about 5 mm in diameter in the central part.

Odor, slight and characteristic; taste, bitter, acid and astringent.

Identification To 0.5 g of pulverized Myrobalan Fruit add 10 mL of water, shake well, and filter. To the filtrate add 1 to 2 drops of iron (III) chloride TS: a dark purple color dévelops.

Loss on drying 〈*5.01*〉 Not more than 14.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 5.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 30.0%.

Containers and storage Containers—Well-closed containers.

ガジュツ末

Powdered Curcuma Rhizome

CURCUMAE RHIZOMA PULERATUM

Powdered Curcuma Rhizome is the powder of Curcuma Rhizome in JP.

Description Powdered Curcuma Rhizome occurs as a light grayish yellow to brown or a light purple-brown to dark purple-brown powder.

Odor and taste are as directed in the Description under Curcuma Rhizome in JP.

Under a microscope 〈*5.01*〉, Powdered Curcuma Rhizome mainly reveals parenchyma containing gelatinized starch masses and yellow-brown to dark brown substances; spiral and scalariform vessels; occasionally fractures of cork tissues, epidermis and thick-walled wood parenchyma cells; rarely hairs and crystals of calcium oxalate are observed.

Identification To 2.0 g of Powdered Curcuma Rhizome add 10 mL of water, shake, add 5 mL of hexane, shake for 10 minutes, centrifuge, and use the hexane layer as the sample solution. Perform the test with this solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (4:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat at 105°C for 5 minutes: a spot of a deep blue to dark brown color and a spot of a red-brown to brown color appear at R_f values of about 0.3 (zederone and curcumenol) and about 0.2 (curcumenone), respectively.

Purity **(1)** Heavy metals 〈*1.07*〉 —Proceed as directed in the Purity under Curcuma Rhizome in JP.

(2) Arsenic 〈*1.11*〉 —Proceed as directed in the Purity under Curcuma Rhizome in JP.

Total ash 〈*5.01*〉 —Proceed as directed in the Total ash under Curcuma Rhizome in JP.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 4.0%.

Containers and storage Containers—Tight containers.

カミツレ

German Chamomile Flower

CHAMOMILLAE FLOS

German Chamomile Flower is the capitulum of *Matricaria chamomilla* Linné (*Compositae*).

Description Conical capitulum, 2 - 8 mm in diameter, 2 - 8 mm in height; consists of yellow-brown tubular florets, light yellow-brown ligulate florets, and involucre; often having floral axis; tubular florets bisexual, corolla 5-toothed at apex; ligulate florets female, 10 to 20 in number, corolla having 4 ribs, 3-toothed at apex; achene is without pappus; involucral scales oblanceolate, squamose, 20 to 30 in number, and imbricated; receptacle hollow, light in texture, brittle.

Odor, characteristic aroma; taste, slightly bitter.

Identification To 1 g of pulverized German Chamomile Flower add 10 mL of methanol, boil gently for 2 minutes, and filter. Evaporate the filtrate to dryness, add 10 mL of water to the residue, heat on a water bath for 2 minutes, and filter after cooling. Transfer the filtrate to a separator, add 20 mL of ethyl acetate, and shake well. Collect the ethyl acetate layer, and evaporate it to dryness. Dissolve the residue in 5 mL of methanol, add 0.1 g of magnesium in ribbon form and 1 mL of hydrochloric acid, and allow to stand: a red-brown color develops.

Total ash 〈*5.01*〉 Not more than 11.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 2.5%.

Containers and storage Containers—Well-closed containers.

カロニン

Trichosanthes Seed

TRICHOSANTIS SEMEN

Trichosanthes Seed is the seed of *Trichosanthes kirilowii* Maximowicz, *Trichosanthes kirilowii* Maximowicz var. *japonica* Kitamura or *Trichosanthes bracteata* Voigt (*Cucurbitaceae*).

Description Compressed ovate to broadly ovate, sometimes oblong; mostly bilaterally asymmetrical; 9 - 20 mm in length, 5 - 10 mm in width, about 3 mm in thickness, grayish brown to dark red-brown or light brown; narrow side has a hilum and chalaza, slightly rising, truncate or obtuse; a fringe 1 - 3 mm in width along the circumference in some seeds, and such fringe is not distinct in others; surface smooth; under a magnifying glass, numerous, small hollows on the surface; when peeled off the seed coat, usually reveals grayish green leaflet.

When cracked, odor, characteristic; taste, bitter and oily.

Identification To 0.1 g of finely cut Trichosanthes Seed add 2 mL of acetic anhydride, warm on a water bath for 2 minutes with shaking, and filter. To the filtrate add gently 0.5 mL of sulfuric acid to make two layers: a red-brown to red color develops at the zone of contact.

Total ash 〈*5.01*〉 Not more than 4.0%.

Containers and storage Containers—Well-closed containers.

カントウカ

Coltsfoot Flower

TUSSILAGINIS FLOS

Coltsfoot Flower is the unopened capitulum (flower bud) of *Tussilago farfara* Linné (*Compositae*).

Description Irregular clavate flower bud; solitary or 2 or 3 of them are connected at the base; capitulum, 1 to 2 cm in length, 0.5 – 1 cm in diameter; slightly thick in upper part, gradually slender to the lower part; sometimes with 1 to 2 cm long stem; capitulum is surrounded by numerous involucral scales; externally red purple to light yellow or brown; sometimes with cottony hairs inside of the involucral scales.

Odor, characteristic; taste, slightly bitter.

Identification To 1.0 g of pulverized Coltsfoot Flower add 20 mL of ethanol, treat with ultrasonic waves for 20 minutes and filter. Evaporate the filtrate to dryness under low pressure (in vacuo), dissolve the residue in 1 mL of ethyl acetate and use this solution as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (4:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat at 105°C for 5 minutes. Examine under ultraviolet light (main wavelength: 365 nm): a fluorescent blue spot is observed at an R_f value of about 0.3.

Purity Heavy metals 〈*1.07*〉 —Prepare the test solution with 1.0 g of pulverized Coltsfoot Flower according to Method 3, and perform the test. Prepare the control solution with 1.5 mL of Standard Lead Solution (not more than 15 ppm).

Loss on drying 〈*5.01*〉 Not more than 18.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 11.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 4.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 35.0%.

Containers and storage Containers—Well-closed containers.

キッピ

Citrus Peel

TACHIBANA PERICARPIUM

Citrus Peel is the pericarp of mature fruit of *Citrus tachibana* Tanaka, *Citrus leiocarpa* Tanaka or *Citrus grandis* Osbeck (*Rutaceae*) (Citrus Peel 1), or of *Citrus unshiu* Marcowicz or *Citrus reticulata* Blanco (*Rutaceae*) (Citrus Peel 2).

Description 1) Citrus Peel 1: Irregular pieces of pericarp, about 1 mm in thickness; externally yellow-brown to red-brown, with numerous small dents associated with oil sacs; inner surface whitish to light red-brown; light and brittle in texture.

Odor, characteristic aroma; taste, bitter.

Under a microscope 〈*5.01*〉, a section reveals round oil sacs 410 - 730 μm in diameter.

2) Citrus Peel 2: Irregular pieces of pericarp, about 2 mm in thickness; externally orange-yellow to dark yellow-brown, with numerous small dents associated with oil sacs; internally white to light grayish yellow-brown; light and brittle in texture.

Odor, characteristic aroma; taste, bitter and slightly pungent.

Under a microscope 〈*5.01*〉, a section reveals round oil sacs 700 - 1350 μm in diameter.

Identification To 1 g of pulverized Citrus Peel add 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 0.3 mL of hydrochloric acid, and allow to stand: a red-purple to dark red-brown color develops.

Loss on drying 〈*5.01*〉 Not more than 15.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 6.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Essential oil content 〈*5.01*〉 Perform the test with 50.0 g of pulverized Citrus Peel, provided that 1 mL of silicone 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—Well-closed containers.

キンギンカ

Lonicera Flower

LONICERAE FLOS

Lonicera Flower is the flower bud of *Lonicera japonica* Thunberg (*Caprifoliaceae*).

Description Slightly curved, clavate, 1.5 - 3.0 cm in length; externally light yellow to yellow-brown; under a magnifying glass, it reveals light brown hairs, tomentose; often mixed with flowers; flowers labiate, having 5 stamens.

Odor, characteristic; taste, slightly astringent and sweet.

Identification To 0.5 g of pulverized Lonicera Flower add 10 mL of methanol, shake for 5 minutes, centrifuge, and use the supernatant liquid as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography ⟨*2.03*⟩. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, water and formic acid (6:1:1) to a distance of about 7 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 365 nm): a fluorescent bluish white spot is observed at an R_f value of about 0.5 (Chlorogenic acid).

Purity **(1)** Stem and leaf—When perform the test of foreign matter ⟨*5.01*⟩, The amount of the stems and leaves contained in Lonicera Flower does not exceed 5.0%.

(2) Foreign matter ⟨*5.01*⟩ —The amount of foreign matter other than stems and leaves contained in Lonicera Flower does not exceed 1.0%.

Loss on drying ⟨*5.01*⟩ Not more than 15.0% (6 hours).

Total ash ⟨*5.01*⟩ Not more than 9.0%.

Extract content ⟨*5.01*⟩ Dilute ethanol-soluble extract: not less than 32.0%.

Containers and storage Containers—Well-closed containers.

クコヨウ

Lycium Leaf

LYCII FOLIUM

Lycium Leaf is the leaf of *Lycium chinense* Miller (*Solanaceae*).

Description Lanceolate to obovate, 3 - 10 cm in length, 1 - 2 cm in width, apex acute or obtuse, base cuneate, margin entire; petiole 0.5 - 1.5 cm in length, upper surface green-brown, lower surface light greenish brown.

Odor, slight; taste, slight.

Identification To 1 g of pulverized Lycium Leaf add 20 mL of water, heat on a water bath for 5 minutes, and filter. Transfer the filtrate to a separator, add 20 mL of diethyl ether, shake, and remove the diethyl ether layer. To the water layer add 20 mL of ethyl acetate, shake well, collect the ethyl acetate layer, and evaporate to dryness. Dissolve the residue in 3 mL of methanol, add 0.1 g of magnesium in ribbon form and 1 mL of hydrochloric acid, and allow to stand: a light red color develops.

Acid-insoluble ash 〈*5.01*〉 Not more than 3.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 18.0%.

Containers and storage Containers—Well-closed containers.

ケイガイ末

Powdered Schizonepeta Spike

SCHIZONEPETAE SPICA PULVERATA

Powdered Schizonepeta Spike is the powder of Schizonepeta Spike in JP.

Description Powdered Schizonepeta Spike occurs as a light green-brown to dark brown powder.

Odor and taste are as directed in the Description under Schizonepeta Spike in JP.

Under a microscope 〈*5.01*〉, Powdered Schizonepeta Spike reveals epidermal cells of a sepal with wavy curved; polygonal sclerenchyma cells of exocarp, fragments of stone cells of endocarp with wavy curved and thickened; glandular scales with head composed of 8 cells and fragments of basal part of glandular scales, short glandular hairs with head composed of 1 to 2 cells, fragments of multicellular hairs composed of 1 to 6 cells.

Identification Proceed as directed in the Identification under Schizonepeta Spike in JP.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Schizonepeta Spike in JP.

Acid-insoluble ash 〈*5.01*〉 Proceed as directed in the Acid-insoluble ash under Schizonepeta Spike in JP.

Extract content 〈*5.01*〉 Proceed as directed in the Extract content under Schizonepeta Spike in JP.

Containers and storage Containers—Tight containers.

ケイシ

Cinnamon Twig

CINNAMOMI RAMULUS

Cinnamon Twig is the twig of *Cinnamomum cassia* J. Presl (*Lauraceae*).

Description Cylindrical, 15 - 100 cm in length, 0.3 - 1.5 cm in diameter, occasionally branched; externally dark red-brown to purple-brown, with scars of petiole and longitudinal ridge; hard, brittle and easily breakable; under a magnifying glass, xylem usually round to elliptical, light yellow-white to brown.

Odor characteristic aroma; taste, sweet and slightly pungent.

Identification To 2.0 g of pulverized Cinnamon Twig add 10 mL of diethyl ether, shake for 3 minutes, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (2:1) to a distance of about 7 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): a spot is observed at an R_f value of about 0.4, which shows a yellow-orange color after spraying evenly 2,4-dinitrophenylhydrazine TS.

Purity Total BHC's and total DDT's 〈*5.01*〉 —Not more than 0.2 ppm, respectively.

Loss on drying 〈*5.01*〉 Not more than 15.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 4.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Essential oil content 〈*5.01*〉 Perform the test with 50.0 g of pulverized Cinnamon Twig, 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 0.1 mL.

Containers and storage Containers—Well-closed containers.

ゲンジン

Scrophularia Root

SCROPHULARIAE RADIX

Scrophularia Root is the root of *Scrophularia ningpoensis* Hemsley or *Scrophularia buergeriana* Miquel (*Scrophulariaceae*).

Description Irregularly curved, long cylindrical to fusiform, 4 - 15 cm in length, 1 - 3 cm in diameter; externally yellow-brown to brown, with coarse, longitudinal wrinkles, transversely elongated lenticels, sparse rootlet scars; hard in texture, but slightly flexible and difficult to break; fractured surface blackish brown.

Odor, slight and characteristic; taste, slightly sweet, followed by a slight bitterness.

Identification **(1)** To 0.5 g of pulverized Scrophularia Root add 20 mL of water, heat on a water bath for 2 to 3 minutes, and filter. To 4 mL of the filtrate add 2 mL of Fehling's TS, and heat in a water bath: a red precipitate is formed.

(2) To 0.3 g of pulverized Scrophularia Root add 5 mL of acetic anhydride, warm on a water bath for 2 minutes with occasional shaking, and filter. To the filtrate add gently 1 mL of sulfuric acid to make two layers: a red-brown color develops at the zone of contact.

Loss on drying 〈*5.01*〉 Not more than 17.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 6.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 2.0%.

Containers and storage Containers—Well-closed containers.

コウジン末

Powdered Red Ginseng

GINSENG RADIX RUBRA PULVERATA

Powdered Red Ginseng is the powder of Red Ginseng in JP.

Assay standard of Powdered Red Ginseng: proceed as directed in the Assay standard under Red Ginseng in JP.

Description Powdered Red Ginseng occurs as a light yellow-brown to red-brown powder.

Odor and taste are as directed in the Description under Red Ginseng in JP.

Under a microscope 〈*5.01*〉, Powdered Red Ginseng reveals fragments of nearly orbicular to rectangular parenchyma cells containing gelatinized starch; fragments of reticulate vessels; scalariform vessels and spiral vessels 10 - 40 μm in diameter; secretory cells containing yellow-brilliant masses; clustered crystals of calcium oxalate, 5 - 60 μm in diameter; solitary crystals of calcium oxalate, 5 - 30 μm in diameter; sometimes observed sclerenchyma cells and cork cells with thin cell wall; starch grains gelatinized.

Identification Proceed as directed in the Identification **(2)** under Red Ginseng in JP.

Purity **(1)** Heavy metals 〈*1.07*〉 —Proceed as directed in the Purity under Red Ginseng in JP.

(2) Arsenic 〈*1.11*〉 —Proceed as directed in the Purity under Red Ginseng in JP.

(3) Total BHC's and total DDT's 〈*5.01*〉 —Proceed as directed in the Purity under Red Ginseng in JP.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Red Ginseng in JP.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Red Ginseng in JP.

Extract content 〈*5.01*〉 Proceed as directed in the Extract content under Red Ginseng in JP.

Assay Proceed as directed in the Assay under Red Ginseng in JP.

Containers and storage Containers—Tight containers.

コウジンエキス

Red Ginseng Extract

Red Ginseng Extract is used as the manufacturing material for single crude drug extract preparation.

Red Ginseng Extract contains not less than 0.10% of ginsenoside Rg_1 ($C_{42}H_{72}O_{14}$: 801.01) and not less than 0.20% of ginsenoside Rb_1 ($C_{54}H_{92}O_{23}$: 1109.29).

Method of preparation Pulverize Red Ginseng in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP to prepare a dry extract.

Description Red Ginseng Extract is light yellow-white to red-brown powder; Odor, characteristic; taste, slightly sweet and acid at first, followed by slight bitterness.

It dissolves in water with a slight turbidity.

Identification To 0.5 g of Red Ginseng Extract add 10 mL of methanol, shake, centrifuge, and use the supernatant liquid as the sample solution. Separately, dissolve 1 mg of ginsenoside Rg_1 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 Thin-layer Chromatography *〈2.03〉*. Spot 5 μL of the sample solution and 2 μL of 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 (14:5:4) to a distance of about 7 cm, and air-dry the plate. Spray evenly vanillin-sulfuric acid-ethanol TS for spraying on the plate, and heat at 105°C for 10 minutes: one of the spot among the several spots obtained from the sample solution has the same color tone and R_f value with the spot obtained from the standard solution.

Purity **(1)** Heavy metals *〈1.07〉* —Prepare the test solution with 1.0 g of Red Ginseng Extract as directed in the Extract **(4)** under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

(2) Arsenic *〈1.11〉* —Prepare the test solution with 0.67 g of Red Ginseng Extract according to Method 3, and perform the test (not more than 3 ppm).

Loss on drying *〈2.41〉* Not more than 11.0% (1 g, 105°C, 5 hours).

Total ash *〈5.01〉* Not more than 9.0% (1 g)

Assay (1) Ginsenoside Rg_1—Weigh accurately about 0.15 g of Red Ginseng Extract, add 15 mL of diluted methanol (3 in 5), shake for 15 minutes, centrifuge, and separate the supernatant liquid. Repeat the procedure with the residue using 7.5 mL of diluted methanol (3 in 5), combine the supernatant liquids, and add diluted methanol (3 in 5) to make exactly 25 mL. Pipet 10 mL of this solution, add 3 mL of dilute sodium hydroxide TS, allow to stand for 30 minutes, add 3 mL of 0.1 mol/L hydrochloric acid TS and, add diluted methanol (3 in 5) to make exactly 20 mL. Use this solution as the sample solution. Separately, weigh accurately about 10 mg of Ginsenoside Rg_1 RS (separately determine the water *〈2.48〉* by coulometric titration, using 10 mg) dissolve

in diluted methanol (3 in 5) to make exactly 25 mL. Use this solution as the standard stock solution. Pipet 2 mL of the standard stock solution, add diluted methanol (3 in 5) to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 20 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉 according to the following conditions, and determine the peak areas, A_T and A_S, of ginsenoside Rg_1 in each solution.

Amount (mg) of ginsenoside Rg_1 ($C_{42}H_{72}O_{14}$)
$= M_S \times A_T / A_S \times 2/25$

M_S: Amount (mg) of ginsenoside Rg_1 RS taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorptionphotometer (wavelength: 203 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (3 μm in particle diameter).

Column temperature: A constant temperature of about 30°C.

Mobile phase: diluted acetonitrile (1 in 5).

Flow rate: 1.0 mL per minute.

System suitability—

System performance: To 1 mg of ginsenoside Re add 4 mL of the standard stock solution and add diluted methanol (3 in 5) to make exactly 100 mL. When the procedure is run with 20 μL of this solution under the above operating conditions, ginsenoside Rg_1 and ginsenoside Re are eluted in this order with the resolution between these peaks being not less than 1.5.

System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of ginsenoside Rg_1 is not more than 1.5%.

(2) Ginsenoside Rb_1—Weigh accurately about 0.15 g of Red Ginseng Extract, add 30 mL of diluted methanol (3 in 5), shake for 15 minutes, centrifuge, and separate the supernatant liquid. Repeat the procedure with the residue using 15 mL of diluted methanol (3 in 5), combine the supernatant liquids, and add diluted methanol (3 in 5) to make exactly 50 mL. Pipet 10 mL of this solution, add 3 mL of dilute sodium hydroxide TS, allow to stand for 30 minutes, add 3 mL of 0.1 mol/L hydrochloric acid TS, and add water to make exactly 20 mL. Apply exactly 5 mL of this solution to a column (about 10 mm in inside diameter and packed with 0.36 g of octadecylsilanized silica gel for pre-treatment (55 – 105 mm in particle size), washed just before use with methanol and then with diluted methanol (3 in 10)), and wash the column in sequence with 2 mL of diluted methanol (3 in 10), 1 mL of sodium carbonate TS and 10 mL of

diluted methanol (3 in 10). Finally, elute with methanol to collect exactly 5 mL, and use this as the sample solution. Separately, weigh accurately about 10 mg of Ginsenoside Rb_1 RS (separately determine the water 〈*2.48*〉 by coulometric titration, using 10 mg), and dissolve in methanol to make exactly 50 mL. Pipet 4 mL of this solution, add methanol to make exactly 20 mL, and use this solution as the standard solution. Perform the test with exactly 20 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉 according to the following conditions, and determine the peak areas, A_T and A_S, of ginsenoside Rb_1 in each solution.

Amount (mg) of ginsenoside Rb_1 ($C_{54}H_{92}O_{23}$)
$= M_S \times A_T / A_S \times 2/5$

M_S: Amount (mg) of ginsenoside Rb_1 RS taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorptionphotometer (wavelength: 203 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 25 cm in length, packed with carbamoyl groups bound silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 60°C.

Mobile phase: A mixture of acetonitrile, water and phosphoric acid (400:100:1).

Flow rate: 1.0 mL per minute.

System suitability—

System performance: When the procedure is run with 20 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of ginsenoside Rb_1 are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of ginsenoside Rb_1 is not more than 1.5%.

Containers and storage Containers—Tight containers.

コウホン

Ligusticum Sinense Rhizome

LIGUSTICI RHIZOMA

Ligusticum Sinense Rhizome is the rhizome and root of *Ligusticum sinense* Oliver or *Ligusticum jeholense* Nakai et Kitagawa (*Umbelliferae*).

Description Rhizome, irregularly knotted to cylindrical; 1.5 - 9 cm in length, 0.5 - 2 cm in diameter, having round, dented scars or short remains of stems on the apex; externally grayish brown to blackish brown, with protruded nodules and scars of roots; texture, light and easily breakable; fractured surface usually slightly fibrous. Root, 1 - 10 cm in length, 2 - 5 mm in diameter; externally grayish yellow-brown to dark yellow-brown, with longitudinal wrinkles and scars of rootlets in dot-like protrusion; texture, somewhat fibrous and difficult to break.

Odor, characteristic; taste, slightly bitter at first, followed by a slightly numbing sensation.

Identification To 0.5 g of pulverized Ligusticum Sinense Rhizome add 5 mL of hexane, allow to stand for 15 minutes with occasional shaking, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography ⟨*2.03*⟩. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (4:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly the plate with dilute sulfuric acid, and heat at 105°C for 5 minutes: a light yellow-brown to yellow-brown principal spot is observed at an R_f value of about 0.6.

Total ash ⟨*5.01*⟩ Not more than 6.0%.

Acid-insoluble ash ⟨*5.01*⟩ Not more than 1.5%.

Containers and storage Containers—Well-closed containers.

ゴオウ末

Powdered Oriental Bezoar

BEZOAR BOVIS PULVERATUM

Powdered Oriental Bezoar is the powder of Oriental Bezoar in JP.

Assay standard of Powdered Oriental Bezoar: proceed as directed in the Assay standard under Oriental Bezoar in JP.

Description Powdered Oriental Bezoar occurs as a yellow-brown to red-brown powder.

Odor and taste are as directed in the Description under Oriental Bezoar in JP.

Under a microscope 〈*5.01*〉, Powdered Oriental Bezoar reveals yellow-brown to red-brown or colorless, nearly spherical or amorphous masses.

Identification Proceed as directed in the Identification under Oriental Bezoar in JP.

Purity (1) Synthetic dye—Proceed as directed in the Purity under Oriental Bezoar in JP.

(2) Starch—Proceed as directed in the Purity under Oriental Bezoar in JP.

(3) Sucrose—Proceed as directed in the Purity under Oriental Bezoar in JP.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Oriental Bezoar in JP.

Acid-insoluble ash 〈*5.01*〉 Not more than 2.0%.

Assay Proceed as directed in the Assay under Oriental Bezoar in JP.

Containers and storage Containers—Tight containers.

ニツサイホ

Drynaria Rhizome

DRINARIAE RHIZOMA

Drynaria Rhizome is the rhizome of *Drynaria roosii* Nakaike (*Drynaria fortunei* J. Smith)(*Polypodiaceae*).

Description Curved plate-like to flattened cylindrical; 5 - 15 cm in length, 0.5 - 2 cm in diameter, 0.2 - 0.8 cm in thickness, often longitudinally cut; externally brown to blackish brown; surface of rhizome or sides of longitudinal slices, covered with hair-like scales or scraped; protrusive scars of sterile leaves and projecting scars with central orbicular hollow of fertile leaves or residues of petiole, rarely short fibrous root observed; texture, light, fragile and easily breakable.

Odor, weak; practically tasteless.

Identification To 1.0 g of pulverized Drynaria Rhizome add 5 mL of methanol, treat with ultrasonic waves for 10 minutes and centrifuge. Use the supernatant liquid as the sample solution. Separately, dissolve 1 mg of naringin for thin-layer chromatogramphy in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 20 μL each of the sample solution and standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, water and formic acid (8:1:1) to a distance of about 7 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): one spot among several spots obtained from the sample solution and a spot obtained from the standard solution show the same color tone and the same R_f value. Prescribe that the moving distance of the spot corresponding to naringin from the sample solution is 1: spots develop at the relative moving distance of about 0.8 (neoeriocitrin) and 1.2 (caffeic acid 4-*O*-β-D-glucoside). The latter spot develops a blue color on spraying evenly 2,6-dibromo-*N*-chloro-1,4-benzoquinone monoimine and leaving to stand in ammonia gas.

Purity (1) Heavy metals 〈*1.07*〉 —Prepare the test solution with 1.0 g of pulverized Drynaria Rhizome according to Method 3, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(2) Arsenic 〈*1.11*〉 —Prepare the test solution with 0.40 g of Drynaria Rhizome according to Method 4, and perform the test (not more than 5 ppm).

(3) *Araiostegia divaricata* M. Kato —Under a magnifying glass, no large vascular bundles with crescent form in a center of the transverse section.

Loss on drying 〈*5.01*〉 Not more than 16.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 8.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.5%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 8.0%.

Containers and storage Containers—Tight containers.

サイコエキス

Bupleurum Root Extract

Bupleurum Root Extract is used as the manufacturing material for single crude drug extract preparation.

Bupleurum Root Extract contains not less than 0.10% of saikosaponin b_2.

Method of preparation Pulverize Bupleurum Root in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP to prepare a dry extract.

Description Bupleurum Root Extract is grayish yellow-brown to dark red-brown powder; Odor, characteristic; taste, slightly bitter and acid at first, sometimes astringent

It dissolves in water with a slight turbidity.

Identification To 1.0 g of Bupleurum Root Extract add 10 mL of water, shake, add 10 mL of 1-butanol, centrifuge and use the 1-butanol layer as sample solution. Separately, dissolve 1 mg of saikosaponin a 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 Thin-layer Chromatography ⟨*2.03*⟩ . Spot 20 μL of the sample solution and 5 μL standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol (99.5), and water (8:2:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly 4-dimethylaminobenzaldehyde TS on the plate, and heat at 105°C for 5 minutes: one of the spot among the several spots obtained from the sample solution has the same color tone and R_f value with the spot obtained from the standard solution (saikosaponin a). Prescribe that the moving distance of the spot corresponding to saikosaponin a from the sample solution is 1: a grayish brown spot develops at the relative moving distance of about 0.7 (saikosaponin c).

Purity (1) Heavy metals ⟨*1.07*⟩ —Prepare the test solution with 1.0 g of Bupleurum Root Extract as directed in the Extract (4) under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

(2) Arsenic ⟨*1.11*⟩ —Prepare the test solution with 0.67 g of Bupleurum Root Extract according to Method 3, and perform the test (not more than 3 ppm).

Loss on drying ⟨*2.41*⟩ Not more than 10.0% (1 g, 105°C, 5 hours).

Total ash ⟨*5.01*⟩ Not more than 14.0% (1 g).

Assay Weigh accurately about 0.1 g of Bupleurum Root Extract, add 50 mL of diluted methanol (1 in 2), shake for 15 minutes, filter, and use the filtrate as the sample solution. Use saikosaponin b_2 standard TS for assay as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography ⟨*2.01*⟩ , and determine the peak areas, A_T and A_S, of saikosaponin a in each solution.

Amount (mg) of saikosaponin b_2
$= C_S \times A_T / A_S \times 50$

C_S: Concentration (mg/mL) of saikosaponin b_2 in saikosaponin b_2 standard TS for assay

Operating conditions—

Detector: An ultraviolet absorptionphotometer (wavelength: 254 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: A mixture of 0.05 mol/L sodium dihydrogen phosphate TS and acetonitrile (5:3).

Flow rate: 1.0 mL per minute.

System suitability—

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of saikosaponin b_2 are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of saikosaponin b_2 is not more than 1.5%.

Containers and storage Containers—Tight containers.

サンシチニンジン

Panax Notoginseng Root

PANACIS NOTOGINSENG RADIX

Panax Notoginseng Root is the root of *Panax notoginseng* Feng Hwai Chen (*Araliaceae*), from which rootlets have been removed.

It contains not less than 2.0% of ginsenoside Rg_1 ($C_{42}H_{72}O_{14}$: 801.01) and not less than 1.5% of ginsenoside Rb_1 ($C_{54}H_{92}O_{23}$: 1109.29), calculated on the basis of dried material.

Description Conical, cylindrical or irregularly massive, 1 - 6 cm in length, 1 - 4 cm in diameter; externally gray to grayish black, or grayish yellow to grayish brown with intermittent longitudinal wrinkles and laterally extended lenticel-like patterns, also with nod-like small protuberances or scales of rootlets; sometimes crown with remains of rhizome; dense and hard in texture; fractured surface light yellow to grayish brown, yellow-green to grayish green, or blackish brown, glossy and horny.

Odor, slight and characteristic; taste, bitter and slightly sweet.

Identification To 0.5 g of pulverized Panax Notoginseng Root add 10 mL of water and 10 mL of 1-butanol, shake for 15 minutes, centrifuge, and use the 1-butanol layer as the sample solution. Separately, dissolve 1 mg of notoginsenoside R_1 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 Thin-layer Chromatography ⟨*2.03*⟩. Spot 2 μL each of the sample solution and standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, water and formic acid (4:1:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, heat at 105°C for 5 minutes, and allow to cool: one spot among several spots obtained from the sample solution and a spot obtained from the standard solution show the same color tone and the same R_f value.

Purity (1) Foreign matter ⟨*5.01*⟩ —The amount of terrestrial stems and other foreign matters contained in Panax Notoginseng Root does not exceed 2.0%.

(2) Heavy metals ⟨*1.07*⟩ —Prepare the test solution with 1.0 g of pulverized Panax Notoginseng Root according to Method 4, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) Arsenic ⟨*1.11*⟩ —Prepare the test solution with 0.40 g of pulverized Panax Notoginseng Root according to Method 4, and perform the test (not more than 5 ppm).

(4) Total BHC's and total DDT's ⟨*5.01*⟩ —Not more than 0.2 ppm, respectively.

Loss on drying ⟨*5.01*⟩ Not more than 16.0% (6 hours).

Total ash ⟨*5.01*⟩ Not more than 4.5%.

Acid-insoluble ash ⟨*5.01*⟩ Not more than 0.5%.

Assay (1) Ginsenoside Rg_1 —Weigh accurately about 0.5 g of pulverized Panax Notoginseng Root, put in a glass-stoppered centrifuge tube, add 30 mL of diluted

methanol (3 in 5), shake for 15 minutes, centrifuge, and separate the supernatant liquid. Repeat the procedure with the residue using 15 mL of diluted methanol (3 in 5). Combine the supernatant liquids, add diluted methanol (3 in 5) to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 10 mg of Ginsenoside Rg_1 RS (separately determine the water), dissolve in diluted methanol (3 in 5) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography ⟨*2.01*⟩ according to the following conditions, and determine the peak areas, A_T and A_S, of ginsenoside Rg_1 in each solution.

Amount (mg) of ginsenoside Rg_1 ($C_{42}H_{72}O_{14}$) taken
$= M_S \times A_T/A_S \times 1/2$

M_S: Amount (mg) of Ginsenoside Rg_1 RS taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 203 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 30°C.

Mobile phase: A mixture of water and acetonitrile (4:1).

Flow rate: Adjust so that the retention time of ginsenoside Rg_1 is about 25 minutes.

System suitability—

System performance: Dissolve 1 mg each of Ginsenoside Rg_1 RS and ginsenoside Re in diluted methanol (3 in 5) to make 10 mL. When the procedure is run with 10 μL of this solution according to the above operating conditions, ginsenoside Rg_1 and ginsenoside Re are eluted in this order with the resolution between these peaks being not less than 1.5.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of ginsenoside Rg_1 is not more than 1.5%.

(2) Ginsenoside Rb_1—Use the sample solution obtained in **(1)** as the sample solution. Separately, weigh accurately about 10 mg of Ginsenoside Rb_1 RS (separately determine the water), dissolve in diluted methanol (3 in 5) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid chromatography ⟨*2.01*⟩ according to the following conditions, and determine the peak areas, A_T and A_S, of ginsenoside Rb_1 in each solution.

Amount (mg) of ginsenoside Rb_1 ($C_{54}H_{92}O_{23}$) taken
$= M_S \times A_T / A_S \times 1/2$

M_S: Amount (mg) of Ginsenoside Rb_1 RS taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 203 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: A mixture of water and acetonitrile (7:3).

Flow rate: Adjust so that the retention time of ginsenoside Rb_1 is about 20 minutes.

System suitability—

System performance: Dissolve 1 mg each of Ginsenoside Rb_1 RS and ginsenoside Rc in diluted methanol (3 in 5) to make 10 mL. When the procedure is run with 10 μL of this solution according to the above operating conditions, ginsenoside Rb_1 and ginsenoside Rc are eluted in this order with the resolution between these peaks being not less than 3.

System repeatability: When the test is repeated 6 times with 10 μL of the sample solution, the relative standard deviation of the peak area of ginsenoside Rb_1 is not more than 1.5%.

Containers and storage Containers—Well-closed containers.

Notoginsenoside R_1 for thin-layer chromatography $C_{47}H_{80}O_{18}$ A white to light yellow-brown crystalline powder or powder. Freely soluble in methanol or ethanol (99.5), and slightly soluble in water.

Identification Determine the infrared absorption spectrum of notoginsenoside R_1 for thin-layer chromatography as directed in the potassium bromide disk method under Infrared Spectrophotometry 〈*2.25*〉 : it exhibits absorption at the wave numbers of about 3400 cm^{-1}, 2930 cm^{-1}, 1385 $cm^{-1}$and 1043 cm^{-1}.

Purity Related substances—Dissolve 1 mg of Notoginsenoside R_1 for thin-layer chromatography in 1 mL of methanol, and use this solution as the sample solution. Pipet 0.5 mL of the sample solution, add methanol to make exactly 10 mL, and use this solution as the standard solution. When the test is performed with 2 μL of the sample solution and standard solution according to the Identification under Panax Notoginseng Root in Non-JPS, the spot other than the principle spot obtained from the sample solution is not more intense than the spot obtained from the standard solution.

サンシチニンジン末

Powdered Panax Notoginseng Root

PANCIS NOTOGINSENG RADIX PULVERATA

Powdered Panax Notoginseng Root is the powder of Panax Notoginseng Root in Non-JPS.

It contains not less than 2.0% of ginsenoside Rg_1 ($C_{42}H_{72}O_{14}$: 801.01) and not less than 1.5% of ginsenoside Rb_1 ($C_{54}H_{92}O_{23}$: 1109.29), calculated on the basis of dried material.

Description Powdered Panax Notoginseng Root occurs as a light yellow-brown to grayish brown powder.

Odor and taste are as directed in the Description under Panax Notoginseng Root in Non-JPS.

Under a microscope 〈*5.01*〉, Powdered Panax Notoginseng Root reveals mainly numerous starch grains; single grains of nearly circular or polygonal in shape, or compound grains; yellow masses of resin, fragments of reticulate vessels, scalariform vessels, parenchyma cells containing starch grains and cork cells, and rarely crystals of calcium oxalate are observed.

Identification Proceed as directed in the Identification under Panax Notoginseng Root in Non-JPS.

Purity (1) Heavy metals 〈*1.07*〉 —Proceed as directed in the Purity under Panax Notoginseng Root in Non-JPS.

(2) Arsenic 〈*1.11*〉 —Proceed as directed in the Purity under Panax Notoginseng Root in Non-JPS.

(3) Total BHC's and total DDT's 〈*5.01*〉 —Proceed as directed in the Purity under Panax Notoginseng Root in Non-JPS.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Panax Notoginseng Root in Non-JPS.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Panax Notoginseng Root in Non-JPS.

Acid-insoluble ash 〈*5.01*〉 Proceed as directed in Acid-insoluble ash under Panax Notoginseng Root in Non-JPS.

Assay (1) Ginsenoside Rg_1—Weigh accurately about 0.5 g of Powdered Panax Notoginseng Root, put in a glass-stoppered centrifuge tube, add 30 mL of diluted methanol (3 in 5), shake for 15 minutes, centrifuge, and separate the supernatant liquid. Repeat the procedure with the residue using 15 mL of diluted methanol (3 in 5). Combine the supernatant liquids, add diluted methanol (3 in 5) to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 10 mg of Ginsenoside Rg_1 RS (separately determine the water), dissolve in diluted methanol (3 in 5) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard

solution as directed under Liquid Chromatography ⟨*2.01*⟩ according to the following conditions, and determine the peak areas, A_T and A_S, of ginsenoside Rg_1 in each solution.

Amount (mg) of ginsenoside Rg_1 ($C_{42}H_{72}O_{14}$) taken
$= M_S \times A_T/A_S \times 1/2$

M_S: Amount (mg) of ginsenoside Rg_1 taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 203 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 30°C.

Mobile phase: A mixture of water and acetonitrile (4:1).

Flow rate: Adjust so that the retention time of ginsenoside Rg_1 is about 25 minutes.

System suitability—

System performance: Dissolve 1 mg each of Ginsenoside Rg_1 RS and ginsenoside Re in diluted methanol (3 in 5) to make 10 mL. When the procedure is run with 10 μL of this solution according to the above operating conditions, ginsenoside Rg_1 and ginsenoside Re are eluted in this order with the resolution between these peaks being not less than 1.5.

System repeatability: When the test is repeated with 6 times with 10 μL of the standard solution, the relative standard deviation of the peak area of ginsenoside Rg_1 is not more than 1.5%.

(2) Ginsenoside Rb_1—Use the sample solution obtained in **(1)** as the sample solution. Separately, weigh accurately about 10 mg of Ginsenoside Rb_1 RS (separately determine the water), dissolve in diluted methanol (3 in 5) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography ⟨*2.01*⟩ according to the following conditions, and determine the peak area, A_T and A_S, of ginsenoside Rb_1 in each solution.

Amount (mg) of ginsenoside Rb_1 ($C_{54}H_{92}O_{23}$) taken
$= M_S \times A_T/A_S \times 1/2$

M_S: Amount (mg) of Ginsenoside Rb_1 RS taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 203 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 25°C.

Mobile phase: A mixture of water and acetonitrile (7:3).

Flow rate: Adjust so that the retention time of ginsenoside Rb_1 is about 20 minutes.

System suitability—

System performance: Dissolve 1 mg each of Ginsenoside Rb_1 RS and ginsenoside Rc in diluted methanol (3 in 5) to make 10 mL. When the procedure is run with 10 μL of this solution according to the above operating conditions, ginsenoside Rb_1 and ginsenoside Rc are eluted in this order with the resolution between these peaks being not less than 3.

System repeatability: When the test is repeated with 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of ginsenoside Rb_1 is not more than 1.5%.

Containers and storage Containers—Tight containers.

サンシュユ末

Powdered Cornus Fruit

CORNI FRUCTUS PULVERATUS

Powdered Cornus Fruit is the powder of Cornus Fruit in JP.

Assay standard of Powdered Cornus Fruit: proceed as directed in the Assay standard under Cornus Fruit in JP.

Description Powdered Cornus Fruit occurs as a reddish brown to reddish light brown powder.

Odor and taste are as directed in the Description under Cornus Fruit in JP.

Under a microscope 〈*5.01*〉, Powdered Cornus Fruit reveals fragments of parenchyma cells containing yellow-red masses, orbicular to oblong, 50 - 160 μm in diameter, fragments of epidermis with thick cuticle and containing yellow-red masses, fragments of spiral vessels, annular vessels and reticulate vessels; vessels 5 - 25 μm in diameter, a few stone cells, fibers, solitary crystals of calcium oxalate, 10 - 25 μm in diameter, inulin sphero-crystals, and very rarely unicellular hairs.

Identification Proceed as directed in the Identification under Cornus Fruit in JP.

Purity Total BHC's and total DDT's 〈*5.01*〉—Proceed as directed in the Purity under Cornus Fruit in JP.

Total ash 〈*5.01*〉 Not more than 6.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Extract content 〈*5.01*〉 Proceed as directed in the Extract content under Cornus Fruit in JP.

Assay Proceed as directed in the Assay under Cornus Fruit in JP.

Containers and storage Containers—Tight containers.

サンズコン

Sophora Subprostrata Root

SOPHORAE SUBPROSTRATAE RADIX

Sophora Subprostrata Root is the root and the rhizome of *Sophora subprostrata* Chun et T. Chen (*Leguminosae*).

Description Root, cylindrical, 5 - 20 cm in length, 0.5 - 2.0 cm in diameter; externally brown to blackish brown; with numerous, longitudinal wrinkles and transversely elongated lenticels; Under a magnifying glass, a transverse section reveals cortex about 0.1 cm in thickness and brownish; xylem light yellow-brown; cortex and xylem clearly separated by the color. Rhizome, irregularly nodded; rarely remains of stem on the apex.

Odor, slight; taste, extremely bitter and persisting.

Identification To 0.5 g of pulverized Sophora Subprostrata Root add 10 mL of dilute acetic acid, allow to stand for 3 minutes with occasional shaking, and filter. Spot 1 drop of the filtrate on a filter paper, air-dry, spray evenly Dragendorff's TS for spraying on it, and allow to stand: a yellow-red color develops.

Total ash 〈*5.01*〉 Not more than 5.5%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 11.0%.

Containers and storage Containers—Well-closed containers.

ジオウ末

Powdered Rehmannia Root

REHMANNIAE RADIX PULVERATA

Powdered Rehmannia Root is the powder of Rehmannia Root in JP.

Description Powdered Rehmannia Root occurs as a dark grayish brown to dark brown powder.

Odor and taste are as directed in the Description under Rehmannia Root in JP.

Under a microscope 〈*5.01*〉, Powdered Rehmannia Root reveals fragments of parenchyma cells containing blackish brown masses; secretory cells filled with yellow-brown granules; reticulate vessels and scalariform vessels 30 - 50 μm in diameter, with distinct perforations, annular vessels about 15 μm in diameter; blackish brown cork cells; fragments of parenchyma cells; occasionally solitary crystals of calcium oxalate observed.

Identification Proceed as directed in the Identification 1) Kan-jio or 2) Juku-jio under Rehmannia Root in JP.

Purity (1) Heavy metals 〈*1.07*〉—Proceed as directed in the Purity under Rehmannia Root in JP.

(2) Arsenic 〈*1.11*〉—Proceed as directed in the Purity under Rehmannia Root in JP.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Rehmannia Root in JP.

For those applying the Identification 2) Juku-jio: not more than 7.0%.

Acid-insoluble ash 〈*5.01*〉 Proceed as directed in the Acid-insoluble ash under Rehmannia Root in JP.

For those applying the Identification 2) Juku-jio: not more than 3.0%.

Containers and storage Containers—Tight containers.

シオン

Aster Root

ASTERIS RADIX

Aster Root is the root and the rhizome of *Aster tataricus* Linné filius (*Compositae*).

Description A short rhizome with numerous caespitose roots; the rhizome massive, 1 - 3 cm in length, 1 - 2 cm in diameter, with short remains of stems and petioles at the apex, and occasionally with runner; the root, 6 - 15 cm in length, 1 - 2 mm in diameter, externally light brown to dark purple-brown, with fine longitudinal wrinkles; slightly flexible in texture and easy to break.

Odor, characteristic; taste, slightly bitter.

Identification **(1)** To 0.2 g of pulverized Aster Root add 10 mL of water, and shake vigorously: a lasting fine foam is produced.

(2) To 0.2 g of pulverized Aster Root add 2 mL of acetic anhydride, warm on a water bath for 2 minutes with shaking, and filter. To the filtrate add gently 0.5 mL of sulfuric acid: a red-brown color develops at the zone of contact.

Loss on drying 〈*5.01*〉 Not more than 18.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 12.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 6.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 30.0%.

Containers and storage Containers—Well-closed containers.

シソシ

Perilla Fruit

PERILLAE FRUCTUS

Perilla Fruit is the fruit of *Perilla frutescens* Britton var. *crispa* W. Deane (*Labiatae*).

Description Mericarp, globose to compressed globose, 1.0 - 1.5 mm in diameter; externally light yellow-brown to dark brown; under a magnifying glass, slightly protruded reticular patterns on the surface. 100 seeds weigh 0.1 - 0.35 g.

Practically odorless, but a characteristic aroma when chewing; taste, slightly oily.

Identification To 1 g of pulverized Perilla Fruit add 10 mL of methanol, warm on a water bath for 10 minutes, and filter. To 3 mL of the filtrate add 1 drop of 2,4-dinitrophenylhydrazine TS, and shake: an orange color develops.

Total ash 〈*5.01*〉 Not more than 10.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 6.0%.

Containers and storage Containers—Well-closed containers.

シテイ

Persimmon Calyx

KAKI CALYX

Persimmon Calyx is the persistent calyx of mature fruit of *Diospyros kaki* Thunberg (*Ebenaceae*).

Description Nearly square, often devoid of sepals; saucer-shaped; 1.5 - 4.0 cm in diameter; sepal almost deltoid, slightly thin; externally grayish brown to brown; internally dark brown to light yellow-brown in the central part, and red-brown to brown in the marginal part; on the outer surface, orbicular hollow scar or, rarely residue, of fruit stalk at the central part; on the inner surface, orbicular protrusion at the central part and brown adpressed hairs occur densely at the marginal part.

Odorless; taste, slightly astringent.

Identification To 2.0 g of pulverized Persimmon Calyx add 10 mL of water and 5 mL of ethyl acetate, shake for 10 minutes, centrifuge, and use the ethyl acetate layer as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, hexane, methanol and acetic acid (100) (20:20:1:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat at 105°C for 5 minutes: a red-purple spot is observed at an R_f value of about 0.5 (ursolic acid).

Loss on drying 〈*5.01*〉 Not more than 15.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 8.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 12.0%.

Containers and storage Containers—Well-closed containers.

シャクヤクエキス

Peony Root Extract

Peony Root Extract is used as the manufacturing material for single crude drug extract preparation.

Peony Root Extract contains not less than 4.0% of paeoniflorin ($C_{23}H_{28}O_{11}$: 480.46).

Method of preparation Pulverize Peony Root in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP to prepare a dry extract.

Description Peony Root Extract is light yellow-brown to brown powder; Odor, characteristic; taste, slightly sweet at first, followed by an astringency and a bitterness. It dissolves in water with a slight turbidity.

Identification To 0.2 g of Peony Root Extract add 10 mL of methanol, warm on a water bath for 5 minutes, cool, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of Paeoniflorin RS or paeoniflorin 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 Thin-layer Chromatography *〈2.03〉*. Spot 10 μL each of the sample solution and standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of acetone, ethyl acetate and acetic acid (100) (10:10:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat at 105°C for 5 minutes: one of the spot among the several spots obtained from the sample solution has the same color tone and R_f value with the spot obtained from the standard solution.

Purity **(1)** Heavy metals *〈1.07〉* —Prepare the test solution with 1.0 g of Peony Root Extract as directed in the Extract **(4)** under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

(2) Arsenic *〈1.11〉* —Prepare the test solution with 0.67 g of Peony Root Extract according to Method 3, and perform the test (not more than 3 ppm).

Loss on drying *〈2.41〉* Not more than 8.0% (1 g, 105°C, 5 hours).

Total ash *〈5.01〉* Not more than 9.0% (1 g).

Assay Weigh accurately about 0.1 g of Peony Root Extract, add 50 mL of diluted methanol (1 in 2), shake for 15 minutes, filter, and use the filtrate as the sample solution. Separately, weigh accurately about 10 mg of Paeoniflorin RS (separately determine the water *〈2.48〉* by coulometric titration, using 10 mg), dissolve in diluted methanol (1 in 2) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography *〈2.01〉* according to the following conditions. Determine the peak areas, A_T and A_S, of paeoniflorin in each solution.

Amount (mg) of paeoniflorin ($C_{23}H_{28}O_{11}$) taken

$= M_S \times A_T / A_S \times 1/2$

M_S: Amount (mg) of Paeoniflorin RS taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 232 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 20°C.

Mobile phase: A mixture of water, acetonitrile and phosphoric acid (850:150:1).

Flow rate: 1.0 mL per minute.

System suitability—

System performance: Dissolve 1 mg each of Paeoniflorin RS and albiflorin in diluted methanol (1 in 2) to make 10 mL. When the procedure is run with 10 μL of this solution under the above operating conditions, albiflorin and paeoniflorin are eluted in this order with the resolution between these peaks being not less than 2.5.

System repeatability: When the test is repeated with 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of paeoniflorin is not more than 1.5%.

Containers and storage Containers—Tight containers.

シャジン

Adenophora Root

ADENOPHORAE RADIX

Adenophora Root is the root of *Adenophora tetraphylla* Fischer, *Adenophora stricta* Miquel, *Adenophora hunanensis* Nannfeldt or *Adenophora triphylla* A. De Candolle (*Campanulaceae*).

Description Long, conical to cylindrical, sometimes branched; 7 - 20 cm in length; the crown, 1 - 3 cm in diameter; externally light yellow-white to light grayish brown; the crown reveals distinct, crosswise, ring-like wrinkles, with cylindrical rhizome at the upper part; most part of the root other than crown, coarse, longitudinal wrinkles and lenticel-like lateral lines; light in texture; cut surface white, often with many cracks.

Odor, slight and characteristic; taste, slightly sweet and somewhat mucilaginous.

Identification To 0.2 g of pulverized Adenophora Root add 2 mL of acetic anhydride, warm on a water bath for 2 minutes, and filter. To 1 mL of the filtrate add gently 0.5 mL of sulfuric acid to make two layers: a red-brown color develops at the zone of contact.

Loss on drying 〈*5.01*〉 Not more than 14.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 5.5%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.5%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 25.0%.

Containers and storage Containers—Well-closed containers.

ショウキョウエキス

Ginger Extract

Ginger Extract is used as the manufacturing material for single crude drug extract preparation.

Ginger Extract contains not less than 0.06% of [6]-gingerol.

Method of preparation Pulverize ginger in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP to prepare a dry extract.

Description Ginger Extract is light grayish yellow-brown to brown powder; Odor, characteristic; taste, hot. It dissolves in water with a slight turbidity.

Identification Shake 1 g of Ginger Extract with 10 mL of water, then add 25 mL of diethyl ether, and shake. Separate the diethyl ether layer, evaporate the solvent under low pressure (in vacuo), add 2 mL of diethyl ether to the residue, and use this solution as the sample solution. Separately, dissolve 1 mg of [6]-gingerol 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 Thin-layer Chromatography *〈2.03〉*. Spot 5 μL of the sample solution and 2 μL of the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate and hexane (1:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly 4-dimethylaminobenzaldehyde TS for spraying on the plate, heat at 105°C for 5 minutes, and allow to cool: one spot among several spots obtained from the sample solution and a spot obtained from the standard solution show the same color tone and the same R_f value.

Purity **(1)** Heavy metals *〈1.07〉*—Prepare the test solution with 1.0 g of Ginger Extract as directed in the Extract **(4)** under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

(2) Arsenic *〈1.11〉*—Prepare the test solution with 0.67 g of Ginger Extract according to Method 3, and perform the test (not more than 3 ppm).

Loss on drying *〈2.41〉* Not more than 12.0% (1 g, 105°C, 5 hours).

Total ash *〈5.01〉* Not more than 22.0% (1 g).

Assay Weigh accurately about 0.2 g of Ginger Extract, add 50 mL of diluted methanol (7 in 10), shake for 15 minutes, filter, and use the filtrate as the sample solution. Separately, weigh accurately about 10 mg of [6]-gingerol for assay, and dissolve in methanol to make exactly 100 mL. Pipet 5 mL of this solution, add methanol to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography *〈2.01〉* according to the following conditions, and determine the peak areas, A_T and A_S, of [6]-gingerol in each solution.

Amount (mg) of [6]-gingerol
$= M_S \times A_T / A_S \times (1/20)$

M_S: Amount (mg) of [6]-gingerol for assay taken

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 282 nm)

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 30° C.

Mobile phase: A mixture of water, acetonitrile and phosphoric acid (620:380:1).

Flow rate: 1.0 mL per minute.

System suitability—

System performance: When the procedure is run with 10 μL of the standard solution according to the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of [6]-gingerol are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of [6]-gingerol is not more than 1.5%.

Containers and storage Containers—Tight containers.

ショウバク

Wheat

TRITICI FRUCTUS

Wheat is the fruit of *Triticum aestivum* Linné (*Gramineae*).

Description Long ovoid to ellipsoid, 5 - 8 mm in length, 2 - 4 mm in width, sometimes containing fragments of fruit; externally light yellow-green to light brown. Ventral side longitudinally and deeply furrowed in the center. Under a magnifying glass, embryo at the base, occasionally covered densely with white hairs at the apex. A transverse section at central portion nearly round to reniform, pericarp in outermost part thin, light brown, inner part nearly white, hard in texture.

Practically odorless and tasteless.

Identification To 2 g of pulverized Wheat add 10 mL of methanol, shake for 10 minutes, centrifuge, and use the supernatant liquid as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane, ethyl acetate and acetic acid (100) (14:6:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly vanillin-sulfuric acid-ethanol TS for spraying on the plate, and heat at 105°C for 5 minutes: a red-orange spot is observed at an R_f value of about 0.4 (5-Henicosylresorcinol).

Loss on drying 〈*5.01*〉 Not more than 15.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 2.0%.

Containers and storage Containers—Well-closed containers.

ショクショウ

Zanthoxylum Peel

ZANTHOXYLI PERICARPIUM

Zanthoxylum Peel is the pericarps of the ripe fruit of *Zanthoxylum bungeanum* Maximowicz or *Zanthoxylum armatum* De Candolle var. *subtrifoliatum* Kitamura, from which the seeds separated from the pericarps have been mostly removed.

Description Capsules of 2 or 3 spherical to flattened spheroidal mericarps, which are dehiscent in 2 pieces each 4 to 6 mm in diameter; the outer surface of pericarp, light red-brown to dark red-brown or brown, with numerous warty protrusions originated from oil sacs, or nearly flat with partly warty protrusions; the inner surface, light yellow-white to light brown.

Odor, characteristically aromatic; taste, at first slightly acrid, subsequently which gives numbing sensation to the tongue.

Identification To 2 g of pulverized Zanthoxylum Peel add 10 mL of water, shake for 5 minutes, add 5 mL of diethyl ether, shake, centrifuge, and use the diethyl ether layer as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, hexane, methanol and acetic acid (100) (20:20:1:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat at 105°C for 5 minutes: a blackish brown spot is observed at an R_f value of about 0.3 (Hydroxy-α-sanshool, Hydroxy-β-sanshool).

Purity **(1)** Seed—When perform the test of foreign matter 〈*5.01*〉, the amount of the seeds contained in Zanthoxylum Peel does not exceed 20.0%.

(2) Peduncle and twig—When perform the test of foreign matter 〈*5.01*〉, the amount of the peduncles and twigs contained in Zanthoxylum Peel does not exceed 5.0%.

(3) Foreign matter 〈*5.01*〉—The amount of foreign matter other than seeds, peduncles and twigs contained in Zanthoxylum Peel does not exceed 1.0%.

Total ash 〈*5.01*〉 Not more than 9.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Essential oil content 〈*5.01*〉 When the test is performed with 30.0 g of pulverized Zanthoxylum Peel, the essential oil content is not less than 0.6 mL.

Containers and storage Containers—Well-closed containers.

ジョテイシ

Ligustrum Fruit

LIGUSTRI FRUCTUS

Ligustrum Fruit is the dried ripe fruit of *Ligustrum lucidum* W.T. Aiton or *Ligustrum japonicum* Thunberg (*Oleaceae*).

Description Ovoid, elliptical or kidney-shaped, 4 - 10 mm in length, 3 - 6 mm in diameter, externally blackish purple to grayish black, with wrinkles, scars of a pedicel or persistent calyx and a short pedicel in the base. Epicarp thin; mesocarp relatively soft, easily stripped off. Endocarp woody, yellow-brown to red-brown with longitudinal wrinkles, includes one or two seed(s) of long ovoid to kidney-shaped.

Odor, slight and characteristic; taste, slightly sweet and slightly bitter.

Identification To 1 g of pulverized Ligustrum Fruit add 5 mL of methanol, shake for 15 minutes, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, methanol and water (7:2:1) to a distance of about 7 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): a spot is observed at an R_f value of about 0.4. The spot shows red-brown color after spraying evenly 1-naphthol-sulfuric acid TS, heating at 105°C for 3 minutes (nuzhenide).

Loss on drying 〈*5.01*〉 Not more than 12.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 6.5%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 20.0%.

Containers and storage Containers—Well-closed containers.

ジリュウ

Earthworm

LUMBRICUS

Earthworm is *Pheretima aspergillum* Perrier or allied animals (*Megascolecidae*), from which internal organs have been removed.

Description Thin ribbon-form plate, 15 - 30 cm in length, 1 - 2 cm in width; dorsal part of the outer surface blackish brown to purple brown, ventral part of the outer surface reveals light yellow-brown, brocade crest (star spot pattern); annellations covering the inner surface, seen as transverse wrinkles running at about 2-mm intervals; both ends cyclic, the one end bears oral section with mouth 1 mm in diameter; flexible, difficult to break but easy to cut off.

Odor, characteristic; taste, mild.

Identification To 1 g of pulverized Earthworm add 10 mL of water, sonicate for 5 minutes, and centrifuge. Transfer the supernatant liquid to a separator, add 30 mL of 1-butanol, and shake. Take the 1-butanol layer, and evaporate under low pressure (in vacuo). Dissolve the residue in 1 mL of methanol, and use this solution as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 3 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, acetone, water and acetic acid (100) (10:6:3:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, and heat at 105°C for 5 minutes: a blue spot is observed at an R_f value of about 0.4.

Purity **(1)** Heavy metals 〈*1.07*〉 —Prepare the test solution with 0.5 g of pulverized Earthworm according to Method 4, and perform the test. Prepare the control solution with 2.5 mL of Standard Lead Solution (not more than 50 ppm).

(2) Arsenic 〈*1.11*〉 —Prepare the test solution with 0.4 g of pulverized Earthworm according to Method 3, and perform the test (not more than 5 ppm).

Loss on drying 〈*5.01*〉 Not more than 12.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 20.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 16.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 9.0%.

Containers and storage Containers—Well-closed containers.

ジンギョウ

Gentiana Macrophylla Root

GENTIANAE MACROPHYLLAE RADIX

Gentiana Macrophylla Root is the root of *Gentiana macrophylla* Pallas, *Gentiana straminea* Maximowicz, *Gentiana crassicaulis* Duthie ex Burkill, *Gentiana dahurica* Fischer, *Gentiana tibetica* King ex Hooker filius, *Gentiana dendrologi* C. Marquand, *Gentiana officinalis* Harry Sm. or their interspecific hybrids (*Gentianaceae*).

Description Nearly conical to cylindrical, usually thick in upper part, thin in lower part, 6 - 30 cm in length, 0.5 - 4 cm in diameter, with longitudinal wrinkles, mostly spirally twisted, often branched; occasionally internally rotted; externally grayish yellow-brown to dark brown, and sometimes with a little remains of leaf sheath at the crown; with scars of rootlets from the center to the apex; a transverse section reveals xylem nearly circular, or divided into several parts when periderm developed; cortex light brown to dark brown; xylem light yellow-brown to yellow-brown.

Odor, characteristic; taste, bitter and persisting.

Identification To 0.5 g of pulverized Gentiana Macrophylla Root add 5 mL of methanol, treat with ultrasonic waves for 20 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 2 mg of gentiopicroside 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 Thin-layer Chromatography 〈*2.03*〉. Spot 1 μL each of the sample solution and standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, ethanol, water and acetic acid (100)(50:10:5:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, heat at 105°C for 5 minutes, and cooling. Examine under ultraviolet light (main wavelength: 365 nm): one spot among several spots obtained from the sample solution has the same R_f value with the yellow-white fluorescent spot from the standard solution, and has yellow-white to brown fluorescence. The spot is more intense than that from standard solution. Prescribe that the moving distance of the spot corresponding to gentiopicroside from the sample solution is 1: a blue-purple to purple fluorescent spot is observed at the relative moving distance of about 0.6 (loganic acid).

Purity **(1)** Heavy metals 〈*1.07*〉 —Proceed with 3.0 g of pulverized Gentiana Macrophylla Root according to Method 3, and perform the test. Prepare the control solution with 3.0 mL of Standard Lead Solution (not more than 10 ppm).

(2) Arsenic 〈*1.11*〉 —Prepare the test solution with 0.40 g of pulverized Gentiana Macrophylla Root according to Method 4, and perform the test (not more than 5 ppm).

Loss on drying 〈*5.01*〉 Not more than 15.5% (6 hours).

Total ash 〈*5.01*〉 Not more than 8.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 3.5%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 25.0%.

Containers and storage Containers—Well-closed containers.

ジンコウ

Agarwood

AQUILARIAE RESINATUM LIGNUM

Agarwood is the wood of *Aquilaria agallocha* Roxburgh, *Aquilaria crassna* Pierre ex Lecomte, *Aquilaria malaccensis* Lamarck, *Aquilaria sinensis* Gilg or *Aquilaria filaria* Merrill (*Thymelaeaceae*), especially splint wood containing penetrated black resin.

Description Irregular shape of wood piece, grayish brown to blackish brown; holes and ditches in places; lustrous black dots in resin-rich portion; hard and heavy in texture.

Odor, slightly aromatic, aromatic fragrance occurs when smoked; taste, slightly bitter and a little pungent.

Identification To 0.3 g of pulverized Agarwood add 10 mL of methanol, shake or sonicate for 10 minutes, centrifuge, and use the supernatant liquid as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 20 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate and hexane (2:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate. Examine under ultraviolet light (main wavelength: 365 nm): a fluorescent bluish white spot is observed at an R_f value of about 0.25 (6,7-dimethoxy-2-(2-phenylethyl) chromon).

Loss on drying 〈*5.01*〉 Not more than 11.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 8.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 8.0%.

Containers and storage Containers—Well-closed containers.

ジンコウ末

Powdered Agarwood

AQUILARIAE RESINATUM LIGNUM PULVERATUM

Powdered Agarwood is the powder of Agarwood in Non-JPS.

Description Powdered Agarwood occurs as a grayish brown to blackish brown powder.

Odor and taste are as a described in the Description under Agarwood in Non-JPS.

Under a microscope 〈*5.01*〉, Powdered Agarwood reveals light brown to blackish brown agglomerate resin; resin deposited parenchyma cells; fragments of pitted vessels; fragments of medullary ray tissues, oblong cells orthogonal to vascular bundles.

Identification Proceed as directed in the Identification under Agarwood in Non-JPS.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Agarwood in Non-JPS.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Agarwood in Non-JPS.

Acid-insoluble ash 〈*5.01*〉 Proceed as directed in the Acid-insoluble ash under Agarwood in Non-JPS.

Extract content 〈*5.01*〉 Proceed as directed in the Extract content under Agarwood in Non-JPS.

Containers and storage Containers—Tight containers.

スイギュウカク

Buffalo Horn

BUBALI CORNU

Buffalo Horn is the horn of *Bubalus bubalis* Linné (*Bovidae*).

Description Slightly flattened and curved conical horn, 30 - 75 cm in length; acute in apex; top part, solid, having longitudinal lines; middle to lower part, hollow, having several horizontal wrinkles and cavity in external side; near triangular to oblong base, 3 - 10 cm in minor axis, 5 - 15 cm in major axis; outer and cut surface, black-brown to grayish black; texture hard; under a magnifying glass, thin transvers section reveals horizontal brown layers with concentrate variations.

Odor, characteristic; practically tasteless.

Identification To 1 g of pulverized Buffalo Horn add 20 mL of methanol, shake for 10 minutes, centrifuge. Evaporate the supernatant liquid to dryness under low pressure (in vacuo), dissolve the residue in 0.5 mL of methanol, and use this solution as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, methanol and acetic acid (100)(8:1:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, heat at 105°C for 5 minutes: a red-purple spot is observed at an R_f value of about 0.5.

Purity Heavy metals 〈*1.07*〉—Prepare the test solution with 1.0 g of pulverized Buffalo Horn according to Method 3, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

Loss on drying 〈*5.01*〉 Not more than 15.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 2.0%.

Containers and storage Containers—Well-closed containers.

セイヒ

Immature Citrus Unshiu Peel

CITRI UNSHIU PERICARPIUM IMMATURUS

Immature Citrus Unshiu Peel is the pericarp of immature fruit of *Citrus unshiu* Marcowicz or *Citrus reticulata* Blanco (*Rutaceae*) (Shika-seihi), or the immature fruit of *Citrus unshiu* Marcowicz or *Citrus reticulata* Blanco (*Rutaceae*) (Ko-seihi).

Description 1) Shika-seihi: Tetra-lobed piece of pericarp, 1 - 3 mm in thickness; externally grayish green to dark green-brown, with numerous small dents associated with oil sacs; inner surface whitish to yellow-brown; slightly hard in texture.

Odor, characteristic aroma; taste, bitter.

2) Ko-seihi: Nearly globose, 1 - 2 cm in diameter; externally grayish green to dark green-brown, with numerous small dents associated with oil sacs; hard in texture; peripheral portion of transversely cut surface is exocarp and mesocarp, 1 - 4 mm in thickness, light yellow-white to yellow-brown; central portion of the cut surface is divided radially into usually 8 - 10 locules, each locule light brown and concave.

Odor, characteristic aroma; taste, bitter.

Identification To 0.5 g of pulverized Immature Citrus Unshiu Peel add 10 mL of methanol, shake or sonicate for 20 minutes, centrifuge, and use the supernatant liquid as the sample solution. Separately, dissolve 1 mg of hesperidin 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 Thin-layer Chromatography ⟨*2.03*⟩. Spot 10 μL each of the sample solution and standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, acetone, water and acetic acid (100) (10:6:3:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly iron (III) chloride-methanol TS on the plate: one spot among several spots obtained from the sample solution and a spot obtained from the standard solution show the same color tone and the same R_f value.

Loss on drying ⟨*5.01*⟩ Not more than 16.0% (6 hours).

Total ash ⟨*5.01*⟩ Not more than 6.0%.

Extract content ⟨*5.01*⟩ Dilute ethanol-soluble extract: not less than 9.0%.

Containers and storage Containers—Well-closed containers.

セキショウコン

Acorus Gramineus Rhizome

ACORI GRAMINEI RHIZOMA

Acorus Gramineus Rhizome is the rhizome of *Acorus gramineus* Solander or *Acorus tatarinowii* Shott (*Araceae*).

Description Somewhat compressed, string-like; 10 - 20 cm in length, 0.3 - 1.0 cm in diameter, slightly curved, often branched; externally light yellow-brown to yellow-red, with many nodes; triangular leaf scars arranged alternately right and left, often hair-like residues of scaly leaves on nodes, and longitudinal wrinkles on internodes; on the undersurface, scars of roots, sometimes short roots remaining; hard in texture, and easily breakable; fractured surface fibrous, light yellow-brown to grayish white.

Odor, characteristic aroma; taste, cool, somewhat acrid and slightly numbing on the tongue.

Identification To 0.5 g of pulverized Acorus Gramineus Rhizome add 10 mL of diethyl ether, shake for 3 minutes, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate and hexane (1:1) to a distance of about 7 cm, and air-dry the plate. Examine the plate under ultraviolet light (main wavelength: 254 nm): a dark purple principal spot is observed at an R_f value of about 0.5 (Asarone).

Total ash 〈*5.01*〉 Not more than 10.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.5%.

Containers and storage Containers—Well-closed containers.

センタイ

Cicada Slough

CICADAE PERIOSTRACUM

Cicada Slough is the exuviae of larvae of *Cryptotympana atrata* Stal, *Platylomia pieli* Kato, *Oncotympana maculaticollis* Distant, *Tanna chekiangensis* Ouchi, *Graptopsaltria tienta* Karsch, *Lyristes pekinensis* Haupt, *Lyristes atrofasciatus* Chou et Lei, *Meimuna mongolica* Distant, *Leptosemia sakaii* Matsumura, *Platypleura kaempferi* Butler or other species of those genera (*Cicadidae*).

Description Long ellipsoidal, hollow, consists of head, thorax and abdomen, 3 - 4 cm in length, 1.3 - 2 cm in width; externally light yellow-brown, translucent and lustrous; head in hemispherical form, having elliptical clypeus and needle-shaped proboscis at the anterior side, and flattened spherical, transparent compound eyes at the lateral sides; a pair of filamentous antennae often fallen away; thorax split vertically at the dorsal side, white fibrous thing visible inside the thorax through the split, and thorax having two pairs of wings on both lateral sides, wings of the one pair about 1.5 cm in length, and those of the other about 0.5 cm in length; 3 pairs of legs attached on the ventral side of thorax, forelegs enlarged and sickle-shaped, midlegs and hindlegs slender; dorsal side of abdomen composed of 9 segments, central part of the ventral side long triangular and uneven like stairs; light and membranaceous in texture, and easy to smash.

Practically odorless and tasteless.

Total ash 〈*5.01*〉 Not more than 10.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 5.0%.

Containers and storage Containers—Well-closed containers.

センナジツ

Senna Pods

SENNAE FRUCTUS

Senna Pods are the fruits of *Cassia angustifolia* Vahl or *Cassia acutifolia* Delile (*Leguminosae*).

Senna Pods contain not less than 1.0% of total sennosides [sennoside A ($C_{42}H_{38}O_{20}$: 862.74) and sennoside B ($C_{42}H_{38}O_{20}$: 862.74)], calculated on the basis of dried material.

Description Reniform to oblong, flat legumes, 3 - 6 cm in length, 1 - 2.5 cm in width; outer surface margin, green-brown; central part containing seeds, brown to blackish brown; internally containing 6 to 8 seeds; seeds flat and triangular, and with a reticulate pattern under a magnifying glass.

Practically odorless and tasteless.

Identification To 1 g of pulverized Senna Pods add 20 mL of a mixture of tetrahydrofuran, methanol and dilute hydrochloric acid (16:4:1), shake for 5 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of Sennoside A RS or sennoside A for thin-layer chromatography in 1 mL of a mixture of tetrahydrofuran and water (7:3), and use this solution as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography ⟨*2.03*⟩. Spot 5 μL each of the sample solution and standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 1-propanol, ethyl acetate, water and acetic acid (100) (40:40:30:1) to a distance of about 7 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 365 nm): one spot among several spots obtained from the sample solution and a spot with red to dark red fluorescence obtained from the standard solution show the same color tone and the same R_f value.

Purity Foreign matter ⟨*5.01*⟩ —The amount of leaves, fruit axes and other foreign matter contained in Senna Fruit does not exceed 1.0%.

Loss on drying ⟨*5.01*⟩ Not more than 10.0% (6 hours).

Total ash ⟨*5.01*⟩ Not more than 8.0%.

Acid-insoluble ash ⟨*5.01*⟩ Not more than 2.0%.

Assay Proceed as directed in the Assay under Senna in JP.

Containers and storage Containers—Well-closed containers.

センナジツ末

Powdered Senna Pods

SENNAE FRUCTUS PULVERATUS

Powdered Senna pods are the powder of Senna Pods in Non-JPS.

Powdered Senna pods contain not less 1.0% of total sennoside [sennoside A ($C_{42}H_{38}O_{20}$: 862.74) and sennoside B ($C_{42}H_{38}O_{20}$: 862.74)], calculated on the basis of dried material.

Description Powdered Senna pods occur as a light green-brown to blackish brown powder.

Odor and taste are as directed in the Description under Senna Pods in Non-JPS.

Under a microscope 〈*5.01*〉, Powdered Senna pods reveal fragments of palisade-like external seed coat; fragments of fiber bundles with crystal cell row of endocarp; fragments of spiral vessels and reticulate vessels; rarely fragments of sclerenchyma cells with distinct pit, fragments of epidermis cells of pericarp with stomata, starch grains, solitary crystals of calcium oxalate and warty unicellular hairs.

Starch grains are simple, below 10 μm in diameter or compound grains.

Identification Proceed as directed in the Identification under Senna Pods in Non-JPS.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Senna Pods in Non-JPS.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Senna Pods in Non-JPS.

Acid-insoluble ash 〈*5.01*〉 Proceed as directed in the Acid-insoluble ash under Senna Pods in Non-JPS.

Assay Proceed as directed in the Assay under Senna in JP.

Containers and storage Containers—Tight containers.

センレンシ

Melia Fruit

MELIAE FRUCTUS

Melia Fruit is the fruit of Melia toosendan Siebold et *Zuccarini* or *Melia azedarach* Linné var. *subtripinnata* Miquel (*Meliaceae*).

Description Nearly globose, 1 - 3 cm in diameter; one end slightly dented, a small dot, corresponding with a scar of style on the other end; externally light yellow-green to brown, or light yellow to red-brown, lustrous, slightly dented or with wrinkles, and with spots of dark brown, yellow-brown or brown.

Odor, characteristic; taste, acid at first, followed by a bitterness.

Identification To 1 g of pulverized Melia Fruit add 10 mL of methanol, shake for 10 minutes, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, methanol and water (15:5:4) to a distance of about 7 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 365 nm): a fluorescent blue spot is observed at an R_f value of about 0.5 (Scopolin), and about 0.7 (Scopoletin).

Purity Foreign matter 〈*5.01*〉 —The amount of peduncle and other foreign matter contained in Melia Fruit does not exceed 1.0%.

Loss on drying 〈*5.01*〉 Not more than 14.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 5.5%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 15.0%.

Containers and storage Containers—Well-closed containers.

ソウジシ

Cocklebur Fruit

XANTHII FRUCTUS

Cocklebur Fruit is the pseudocarp of *Xanthium strumarium* Linné subsp. *sibiricum* Greuter (*Xanthium sibiricum* Patrin ex Widder), *Xanthium strumarium* Linné, *Xanthium orientale* Linné, *Xanthium orientale* Linné subsp. *italicum* Greuter or their interspecific hybrids (*Compositae*).

Description Achene, covered with involucre having many thorns; fusiform or ovoid, 1 -3 cm in length, 0.4 -2 cm in width including thorns, externally yellow brown to brown or grayish green, covered by many needle-shaped thorns, two bill-shaped big splinters at the apex; internally divided into 2 loculi by septum, each containing 1 achene; achene, nearly fusiform, a scar of the base of prominent style; pericarp, grayish black; seed, grayish yellow to grayish yellowish brown, vertical patterns on surface.

Practically odorless; taste, slightly bitter.

Identification To 0.5 g of pulverized Cocklebur Fruit add 5 mL of acetic anhydride, shake thoroughly, allow to stand for 2 minutes, and filter. To 1 mL of the filtrate add carefully 0.5 mL of sulfuric acid to make two layers: a red-brown color develops at the zone of contact.

Loss on drying 〈*5.01*〉 Not more than 12.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 5.5%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 3.0%.

Containers and storage Containers—Well-closed containers.

ソウズク

Alpinia Katsumadai Seed

ALPINIAE KATSUMADAI SEMEN

Alpinia Katsumadai Seed is the seed mass of *Alpinia Katsumadai* Hayata (*Zingiberaceae*).

Description Nearly spherical, 1.3 - 3 cm in diameter; externally grayish brown to brown; seed mass divided into 3 loculi by yellow thin membranes, each contains 25 to 110 seeds joining by aril; seed ovate and polygonal, 3 - 5 mm in length, 2.5 - 3 mm in diameter, externally light brown and covered with membranous aril, roundly concave hilum at one thick end and slightly concave chalaza at the other end, a longitudinal groove in each of ventral and dorsal surface; hard seed, seed section grayish white.

Characteristic aroma when cracked, and taste acrid and slightly bitter.

Identification To 1 g of pulverized Alpinia Katsumadai Seed add 5 mL of methanol, heat on a water bath for 5 minutes with occasional shaking, cool, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate and hexane (1:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly Iron (III) chloride-methanol TS on the plate: a yellow-brown spot is observed at an R_f value of about 0.4 (Cardamonin), and a brown spot is observed at an R_f value of about 0.55 (Pinocembrin).

Total ash 〈*5.01*〉 Not more than 5.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.5%.

Containers and storage Containers—Well-closed containers.

ダイフクヒ

Areca Pericarp

ARECAE PERICARPIUM

Areca Pericarp is the pericarp of *Areca catechu* Linné or *Areca dicksonii* Roxburgh (*Palmae*).

Description Fusiform to long ellipsoidal, usually longitudinally cut, 3 - 6 cm in length, 2.5 - 4 cm in diameter, and 0.2 - 0.8 cm in thickness; externally light grayish brown to dark brown, with longitudinal wrinkles; internally yellow-brown to dark brown, somewhat lustrous, usually with fine, longitudinal wrinkles; fractured surface remarkably fibrous; transverse section light yellow-brown, under a magnifying glass, group of fibers appears as light brown to dark brown spots.

Odor, slight and characteristic; practically tasteless.

Identification To 2 g of pulverized Areca Pericarp add 30 mL of water and 3 drops of hydrochloric acid, warm on a water bath for 5 minutes with occasional shaking, and filter. To 0.5 mL of the filtrate add 2.5 mL of calcium hydroxide TS: a yellow-red to orange-yellow color develops, and, when allowed to stand, a yellow-red to orange-yellow, flocculent precipitate is produced.

Loss on drying 〈*5.01*〉 Not more than 11.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 6.0%.

Containers and storage Containers—Well-closed containers.

タラコンピ

Aralia Elata Root Bark

ARALIAE RADICIS CORTEX

Aralia Elata Root Bark is the root bark of *Aralia elata* Seemann (*Araliaceae*).

Description Tubular to semi-tubular bark piece, 1.0 - 2.5 cm in thickness; externally light brown; periderm easily separable in fine scales; internally light brown; brittle in texture, and easily breakable.

Odor, slight; taste, slightly astringent.

Identification **(1)** To 0.1 g of pulverized Aralia Elata Root Bark add 10 mL of water, and shake vigorously: a lasting fine foam is produced.

(2) To 0.2 g of pulverized Aralia Elata Root Bark add 2 mL of acetic anhydride, warm on a water bath for 2 minutes, and filter. To the filtrate add gently 0.5 mL of sulfuric acid to make two layers: a red-brown color develops at the zone of contact.

Loss on drying 〈*5.01*〉 Not more than 13.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 9.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 2.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 17.0%.

Containers and storage Containers—Well-closed containers.

チクジョ

Bamboo Culm

BAMBUSAE CAULIS

Bamboo Culm is the inner layer of the culm of *Bambusa textilis* McClure, *Bambusa pervariabilis* McClure, *Bambusa beecheyana* Munro, *Bambusa tuldoides* Munro, *Phyllostachys nigra* Munro var. *henonis* Stapf ex Rendle or *Phyllostachys bambusoides* Siebold et Zuccarini (*Gramineae*).

Description Thin, cord-like, 0.5 - 3 mm in thickness, light yellow-white to grayish white or light green-brown; often formed spherical or in bundle; light in texture, fibrous and occasionally with exodermis.

Odorless; practically tasteless.

Identification **(1)** To 0.5 g of pulverized Bamboo Culm add 10 mL of acetone, warm on a water bath for 2 minutes with shaking, and filter. Evaporate the filtrate to dryness, dissolve the residue in 0.5 mL of acetic anhydride, and add 1 drop of sulfuric acid: a dark green-brown to brown color develops.

(2) To 0.5 g of pulverized Bamboo Culm add 10 mL of water, warm on a water bath for 2 minutes with shaking, and filter. To 1 mL of the filtrate add 1 mL of a solution of phenol (1 in 20), shake well, add 2 mL of sulfuric acid, and shake: a light brown to red-brown color develops.

Loss on drying 〈*5.01*〉 Not more than 11.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 3.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.5%.

Containers and storage Containers—Well-closed containers.

チクヨウ

Bamboo Leaf

PHYLLOSTACHYDIS FOLIUM

Bamboo Leaf is the leaf of *Phyllostachys nigra* Munro var. *henonis* Stapf ex Rendle, *Phyllostachys bambusoides* Siebold et Zuccarini, *Bambusa textilis* McClure or *Bambusa emeiensis* L.C. Chia et H.L. Fung (*Gramineae*).

Description Lanceolate, acute at apex, attenuate at base, 5 - 16 cm in length, 1 - 2 cm in diameter; upper surface blue-green to green; lower surface light greenish white, occasionally pubescent; with parallel veins, especially distinct in lower surface. Occasionally with petioles and twigs.

Practically odorless and tasteless.

Identification To 2 g of pulverized Bamboo Leaf add 30 mL of dilute hydrochloric acid, shake, heat in a boiling water bath for 20 minutes, cool, and filter. To the filtrate add 5 mL of diethyl ether, shake for 5 minutes, centrifuge, and use the diethyl ether layer as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, hexane and acetic acid (100) (20:20:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, heat at 105°C for 5 minutes: a red-purple spot is observed at an R_f value of about 0.4 (4-hydroxycinnamic acid).

Purity Lophatherum Herb—To 2 g of pulverized Bamboo Leaf add 30 mL of dilute hydrochloric acid, shake for 5 minutes, heat in a boiling water bath for 20 minutes, cool, and filter. To the filtrate add 5 mL of diethyl ether, shake, centrifuge, and use the diethyl ether layer as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 20 μL of the sample solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, water, and formic acid (10:1:1) to a distance of about 7 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): no unified spots are observed at an R_f value of 0.6 to 0.7 ((*E*)-aconitic acid).

Loss on drying 〈*5.01*〉 Not more than 13.5% (6 hours).

Total ash 〈*5.01*〉 Not more than 15.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 11.5%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 9.5%.

Containers and storage Containers—Well-closed containers.

チクレキ

Bamboo Sap

PHYLLOSTACHYDIS SUCCUS

Bamboo Sap is the sap flowing from the cut edge of *Phyllostachys nigra* Munro var. *henonis* Stapf ex Rendle or *Phyllostachys bambusoides* Siebold et Zuccarini (*Gramineae*) in roasting the culm.

Description Bamboo sap is a translucent light blue-yellow to yellow-brown liquid. It has a burnt odor and a slight taste.

Identification To 10 mL of Bamboo Sap add 10 mL of water and 5 mL of 1-butanol, shake, centrifuge, and use the 1-butanol layer as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, acetone, water and acetic acid (100) (10:6:3:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly vanillin-sulfuric acid-ethanol TS for spraying on the plate, and heat at 105°C for 5 minutes: a blue spot is observed at an R_f value of about 0.3.

Containers and storage Containers—Tight containers.

チャヨウ

Green Tea Leaf

CAMELLIAE SINENSIS FOLIUM

Green Tea Leaf is the leaf of *Camellia sinensis* Kuntze (*Theaceae*), often with twigs.

Description Rolled stick-like or contracted and wrinkled leaves or its broken ones, light green-brown to dark green in both surface. When smoothed by immersion in water, the lamina elliptically lanceolate, obtuse at apex, 5 - 9 cm in length, 2 - 4 cm in width, the margin, serrate; the base, broadly cuneate; petiole, 3 - 7 mm in length. Under a magnifying glass, appressed hairs occasionally observed. Stems of twigs cylindrical, 0.5 - 3.5 cm in length, 0.4 - 1.5 mm in diameter, externally yellow-green to green, or dark green.

Odor, characteristic; taste, astringent and bitter.

Identification To 1 g of pulverized Green Tea Leaf add 10 mL of methanol, shake for 10 minutes, centrifuge, and use the supernatant liquid as the sample solution. Separately, dissolve 1 mg of Caffeine Hydrate in 1 mL of methanol, and use this solution as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL each of the sample solution and standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, acetone and formic acid (10:2:1) to a distance of about 7 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): one spot among several spots obtained from the sample solution and a spot obtained from the standard solution show the same color tone and the same R_f value, and spray evenly iron (III) chloride TS on the plate: a blue-purple to dark purple spot is observed at an R_f value of about 0.6 (Epigallocatechin 3-*O*-gallate).

Loss on drying 〈*5.01*〉 Not more than 9.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 7.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Extract content 〈*5.01*〉 Dilute ethanol-insoluble extract: not less than 27.0%.

Containers and storage Containers—Well-closed containers.

チョウトウコウエキス
Uncaria Hook Extract

Uncaria Hook Extract is used as the manufacturing material for single crude drug extract preparation.

Uncaria Hook Extract contains not less than 0.06% of total alkaloids (rhynchophylline and hirsutine).

Method of preparation Pulverize Uncaria Hook in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP to prepare a dry extract.

Description Uncaria Hook Extract is yellowish red-brown to dark red-brown powder; Odor, characteristic; taste, slightly sweet, astringent and slightly bitter.

It dissolves in water with a slight turbidity.

Identification To 0.1 g of Uncaria Hook Extract add 20 mL of methanol, heat under a reflux condenser for 5 minutes, and filter. Evaporate the filtrate to dryness, add 1 mL of dilute acetic acid to the residue, heat on a water bath for 1 minute, and filter after cooling. Spot 1 drop of the filtrate to a filter paper, air-dry, spray Dragendorff's TS for spraying on it, and allow to stand: a yellow-red color develops.

Purity (1) Heavy metals 〈*1.07*〉 —Prepare the test solution with 1.0 g of Uncaria Hook Extract as directed in the Extract (4) under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

(2) Arsenic 〈*1.11*〉 —Prepare the test solution with 0.67 g of Uncaria Hook Extract according to Method 3, and perform the test (not more than 3 ppm).

Loss on drying 〈*2.41*〉 Not more than 10.0% (1 g, 105°C, 5 hours).

Total Ash 〈*5.01*〉 Not more than 20.0% (1 g).

Assay Weigh accurately about 0.5 g of Uncaria Hook Extract, add 40 mL of a mixture of methanol and dilute acetic acid (7:3), sonicate for 30 minutes, add a mixture of methanol and dilute acetic acid (7:3) to make exactly 50 mL, and use this solution as the standard solution. Separately, weigh accurately about 5 mg of rhynchophylline for assay, previously dried in a desiccator (silica gel) for 24 hours, dissolve in a mixture of methanol and dilute acetic acid (7:3) to make exactly 100 mL, and use this solution as the standard stock solution (1). Separately, weigh accurately about 5 mg of hirsutine for assay, previously dried in a desiccator (silica gel) for 24 hours, dissolve in a mixture of methanol and dilute acetic acid (7:3) to make exactly 100 mL, and use this solution as the standard stock solution (2). Pipet 10 mL each of the standard stock solution (1) and (2), mix, add a mixture of methanol and dilute acetic acid (7:3) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 20 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉 according to the

following conditions, and determine the peak areas of rhyncophylline and hirsutine, A_{TR} and A_{TH}, and A_{SR} and A_{SH}, in each solution.

Amount (mg) of the total alkaloid (rhyncophylline and hirsutine)
$= M_{SR} \times A_{TR}/A_{SR} \times 1/20 + M_{SH} \times A_{TH}/A_{SH} \times 1/20$

M_{SR}: Amount (mg) of rhyncophylline for assay taken
M_{SH}: Amount (mg) of hirsutine for assay taken

Operating conditions—
Detector: An ultraviolet absorption photometer (wavelength: 245 nm).
Column: A stainless steel column 4.6 mm in inside diameter and 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).
Column temperature: A constant temperature of about 40°C.
Mobile phase: Dissolve 3.85 g of ammonium acetate in 200 mL of water, add 10 mL of acetic acid (100) and water to make 1000 mL, and add 350 mL of acetonitrile.
Flow rate: Adjust so that the retention time of rhynchophylline is about 17 minutes.

System suitability—
System performance: To 5 mL of the standard stock solution (1) add 1 mL of ammonia solution (28), and reflux for 10 minutes or warm at about 50°C for 2 hours. After cooling, to 1 mL of the solution obtained add a mixture of methanol and dilute acetic acid (7:3) to make 5 mL. When the procedure is run with 20 μL of this solution under the above operating conditions, the peak of isorhynchophylline appears in addition to the peak of rhynchophylline, and the resolution between these peaks is not less than 1.5.
System repeatability: Pipet 10 mL of the standard stock solution (1), add a mixture of methanol and dilute acetic acid (7:3) to make exactly 100 mL. When the test is repeated 6 times with 20 μL of this solution under the above operating conditions, the relative standard deviation of the peak areas of rhynchophylline is not more than 1.5%.

Containers and storage Containers—Tight containers.

チンピ末

Powdered Citrus Unshiu Peel

CITRI UNSHIU PERICARPIUM PULVERATUM

Powdered Citrus Unshiu Peel is the powder of Citrus Unshiu Peel in JP.

Assay standard of Powdered Citrus Unshiu Peel: proceed as directed in the Assay standard under Citrus Unshiu Peel in JP.

Description Powdered Citrus Unshiu Peel occurs as a light grayish yellow to yellow-brown powder.

Odor and taste are as directed in the Description under Citrus Unshiu Peel in JP.

Under a microscope 〈*5.01*〉, Powdered Citrus Unshiu Peel reveals fragments of light yellowish parenchyma and colorless parenchyma; fragments of epidermis composed of polygonal epidermal cells; fragments of spiral vessels, annular vessels, scalariform vessels, reticulate vessels, and pitted vessels, vessels 10 - 30 μm in diameter; round and yellow solid substances; solitary crystals of calcium oxalate usually 5 - 30 μm in diameter, solitary crystals of calcium oxalate rarely lined in a raw forming a crystal cell row.

Identification Proceed as directed in the Identification under Citrus Unshiu Peel in JP.

Purity Total BHC's and total DDT's 〈*5.01*〉—Proceed as directed in the Purity under Citrus Unshiu Peel in JP.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Citrus Unshiu Peel in JP.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Citrus Unshiu Peel in JP.

Extract content 〈*5.01*〉 Proceed as directed in the Extract content under Citrus Unshiu Peel in JP.

Assay Proceed as directed in the Assay under Citrus Unshiu Peel in JP.

Containers and storage Containers—Tight containers.

チンピエキス

Citrus Unshiu Peel Extract

Citrus Unshiu Peel Extract is used as the manufacturing material for single crude drug extract preparation.

Citrus Unshiu Peel Extract contains not less than 1.8 ～ 4.6% of hesperidin.

Method of preparation Pulverize Citrus Unshiu Peel in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP to prepare a dry extract.

Description Citrus Unshiu Peel Extract is light yellow to light yellow-brown powder; Odor, characteristic; taste, sweet followed by a slight bitterness and mucous, sometimes pungent.

It dissolves in water with a slight turbidity.

Identification Use the sample solution and the standard solution obtained in the Assay as the sample solution and the standard solution, respectively. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography ⟨*2.01*⟩ according to the same conditions as those in the Assay: one of the two main peaks in the chromatogram obtained from the sample solution shows the same retention time with the peak of narindin in the chromatogram obtained from the standard solution. Another peak shows the relative retention time of about 0.7 to the peak corresponding to narindin (narirutin).

Purity **(1)** Heavy metals ⟨*1.07*⟩ —Prepare the test solution with 1.0 g of Citrus Unshiu Peel Extract as directed in the Extract **(4)** under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

(2) Arsenic ⟨*1.11*⟩ —Prepare the test solution with 0.67 g of Citrus Unshiu Peel Extract according to Method 3, and perform the test (not more than 3 ppm).

Loss on drying ⟨*2.41*⟩ Not more than 10.0% (1 g, 105°C, 5 hours).

Total ash ⟨*5.01*⟩ Not more than 6.2% (1 g).

Assay Weigh accurately about 0.1 g of Citrus Unshiu Peel Extract, add 50 mL of diluted tetrahydrofuran (1 in 4), shake for 30 minutes, centrifuge, and use the supernatant liquid as the sample solution. Separately, weigh accurately about 10 mg of hesperidin for assay, previously dried in a desiccator (silica gel) for 24 hours, dissolve in methanol to make exactly 100 mL. Pipet 10 mL of this solution, add diluted tetrahydrofuran (1 in 4) to make exactly 20 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography ⟨*2.01*⟩ according to the following conditions. Determine the peak areas, A_T and A_S, of hesperidin in each solution.

Amount (mg) of hesperidin taken

$= M_S \times A_T / A_S \times 1/4$

M_S: Amount (mg) of hesperidin taken

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 285 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: A mixture of water, acetonitrile and acetic acid (100) (82:18:1).

Flow rate: Adjust so that the retention time of hesperidin is about 15 minutes.

System suitability—

System performance: Dissolve 1 mg each of hesperidin for assay and naringin for thin-layer chromatography in methanol to make 10 mL. Pipet 5 mL of this solution, add diluted tetrahydrofuran (1 in 4) to make exactly 10 mL. When the procedure is run with 10 μL of this solution under the above operating conditions, naringin and hesperidin are eluted in this order with the resolution between these peaks being not less than 1.5.

System repeatability: When the test is repeated with 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of hesperidin is not more than 1.5%.

Containers and storage Containers—Tight containers.

テンナンショウ

Arisaema Tuber

ARISAEMATIS TUBER

Arisaema Tuber is the tuber of *Arisaema heterophyllum* Blume, *Arisaema erubescens* Schott, *Arisaema amurense* Maximowicz or other species of the same genus (*Araceae*), from which the cork layer is removed.

Description Slightly flattened spherical to irregular-shaped, 0.7 - 3.5 cm in diameter, 0.7 - 2 cm in height; externally whitish or light grayish brown to light brown; the upper end dented, where the stem removed, with root scars dented as numerous small spots on the circumference; hard in texture; cut surface whitish and powdery.

Practically odorless; taste, mild at first, followed by an acrid taste.

Under a microscope 〈*5.01*〉, a transverse section reveals mainly parenchyma cells filled with starch grains, and mucilage canals and mucilage cells containing raphides of calcium oxalate are observed.

Identification **(1)** To 0.5 g of pulverized Arisaema Tuber add 10 mL of water, and shake vigorously: a lasting fine foam is produced.

(2) To 0.2 g of pulverized Arisaema Tuber add 2 mL of acetic anhydride, warm on a water bath for 2 minutes, and filter. To the filtrate add gently 0.5 mL of sulfuric acid to make two layers: a light brown color develops at the zone of contact.

(3) To the cut surface of Arisaema Tuber spot dilute iodine TS dropwise: a dark blue-purple color develops.

Loss on drying 〈*5.01*〉 Not more than 13.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 5.0%.

Containers and storage Containers—Well-closed containers.

トウシンソウ

Common Rush

JUNCI HERBA

Common Rush is 1) the terrestrial part or sometimes 2) the pith only of stem of *Juncus effusus* Linné (Tohsin) (*Juncaceae*).

Description 1) Terrestrial part: stem usually transversely cut, slender and cylindrical, 1 - 3 mm in diameter; externally light yellow-green to brown, with many longitudinal lines; under a magnifying glass a transversely cut surface of stem reveals almost circular, the center portion spongy like and white, the peripheral portion fibrous and light yellow-green to light brown.

Odor, slight; practically tasteless.

Under a microscope 〈*5.01*〉, a transverse section of stem reveals epidermis one-cell layered and covered with cuticle, fiber bundles occur only beneath epidermis of protruded part of stem, the other portion beneath epidermis is composed of parenchyma of 2 or 3 cells layered; numerous collateral vascular bundles arranged in 2 or 3 wholes, the inner vascular bundles larger than the outer ones, vascular bundle sheath composed of fibers occurring outside of phloem and xylem, sometimes vascular bundle sheath surrounds vascular bundles; usually only parenchyma cells around vascular bundle sheath persist and form bridges between vascular bundles; pith consists of star shaped parenchyma cells with 4 - 8 protuberances, star shaped parenchyma cells connect with one another and form a network system, cell walls of connective parts of cells thickened and look like a string of beads.

2) Pith of stem (Tohsin): slender and cylindrical, 1 - 3 mm in diameter; externally white to yellow-white, with longitudinal furrows, soft, easily torn off when pull; cut surface white to yellow-white, spongy.

Practically odorless and tasteless.

Under a microscope 〈*5.01*〉, a transverse section of pith reveals star shaped parenchyma cells with 4 - 8 protuberances, star shaped parenchyma cells connect with one another and form a network system, cell walls of connective parts of cells thickened and look like a string of beads.

Identification To 1 g of pulverized Common Rush add 20 mL of methanol, shake for 10 minutes, and filter. Evaporate the filtrate to dryness under low pressure (in vacuo), dissolve the residue in 1 mL of methanol, and use this solution as the sample solution. Separately, dissolve 1 mg of luteolin 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 Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL each of the sample solution and standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, 2-butanone, water and formic acid (25:3:1:1) to a distance of about 7 cm, and air-dry the plate.

Examine under ultraviolet light (main wavelength: 365 nm): a fluorescent bluish white spot is observed at an R_f value of about 0.4 (Luteolin 3',5-dimethyl ether). When spray evenly iron (III) chloride-methanol TS on the plate: one spot among several spots obtained from the sample solution and a spot obtained from the standard solution show the same color tone and the same R_f value.

Loss on drying 〈*5.01*〉 Not more than 13.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 7.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.5%.

Containers and storage Containers—Well-closed containers.

トウドクカツ

Angelica Pubescens Root

ANGELICAE PUBESCENTIS RADIX

Angelica Pubescens Root is the root of *Angelica pubescens* Maximowicz or *Angelica biserrata* Shan et Yuan (*Umbelliferae*).

Description A short main root with branched long roots, nearly fusiform, 10 - 20 cm in length, externally brown to dark brown; the crown, with ring-nodes closely protruded, and with a few remains of stem and leaf sheath; the root, with longitudinal wrinkles, and with numerous scars of rootlets laterally elongated and protruded; somewhat flexible in texture; under a magnifying glass, a transversely cut surface light brown to dark brown; the resin canals, dark brown and almost concentrically arranged.

Odor, characteristic; taste, bitter and acrid.

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

Purity Under a microscope 〈*5.01*〉, the transverse section of Angelica Pubescens Root reveals no cork stone cell and clustered crystal of calcium oxalate.

Loss on drying 〈*5.01*〉 Not more than 15.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 9.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Containers and storage Containers—Well-closed containers.

トウヒ末

Powdered Bitter Orange Peel

AURANTII PERICARPIUM PULVERATUM

Powdered Bitter Orange Peel is the powder of Biter Orange Peel in JP.

Description Powdered Bitter Orange Peel occurs as a light yellow-brown to yellow-brown powder.

Odor and taste are as directed in the Description under Biter Orange Peel in JP.

Under a microscope 〈*5.01*〉, Powdered Bitter Orange Peel reveals fragments of light yellowish parenchyma and colorless parenchyma; fragments of epidermis composed of polygonal epidermal cells; fragments of spiral vessels, annular vessels, scalariform vessels, reticulate vessels, and pitted vessels, vessels 10 - 30 μm in diameter; solitary crystals of calcium oxalate usually 5 - 30 μm in diameter, solitary crystals of calcium oxalate rarely lined in a raw forming a crystal cell row.

Identification Proceed as directed in the Identification under Bitter Orange Peel in JP.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Bitter Orange Peel in JP.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Bitter Orange Peel in JP.

Acid-insoluble ash 〈*5.01*〉 Proceed as directed in the Acid-insoluble ash under Bitter Orange Peel in JP.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 25.0%.

Containers and storage Containers—Tight containers.

ドベッコウ

Soft Shell Turtle Carapace

AMYDAE TESTUDO

Soft Shell Turtle Carapace is the back shell of *Amyda japonica* Temmink et Schlegel or *Amyda sinensis* Wiegmann (*Trionychidae*).

Description Asymmetrically plate-like and curved, broadly elliptical to orbicular-ovate, 10 - 20 cm in length, 7 - 15 cm in width, 1.5 - 3 mm in thickness; externally blackish brown to blackish green; middle part of the shell slightly swollen due to backbone, rib-like lines and fine wrinkles on both sides; internally whitish; backbone situated at the middle position, 8 pairs of ribs projecting towards lateral direction; corneous and hard in texture, easy to break.

Odor, characteristic; practically tasteless.

Containers and storage Containers—Well-closed containers.

ナンテンジツ

Nandina Fruit

NANDINAE FRUCTUS

Nandina Fruit is the fruit of *Nandina domestica* Thunberg forma *leucocarpa* Makino or *Nandina domestica* Thunberg (*Berberidaceae*).

Description Globose, 7 - 9 mm in diameter; externally light yellow to light grayish brown or reddish brown; protrusion of residue of style at the upper part, and dotted scars of peduncles at the lower part; pericarp thin and easily breakable; internally having 2 or 3 hard seeds.

Practically odorless; taste, slightly bitter.

Identification To 1 g of pulverized Nandina Fruit add 10 mL of dilute acetic acid, heat on a water bath for 5 minutes, cool, and filter. Spot 1 drop of the filtrate to a filter paper, air-dry, spray evenly Dragendorff's TS for spraying on it, and allow to stand: a yellow-red color develops.

Purity Foreign matter 〈*5.01*〉 —The amount of peduncles and other foreign matter contained in Nandina Fruit does not exceed 1.0%.

Total ash 〈*5.01*〉 Not more than 5.0%.

Containers and storage Containers—Well-closed containers.

ニクズク末

Powdered Nutmeg

MYRISTICAE SEMEN PULVERATUM

Powdered Nutmeg is the powder of Nutmeg in JP.

Description Powdered Nutmeg occurs as a light brown to red-brown powder.

Odor and taste are as directed in the Description under Nutmeg in JP.

Under a microscope 〈*5.01*〉, Powdered Nutmeg reveals parenchyma containing red-brown to dark red-brown masses; simple or compound starch grains, aleurone grains, and crystals of calcium oxalate; rarely spiral vessels.

Identification Proceed as directed in the Identification under Nutmeg in JP.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Nutmeg in JP.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Nutmeg in JP.

Essential oil content 〈*5.01*〉 Perform the test with 10.0 g of Powdered Nutmeg: the volume of essential oil is not less than 0.3 mL.

Containers and storage Containers—Tight containers.

ニンジンエキス

Ginseng Extract

Ginseng Extract is used as the manufacturing material for single crude drug extract preparation.

Ginseng Extract contains not less than 0.10% of ginsenoside Rg_1 ($C_{42}H_{72}O_{14}$: 801.01) and not less than 0.20% of ginsenoside Rb_1 ($C_{54}H_{92}O_{23}$: 1109.29).

Method of preparation Pulverize Ginseng in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP to prepare a dry extract.

Description Ginseng Extract is light grayish yellow to light brown powder; Odor, characteristic; taste, slightly sweet at first, followed by slight bitterness, sometimes acid.

It dissolves in water with a slight turbidity.

Identification To 0.5 g of Ginseng Extract add 10 mL of methanol, shake, centrifuge, and use the supernatant liquid as the sample solution. Separately, dissolve 1 mg of ginsenoside Rg_1 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 Thin-layer Chromatography *〈2.03〉*. Spot 5 μL of the sample solution and 2 μL of 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 (14:5:4) to a distance of about 7 cm, and air-dry the plate. Spray evenly vanillin-sulfuric acid-ethanol TS for spraying on the plate, and heat at 105°C for 10 minutes: one of the spot among the several spots obtained from the sample solution has the same color tone and R_f value with the spot obtained from the standard solution.

Purity **(1)** Heavy metals *〈1.07〉* —Prepare the test solution with 1.0 g of Ginseng Extract as directed in the Extract **(4)** under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

(2) Arsenic *〈1.11〉* —Prepare the test solution with 0.67 g of Ginseng Extract according to Method 3, and perform the test (not more than 3 ppm).

Loss on drying *〈2.41〉* Not more than 11.0% (1 g, 105°C, 5 hours).

Total ash *〈5.01〉* Not more than 9.0% (1 g)

Assay (1) Ginsenoside Rg_1—Weigh accurately about 0.15 g of Ginseng Extract, add 15 mL of diluted methanol (3 in 5), shake for 15 minutes, centrifuge, and separate the supernatant liquid. Repeat the procedure with the residue using 7.5 mL of diluted methanol (3 in 5), combine the supernatant liquids, and add diluted methanol (3 in 5) to make exactly 25 mL. Pipet 10 mL of this solution, add 3 mL of dilute sodium hydroxide TS, allow to stand for 30 minutes, add 3 mL of 0.1 mol/L hydrochloric acid TS, and add diluted methanol (3 in 5) to make exactly 20 mL. Use this solution as the sample solution. Separately, weigh accurately about 10 mg of Ginsenoside Rg_1 RS

(separately determine the water ⟨*2.48*⟩ by coulometric titration, using 10 mg) dissolve in diluted methanol (3 in 5) to make exactly 25 mL. Use this solution as the standard stock solution. Pipet 2 mL of the standard stock solution, add methanol to make exactly 50 mL, and use this solution as the standard solution. Perform the test with exactly 20 μL each of the sample solution and standard solution as directed under Liquid Chromatography ⟨*2.01*⟩ according to the following conditions, and determine the peak areas, A_T and A_S, of ginsenoside Rg_1 in each solution.

Amount (mg) of ginsenoside Rg_1 ($C_{42}H_{72}O_{14}$)
$= M_S \times A_T/A_S \times 2/25$

M_S: Amount (mg) of ginsenoside Rg_1 RS taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorptionphotometer (wavelength: 203 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (3 μm in particle diameter).

Column temperature: A constant temperature of about 30°C.

Mobile phase: diluted acetonitrile (1 in 5).

Flow rate: 1.0 mL per minute.

System suitability—

System performance: To 1 mg of ginsenoside Re add 4 mL of the standard stock solution and add diluted methanol (3 in 5) to make exactly 100 mL. When the procedure is run with 20 μL of this solution under the above operating conditions, ginsenoside Rg_1 and ginsenoside Re are eluted in this order with the resolution between these peaks being not less than 1.5.

System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of ginsenoside Rg_1 is not more than 1.5%.

(2) Ginsenoside Rb_1—Weigh accurately about 0.15 g of Red Ginseng Extract, add 30 mL of diluted methanol (3 in 5), shake for 15 minutes, centrifuge, and separate the supernatant liquid. Repeat the procedure with the residue using 15 mL of diluted methanol (3 in 5), combine the supernatant liquids, and add diluted methanol (3 in 5) to make exactly 50 mL. Pipet 10 mL of this solution, add 3 mL of dilute sodium hydroxide TS, allow to stand for 30 minutes, add 3 mL of 0.1 mol/L hydrochloric acid TS, and add water to make exactly 20 mL. Apply exactly 5 mL of this solution to a column (about 10 mm in inside diameter and packed with 0.36 g of octadecylsilanized silica gel for pre-treatment (55 – 105 mm in particle size), washed just before use with methanol and then with diluted methanol (3 in 10)), and wash the column in sequence

with 2 mL of diluted methanol (3 in 10), 1 mL of sodium carbonate TS and 10 mL of diluted methanol (3 in 10). Finally, elute with methanol to collect exactly 5 mL, and use this as the sample solution. Separately, weigh accurately about 10 mg of Ginsenoside Rb_1 RS (separately determine the water 〈*2.48*〉 by coulometric titration, using 10 mg), and dissolve in methanol to make exactly 50 mL. Pipet 4 mL of this solution, add methanol to make exactly 20 mL, and use this solution as the standard solution. Perform the test with exactly 20 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉 according to the following conditions, and determine the peak areas, A_T and A_S, of ginsenoside Rb_1 in each solution.

Amount (mg) of ginsenoside Rb_1 ($C_{54}H_{92}O_{23}$)
$= M_S \times A_T / A_S \times 2/5$

M_S: Amount (mg) of ginsenoside Rb_1 RS taken, calculated on the anhydrous basis

Operating conditions—

Detector: An ultraviolet absorptionphotometer (wavelength: 203 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 25 cm in length, packed with carbamoyl groups bound silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 60°C.

Mobile phase: A mixture of acetonitrile, water and phosphoric acid (400:100:1).

Flow rate: 1.0 mL per minute.

System suitability—

System performance: When the procedure is run with 20 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of ginsenoside Rb_1 are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 20 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of ginsenoside Rb_1 is not more than 1.5%.

Containers and storage Containers—Tight containers.

バイモ末

Powdered Fritillaria Bulb

FRITILLARIAE BULBUS PULVERATUS

Powdered Fritillaria Bulb is the powder of Fritillaria Bulb in JP.

Description Powdered Fritillaria Bulb occurs as white to light yellow-brown powder.

Odor and taste are as directed in the Description under Fritillaria Bulb in JP.

Under a microscope 〈*5.01*〉, Powdered Fritillaria Bulb reveals parenchyma cells containing starch grains and solitary crystals of calcium oxalate and fragments of them; fragments mainly of spiral vessels, 10 - 40 μm in diameter; starch grains are mainly simple (rarely 2- to 3-compound), 5 - 60 μm in diameter, narrowly ovate to ovate or triangular-obovate, stratiform figure obvious; solitary crystals of calcium oxalate, 2 or 30 μm in diameter.

Identification Proceed as directed in the Identification under Fritillaria Bulb in JP.

Purity **(1)** Heavy metals 〈*1.07*〉 —Proceed as directed in the Purity under Fritillaria Bulb in JP.

(2) Arsenic 〈*1.11*〉 —Proceed as directed in the Purity under Fritillaria Bulb in JP.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Fritillaria Bulb in JP.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Fritillaria Bulb in JP.

Acid-insoluble ash 〈*5.01*〉 Proceed as directed in the Acid-insoluble ash under Fritillaria Bulb in JP.

Extract content 〈*5.01*〉 Proceed as directed in the Extract content under Fritillaria Bulb in JP.

Containers and storage Containers—Tight containers.

ハトムギ

Coix Fruit with Involucre

COICIS FRUCTUS CUM INVOLUCRIS

Coix Fruit with Involucre is the caryopsis covered with involucre of *Coix lachrymajobi* Linné var. *mayuen* Stapf (*Gramineae*).

Description Nearly ovoid-globose, 7 - 14 mm in length, 5 - 9 mm in width, 4 - 8 mm in thickness; externally blackish brown to grayish brown; lustrous, with fine longitudinal stripes; the upper end slightly pointed with 1 oblique pore nearby; a scar of gynophore at the other end; involucre can be broken with nail; in involucre peduncle of male spicule, membranaceous scales, 2 degenerated spicules, and one fruit covered with five, light grayish brown to light yellow, lustrous, and membranaceous envelopes; fruit light brown to red-brown, hard in texture.

Practically odorless; involucre is tasteless, fruit is slightly sweet and sticky on chewing.

Under a microscope 〈*5.01*〉, a transverse section of involucre reveals outermost layer of abaxial side is epidermis, sclerenchyma beneath epidermis; vascular bundle with fiber bundle scattered in the inner portion of sclerenchyma; fibers arranged horizontally inside the sclerenchyma; outermost layer of adaxial side is epidermis; a transverse section of central part of fruit reveals outermost part is pericarp composed of cells with thin cell wall, and seed coat; scutellum lays along ventral furrow, plumule sheath or hypocotyle observed in the center; albumen surrounding scutellum at dorsal side, parenchyma cells of albumen contain starch grains.

Purity Cut transversely 20 pieces of Coix Fruit with Involucre, macerate in diluted iodine TS (1 in 10) for 5 seconds, take out them, swab the excess test solution, and observe the cut surface: a dark red-brown color develops, of which not more than 6 pieces develop blue-purple color. If 7 or 8 pieces develop blue-purple color, repeat the test with further 40 samples in the same manner, and of which not more than 12 pieces develop blue-purple color: it meets the requirement.

Loss on drying 〈*5.01*〉 Not more than 14.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 8.0%.

Containers and storage Containers—Well-closed containers.

ハンピ

Hampi

GLOYDII MUSCULUS ET OS

Hampi is the body of *Gloydius blomhoffii* H. Boie, *Glyodius brevicaudus* or congeners (*Viperidae*) (Hampi 1), or of *Ptyas dhumnades* Cantor or congeners (*Colubridae*) (Hampi 2), from which the skin and internal organ are removed.

Description 1) Hampi 1: Composed of head, torso and tail, slimline and nearly semi-tubular, 30 - 100 cm in length, 1.5 - 3 cm in width; head nearly ovoid covered with scale, brown to black, caving in between eyes and nasal cavity; mouth deeply split, tooth lined; two long solenoglyphic teeth in front edge of maxilla; many opposite ribs in arc arranged in semi-tubular, covered with muscle, light yellow-brown to brown; tail nearly cylindrical, gradually tapering.

Odor, characteristic; practically tasteless.

2) Hampi 2: Composed of head, torso and tail, slimline and nearly semi-tubular, 50 - 250 cm in length, 0.6 - 3.5 cm in width; head nearly ovoid covered with scale, brown to black, no caving in between eyes and nasal cavity; eyes deeply sunken; mouth deeply split, tooth lined; many opposite ribs in arc and extremely raised backbones arranged in semi-tubular, covered with muscle, light yellow-brown to brown; tail nearly cylindrical, gradually tapering.

Odor, characteristic; practically tasteless.

Identification To 2 g of pulverized Hampi add 20 mL of methanol, shake for 5 minutes, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉.

Spot 20 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of water, ethanol (99.5) and ethyl acetate (1:1:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly ninhydrin TS on the plate, and heat at 105°C for 5 minutes: one or two red-purple spots are observed at an R_f value of about 0.7.

Loss on drying 〈*5.01*〉 Not more than 13.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 40.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 8.0%.

Containers and storage Containers—Well-closed containers.

ヒシノミ

Water Chestnut

TRAPAE FRUCTUS

Water Chestnut is the fruit of *Trapa japonica* Flerow, T*rapa incisa* Siebold et Zuccarini or *Trapa japonica* Flerow var. *rubeola* Ohwi (*Trapaceae*).

Description A slightly flat, depressed, triangular drupe, 3 - 6 cm in length, with 2 to 4 pointed prickly protuberances; externally blackish brown in color; hard pericarp; fruit containing 1 seed.

Practically odorless; inner part has a slightly characteristic taste on chewing.

Identification To 0.5 g of pulverized Water Chestnut add 2 mL of acetic anhydride, shake well, allow to stand for 2 minutes, and filter. To the filtrate add gently 1 mL of sulfuric acid to make two layers: a red-brown color develops at the zone of contact, and a blue-green color develops in the upper layer.

Loss on drying 〈*5.01*〉 Not more than 15.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 4.5%.

Containers and storage Containers—Well-closed containers.

ビャッキョウサン

Stiff Silkworm

BOMBYX BATRYTICATUS

Stiff Silkworm is the stiff larva of *Bombyx mori* Linné (*Bombycidae*), infected with *Beauveria bassiana* Vuillemin (*Cordycepitaceae*).

Description Cylindrical, narrow in places, and sometimes curved; 2 - 5 cm in length, 0.3 - 1.0 cm in diameter; externally covered with whitish to yellow-white powder, easily breakable, fractured surface of middle portion lustrous and blackish green to blackish brown.

Odor, characteristic; taste, slightly salty.

Identification To 0.5 g of pulverized Stiff Silkworm add 10 mL of methanol, shake or sonicate for 10 minutes, centrifuge, and use the supernatant liquid as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (7:3) to a distance of about 7 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 365 nm): a fluorescent bluish white spot is observed at an R_f value of about 0.45.

Loss on drying 〈*5.01*〉 Not more than 13.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 8.5%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 18.0%.

Containers and storage Containers—Well-closed containers.

ボウイ末

Powdered Sinomenium Stem and Rhizome

SINOMENI CAULIS ET RHIZOMA PULVERATUM

Powdered Sinomenium Stem and Rhizome is the powder of Sinomenium Stem and Rhizome in JP.

Description Powdered Sinomenium Stem and Rhizome occurs as a light brown to dark brown powder.

Odor and taste are as directed in the Description under Sinomenium Stem and Rhizome in JP.

Under a microscope 〈*5.01*〉, Powdered Sinomenium Stem and Rhizome reveals usually round to polygonal stone cells with remarkably thick-walled, starch grains and small needle crystals of calcium oxalate, parenchyma cells and fragments of them; fragments of reticulate vessels and pitted vessels, 20 - 160 μm in diameter; fibers or fiber bundles, 5 - 40 μm in diameter; starch grains are mainly simple, 3 - 20 μm in diameter; small needle crystals of calcium oxalate, 3 - 30 μm in length.

Identification Proceed as directed in the Identification under Sinomenium Stem and Rhizome in JP.

Loss on drying 〈*5.01*〉 Not more than 11.0% (6 hours).

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Sinomenium Stem and Rhizome in JP.

Acid-insoluble ash 〈*5.01*〉 Proceed as directed in the Acid-insoluble ash under Sinomenium Stem and Rhizome in JP.

Containers and storage Containers—Tight containers.

ホップ
Hop Strobile
LUPULI STROBILUS

Hop Strobile is the mature cone-shaped spike of *Humulus lupulus* Linné (*Moraceae*).

Description Broad-ovoid to globose, 2 - 5 cm in length, 2 - 3 cm in diameter, and yellow-green or green-brown; spike consists of a rachis bearing bract and bracteoles for every pedicel; bract and bracteole overlapping to form cone-shape, easily shed from the rachis; bract ovate, 0.8 - 3 cm in length, 0.5 - 1 cm in width, membranous with distinct veins on adaxial side; bracteole inside the bract is ovate, somewhat smaller than the bract, thin, and enclosing an achene at the basal part; the basal part of bract and bracteole and whole achene covered with a number of orange-yellow to brown glandular trichomes.

Odor, characteristic aroma; taste, bitter.

Under a microscope 〈*5.01*〉, the surface view of bract and bracteole reveals that epidermal cells have sinuous anticlinal walls, attached by glandular trichomes and unicellular hairs; parenchyma of mesophyll contains clustered crystals of calcium oxalate, below 30 μm in diameter; glandular trichome multicellular, with a cup-shaped or spherical head of 100 - 250 μm in diameter, filled with secretions.

Identification To 1 g of pulverized Hop Strobile add 10 mL of methanol, shake for 20 minutes, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, hexane and acetic acid (100) (7:7:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly potassium hydroxide-ethanol TS on the plate: a yellow spot is observed at an R_f value of about 0.4 (Xanthohumol).

Purity Foreign matter 〈*5.01*〉—The amount of stems, leaves, and other foreign matter contained in Hop Strobile does not exceed 2.0%.

Loss on drying 〈*5.01*〉 Not more than 15.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 14.5%.

Acid-insoluble ash 〈*5.01*〉 Not more than 5.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 20.0%.

Containers and storage Containers—Well-closed containers.

マオウ末

Powdered Ephedra Herb

EPHEDRAE HERBA PULVERATA

Powdered Ephedra Herb is the powder of Ephedra Herb in JP.

Assay standard of Powdered Ephedra Herb: proceed as directed in the Assay standard under Ephedra Herb in JP.

Description Powdered Ephedra Herb occurs as a light grayish green to dark brown powder.

Odor and taste are as directed in the Description under Ephedra Herb in JP.

Under a microscope 〈*5.01*〉, Powdered Ephedra Herb reveals brown and colorless fragments of parenchyma, epidermis consisting of rectangle epidermal cells, fibers, fiber bundles, fragments of spiral vessels, pitted vessels, vessels usually 5 - 25 μm in diameter, sometimes fragments of tracheid; solitary and sand crystals of calcium oxalate.

Identification Proceed as directed in the Identification under Ephedra Herb in JP.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Ephedra Herb in JP.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Ephedra Herb in JP.

Acid-insoluble ash 〈*5.01*〉 Proceed as directed in the Acid-insoluble ash under Ephedra Herb in JP.

Assay Proceed as directed in the Assay under Ephedra Herb in JP.

Containers and storage Containers—Tight containers.

マンケイシ

Shrub Chaste Tree Fruit

VITICIS FRUCTUS

Shrub Chaste Tree Fruit is the fruit of *Vitex rotundifolia* Linné filius or *Vitex trifolia* Linné (*Verbenaceae*).

Description Spherical to obovoid, 3 - 7 mm in diameter, externally grayish black to grayish brown in color; usually thin, grayish white sepal, sometimes with short fruit stalk, covers the lower half of the fruit; fruit, internally divided into 4 loculi, each containing 1 seed.

Odor, characteristic; taste, slightly pungent.

Identification To 0.5 g of pulverized Shrub Chaste Tree Fruit add 10 mL of methanol, shake well, and filter. To 5 mL of the filtrate add 0.1 g of magnesium in ribbon form and 0.3 mL of hydrochloric acid, and allow to stand: a light red to red-purple color develops.

Purity (1) Peduncle and leaf—When perform the test of foreign matter 〈*5.01*〉, the amount of the peduncles and leaves contained in Shrub Chaste Tree Fruit does not exceed 4.0%.

(2) Foreign matter 〈*5.01*〉—The amount of foreign matter other than peduncles and leaves contained in Shrub Chaste Tree Fruit does not exceed 1.0%.

Loss on drying 〈*5.01*〉 Not more than 12.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 9.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 3.5%.

Containers and storage Containers—Well-closed containers.

メリロート

Melilot

MELILOTI HERBA

Melilot is the terrestrial part of *Melilotus officinalis* Lamarck (*Leguminosae*).

Melilot contains not less than 0.3% of coumarin, calculated on the basis of dried material.

Description Melilot is the stem and the peduncle, usually, cut and the leaf fallen away practically. Stem, cylindrical, 4 - 30 cm in length, 1 - 3 mm in diameter, often branched. externally green to yellow-brown, with slender ridges. Leaf, ternate compound leaf with petiole, leaflet margin serrate. Raceme about 5 cm in length, butterfly-like flower 2 - 7 mm in length, sepal with hair. Fruit, oblong, yellow-brown to brown, apex acuminate, externally reticulated wrinkles, containing 1 seed.

Odor, characteristic; taste, slightly bitter.

Identification To 1 g of pulverized Melilot add 10 mL of diluted ethanol (7 in 10), shake for 10 minutes, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate and hexane (1:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly potassium hydroxide-ethanol TS on the plate, allow to stand for 10 minutes, and examine under ultraviolet light (main wavelength: 365 nm): a blue-green fluorescence spot is observed at an R_f value of about 0.55 (Coumarin).

Purity Foreign matter 〈*5.01*〉 —The amount of foreign matter contained in Melilot does not exceed 2.0%.

Loss on drying 〈*5.01*〉 Not more than 12.0% (2 hours).

Total ash 〈*5.01*〉 Not more than 10.0%.

Assay Weigh accurately about 2.0 g of pulverized Melilot, add 50 mL of methanol, heat under a reflux condenser for 30 minutes, cool, and filter. To the residue add 30 mL of methanol, and repeat the above procedure. Combine the filtrate, add methanol to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 10 mg of coumarin for assay, and dissolve in methanol to make exactly 100 mL. Pipet 10 mL of this solution, add methanol to make exactly 20 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉, and determine the peak areas, A_T and A_S, of coumarin in each solution.

Amount (mg) of coumarin

$= M_S \times A_T / A_S \times 1/2$

M_S: Amount (mg) of coumarin for assay taken

Operating conditions—

Detector: An ultraviolet absorptionphotometer (wavelength: 273 nm).

Column: A stainless steel column 4 to 6 mm in inside diameter and 15 to 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40° C.

Mobile phase: A mixture of water, acetonitrile and acetic acid (100) (750:250:1).

Flow rate: Adjust so that the retention time of coumarin is about 12 minutes.

System suitability—

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of coumarin are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 μL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of coumarin is not more than 1.5%.

Containers and storage Containers—Well-closed containers.

Coumarin for assay $C_9H_6O_2$ A clear or white to pale brown crystals, having characteristic aromatic odor. It is soluble in methanol or ethanol (99.5), and practically insoluble in water.

Optical rotation 〈*2.24*〉 $E_{1\%}^{1cm}$ (273 nm): 735 - 760 (5 mg, methanol, 1000 mL).

Identification Determine the infrared absorption spectrum of coumarin for assay as directed in the potassium bromide disk method under Infrared Spectrophotometry 〈*2.25*〉 : it exhibits absorption at the wave numbers of about 1705 cm^{-1}, 1604 cm^{-1}, 1487 $cm^{-1}$and 1259 cm^{-1}.

Purity Related substances—Dissolve 5 mg of coumarin for assay in 50 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉 according to the following conditions. Determine each peak area by the automatic integration method: the total area of the peaks other than the peak of coumarin and the solvent peak obtained from the sample solution is not larger than the peak area of coumarin obtained from the standard solution.

Operating conditions

Detector: An ultraviolet absorption photometer (wavelength: 273 nm).

Column: A stainless steel column 4.6 mm in inside diameter and 15 cm in length,

packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40° C.

Mobile phase: A mixture of water, acetonitrile and acetic acid (100) (750:250:1).

Flow rate: Adjust so that the retention time of coumarin is about 12 minutes.

Time span of measurement: About 3 times as long as the retention time of coumarin, beginning after the solvent peak.

System suitability

System performance: When the procedure is run with 10 μL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of coumarin are not less than 5000 and not more than 1.5, respectively.

メリロートエキス

Melilot Extract

Melilot Extract contains not less than 0.3% and not more than 0.9% of coumarin.

Method of preparation Pulverize Melilot in Non-JPS to suitable sizes and extract it with 30 vol% ethanol as directed under Extracts in General Rules for Preparations in JP.

Description Melilot Extract is brown to dark brown viscous extract; Odor, characteristically aromatic; taste, slightly bitter. It dissolves in water with a turbidity.

Identification To 0.1 g of Melilot Extract add 5 mL of diluted ethanol (7 in 10), stir, filter, and use the filtrate as the sample solution. Then, proceed as directed in the Identification under Melilot in Non-JPS.

Purity Heavy metals 〈*1.07*〉 —Prepare the test solution with 1.0 g of Melilot Extract as directed in the Extract **(4)** under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

Loss on drying 〈*2.41*〉 Not more than 28.0% (2 g, 105°C, 6 hours).

Total ash 〈*5.01*〉 Not more than 15.0% (2 g).

Assay Weigh accurately about 1.0 g of Melilot Extract, add a mixture of water and methanol (1:1) to dissolve, and add a mixture of water and methanol (1:1) to make exactly 100 mL. Pipet 10 mL of this solution, add a mixture of water and methanol (1:1) to make exactly 100 mL, and use this solution as the sample solution. Separately, weigh accurately about 15 mg of coumarin for assay, and dissolve in a mixture of water and methanol (1:1) to make exactly 100 mL. Pipet 10 mL of this solution, add a mixture of water and methanol (1:1) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with exactly 10 μL each of the sample solution and standard solution as directed under Liquid Chromatography 〈*2.01*〉 according to the following conditions, and determine the peak areas, A_T and A_S, of coumarin in each solution.

Amount of coumarin
$= M_S \times A_T / A_S$

M_S: Amount (mg) of coumarin for assay taken

Operating conditions—

Detector: An ultraviolet absorptionphotometer (wavelength: 273 nm).

Column: A stainless steel column 4 to 6 mm in inside diameter and 15 to 25 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: A mixture of water, acetonitrile and acetic acid (100) (750:250:1).

Flow rate: Adjust so that the retention time of coumarin is about 12 minutes.

System suitability—

System performance: When the procedure is run with 10 µL of the standard solution under the above operating conditions, the number of theoretical plates and the symmetry factor of the peak of coumarin are not less than 5000 and not more than 1.5, respectively.

System repeatability: When the test is repeated 6 times with 10 µL of the standard solution under the above operating conditions, the relative standard deviation of the peak area of coumarin is not more than 1.5%.

Containers and storage Containers—Tight containers.

モッカ

Chaenomeles Fruit

CHAENOMELIS FRUCTUS

Chaenomeles Fruit is the pseudocarp of 1) *Chaenomeles sinensis* Koehne (Kohi-mokka) or 2) *Chaenomeles speciosa* Nakai (*Rosaceae*) (Shuhi-mokka).

Description 1) Kohi-mokka: Ellipsoidal to ovoid, usually cut lengthwise, 6.5 - 10 cm in length, 3.5 - 5.0 cm in width; often cut crosswise; externally red-brown to dark brown; cut surface of sarcocarp, red-brown to yellowbrown, with granular spots; sarcocarp, 1 - 2 cm in thickness, internally has septum with many seeds or sometimes devoid of septum and hollow; seed, flat and nearly teardrop-shaped, 0.5 - 1.0 cm in length, 0.2 - 0.5 cm in width, hard, dark brown.

Odor, slight and characteristic; taste, acid and astringent.

Under a microscope 〈*5.01*〉, a transverse section reveals epidermis coated with cuticle in the outermost layer; pulp reveals numerous stone cell; stone cells independent or in indefinite groups in outer to middle portion, stone cells in rather large groups in innermost portion.

2) Shuhi-mokka: Ellipsoidal to ovoid, usually cut lengthwise, 4 - 9 cm in length, 2 - 5 cm in width; often cut crosswise; externally red-purple to red-orange, covered with irregular, dispersed coarse wrinkles; cut surface of sarcocarp, red-brown to yellowbrown, wrinkled margin rolled inside; internally has septum with many seeds or sometimes devoid of septum and hollow; seed, flat and triangular, 0.5 - 1.0 cm in length, 0.2 - 0.5 cm in width, hard, dark brown.

Odor, slight and characteristic; taste, acid and astringent.

Under a microscope 〈*5.01*〉, a transverse section reveals epidermis coated with cuticle in the outermost layer; pulp reveals indefinite stone cell in outer portion, usually large groups of stone cells in innermost portion, no stone cell in middle portion.

Identification To 1 g of pulverized Chaenomeles Fruit add 10 mL of water, warm on a water bath for 10 minutes with occasional shaking, and filter. To the filtrate add 1 drop of iron (III) chloride TS: a dirty green color develops.

Loss on drying 〈*5.01*〉 Not more than 12.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 5.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 18.0%.

Containers and storage Containers—Well-closed containers.

ヤカン

Blackberry-lily Rhizome

IRIDIS DOMESTICAE RHIZOMA

Blackberry-lily Rhizome is the rhizome of *Iris domestica* Goldblatt et Mabberley (*Belamcanda chinensis* De Candolle)(*Myricaceae*).

Description Irregularly knotted rhizome, 3 – 10 cm in length, 1 – 2 cm in diameter; externally yellow brown to dark brown, wrinkled and contracted surface usually with densely disposed ring crest; scars of stems shape disk-like dents on the upper part, sometimes with remains of stems; numerous spot-like scars of roots in the lower part, sometimes with remains of fine rootlets; hard in texture; fracture surface, light yellow to orange or light yellow brown to light brown.

Odor, slight; taste, slightly bitter.

Identification To 1.0 g of pulverized Blackberry-lily Rhizome add 10 mL of methanol, treat with ultrasonic waves for 20 minutes, centrifuge, and use the supernatant liquid as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, methanol and water (10:2:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly iodine TS on the plate: a yellow-brown spot is observed at an R_f value of about 0.7 (irisflorentin).

Purity (1) Heavy metals 〈*1.07*〉—Prepare the test solution with 3.0 g of pulverized Blackberry-lily Rhizome according to Method 3, and perform the test. Prepare the control solution with 3.0 mL of Standard Lead Solution (not more than 10 ppm).

(2) Arsenic 〈*1.11*〉—Prepare the test solution with 0.40 g of Blackberry-lily Rhizome according to Method 4, and perform the test (not more than 5 ppm).

Loss on drying 〈*5.01*〉 Not more than 13.5% (6 hours).

Total ash 〈*5.01*〉 Not more than 7.5%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 18.0%.

Containers and storage Containers—Well-closed containers.

ヨウバイヒ

Myrica Rubra Bark

MYRICAE CORTEX

Myrica Rubra Bark is the bark of *Myrica rubra* Siebold et Zuccarini (*Myricaceae*).

Description Flat, rolled tubular or semitubular pieces of bark, 1 - 5 mm in thickness; externally grayish brown with vertically striped shallow crack and cascades small lenticels; internally dark brown and smooth; easy to break; fractured surface red-brown and granulated.

Practically odorless; taste, astringent and bitter.

Under a microscope 〈*5.01*〉, a transverse section reveals cork layer consisting of many layers of cork cells with U-shaped thick cell walls; fiber bundles scattered in secondary cortex; many stone cells scattered in outer part of secondary cortex; parenchyma cells contain starch grains and blackish brown to brown substances; often yellow-red tannin-like substances in cortex; fiber bundles often accompanied with cells containing a solitary crystal of calcium oxalate, the crystal cells take on crystal cell rows in a longitudinal section.

Identification To 0.1 g of pulverized Myrica Rubra Bark add 10 mL of methanol, warm on a water bath for 5 minutes with occasional shaking, cool, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, methanol, water and formic acid (12:2:1:1) to a distance of about 7 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): a principal spot is observed at an R_f value of about 0.55 (Myricitrin).

Loss on drying 〈*5.01*〉 Not more than 13.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 4.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 35.0%.

Containers and storage Containers—Well-closed containers.

ヨウバイヒ末

Powdered Myrica Rubra Bark

MYRICAE CORTEX PULVERATUS

Powdered Myrica Rubra Bark is the powder of Myrica Rubra Bark in Non-JPS.

Description Powdered Myrica Rubra Bark occurs as a grayish red-brown powder; practically odorless, but irritates the nasal mucous membranes; taste is as a described in the Description under Powdered Myrica Rubra Bark in Non-JPS 2015.

Under a microscope 〈*5.01*〉, Powdered Myrica Rubra Bark reveals stone cells, fibers, parenchyma cells, cork cells with U-shaped thick cell walls, solitary crystals of calcium oxalate, and starch grains; stone cells irregularly shaped, polygonal to circular, 50 to 200 μm in major axis, 3 - 25 μm in cell wall thickness, pits and layers distinct; parenchyma cells containing starch grains; starch grains consisting of simple grains or 2- or 3-compound grains, with 4 - 7 μm in diameter; often yellow-red tannin-like substances in parenchyma cells and stone cells; two types of fibers: one has pits and 5 - 6 μm in cell wall thickness, often with crystal cell rows containing solitary crystals of calcium oxalate, the other with distinct oblique pit and about 2 μm in cell wall thickness; solitary crystals 10 to 30 μm in diameter.

Identification Proceed as directed in the Identification under Myrica Rubra Bark in Non-JPS.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Myrica Rubra Bark in Non-JPS.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Myrica Rubra Bark in Non-JPS.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Extract content 〈*5.01*〉 Proceed as directed in the Extract content under Myrica Rubra Bark in Non-JPS.

Containers and storage Containers—Tight containers.

ヨクイニンエキス
Coix Seed Extract

Method of preparation Pulverize Coix Seed in JP to suitable sizes and extract it with Water, Purified Water or Purified Water in Container (JP grade) as directed under Extracts in General Rules for Preparations in JP to prepare a dry extract.

Description Coix Seed Extract is light yellow-white to light yellow-brown powder; Odor, characteristic; taste, slightly sweet. It dissolves in water with a turbidity.

Identification **(1)** To 0.1 g of Coix Seed Extract add 50 mL of water, and heat in a water bath for 5 minutes with shaking occasionally. After cooling, add 5 drops of iodine TS, and shake: a blue-purple color develops.

(2) To 2 g of Coix Seed Extract add 40 mL of methanol, treat with ultrasonic waves for 20 minutes, and filter. Evaporate the filtrate to dryness under low pressure (in vacuo), dissolve the residue in 2 mL of methanol, and use this solution as the sample solution. Separately, to 0.5 g of coix seed in JP add 40 mL of methanol, treat with ultrasonic waves for 20 minutes, centrifuge, and use the supernatant liquid as the standard solution. Perform the test with these solutions as directed under Thin-layer Chromatography *〈2.03〉*. Spot 10 μL each of the sample solution and standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane, ethyl acetate and acetic acid (100)(80:20:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehyde-sulfuric acid TS on the plate, heat at 105°C for 5 minutes and then cooling: two spots among several spots obtained from the sample solution and blue-prple to blue-green spots (R_f values of about 0.3 and 0.6) obtained from the standard solution show the same color tone and the same R_f value.

Purity Heavy metals *〈1.07〉* —Prepare the test solution with 1.0 g of Coix Seed Extract as directed in the Extract **(4)** under General Rules for Preparations in JP, and perform the test (not more than 30 ppm).

Loss on drying *〈2.41〉* Not more than 8.0% (1 g, 105°C, 5 hours).

Total ash *〈5.01〉* Not more than 5.0% (1 g).

Containers and storage Containers—Tight containers.

ランオウ末

Dried Egg Yolk Powder

VITELLUS

Dried Egg Yolk Powder is the powder of yolk from *Gallus gallus* Brisson subsp. *domesticus* Brisson (*Phasianidae*).

Description Yellow to yellow-orange powder; Odor and taste, characteristic.

Identification To 1 g of Dried Egg Yolk Powder add 20 mL of methanol, shake for 20 minutes, centrifuge, and use the supernatant liquid as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography ⟨*2.03*⟩. Spot 2 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate and hexane (3:2) to a distance of about 7 cm, and air-dry the plate. Spray evenly 4-methoxybenzaldehide-sulfric acid TS on the plate, and heat at 105°C for 2 minutes: a dark blue spot is observed at an R_f value of about 0.5.

Loss on drying ⟨*5.01*⟩ Not more than 4.0% (6 hours).

Total ash ⟨*5.01*⟩ Not more than 7.0%.

Containers and storage Containers—Tight containers.

リヒ

Plum Bark

PRUNI SALICINAE CORTEX

Plum Bark is the bark or the root bark of *Prunus salicina* Lindley (*Rosaceae*).

Description Flat or rolled tubular pieces of bark, 2 - 5 mm in thickness; externally rough, grayish brown to blackish brown, sometimes red-brown without periderm; internally smooth, light yellow-white to red-brown; fractured surface fibrous, light yellow-white to light brown.

Odor, slight; taste, bitter and astringent.

Identification To 1 g of pulverized Plum Bark add 10 mL of dilute hydrochloric acid, shake, and heat in a boiling water bath for 10 minutes. After cooling, add 5 mL of diethyl ether, shake for 10 minutes, centrifuge, and use the diethyl ether layer as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, hexane and acetic acid (100) (20:20:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly vanillin-sulfuric acid-ethanol TS for spraying on the plate, and heat at 105°C for 5 minutes: an orange spot is observed at an R_f value of about 0.5 (2,6-Dihydroxy-4-methoxyacetophenone).

Loss on drying 〈*5.01*〉 Not more than 13.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 9.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.5%.

Containers and storage Containers—Well-closed containers.

レンギョウ末

Powdered Forsythia Fruit

FORSYTHIAE FRUCTUS PULVERATUS

Powdered Forsythia Fruit is the powder of Forsythia Fruit in JP.

Description Light yellow-brown to dark brown in color; odor as directed in the description under Forsythia Fruit in JP; taste, slightly bitter and astringent.

Under a microscope 〈*5.01*〉, Powdered Forsythia Fruit reveals fragments of brown and colorless parenchyma, stone cells, fibers and fiber bundles; fragments of mainly spiral and reticulate vessels; fragment of epidermis; occasionally starch grains, 15 - 35 μm in diameter, aggregated crystals of calcium oxalate, 10 - 30 μm in diameter.

Identification Proceed as directed in the Identification under Forsythia Fruit in JP.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Forsythia Fruit in JP.

Extract content 〈*5.01*〉 Proceed as directed in the Extract content under Forsythia Fruit in JP.

Containers and storage Containers—Tight containers.

ロクジョウ

Antler Velvet

CERVI CORNU PANTOTRICHUM

Antler velvet is the young unossified antler or the antler cut crosswise of male *Cervus nippon* Temminck, *Cervus elaphus* Linné, *Cervus canadensis* Erxleben or congeners (*Cervidae*).

Description Young antler covered with fur skin, obtuse at upper end, branched to 1 - 4 branches, 15 - 100 cm in length, densely covered with yellow-brown to bluish brown short hairs, or cut into flattened rotund to oblong slice, 1 to 15 cm in diameter, about 0.2 cm in thickness; cortex thin, slightly lustrous; medulla porous, grayish yellow to dark red-brown; under a magnifying glass, transverse section of red-brown to dark red-brown slice reveals the same color tone masses in pores.

Odor, characteristic; taste, slightly salty.

Under a microscope 〈*5.01*〉, transverse section or powder reveal guard hair; septum in hair medulla usually reveals ladder like structures, no scale like structures; if any, very few.

Identification To 0.5 g of pulverized Antler Velvet add 10 mL of methanol, treat with ultrasonic waves for 15 minutes, and filter. Evaporate the filtrate under low pressure (in vacuo) to dryness, add 1 mL of methanol to the residue, and use this solution as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate and hexane (1:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat at 105°C for 2 minutes: a red-purple spot is observed at an R_f value of about 0.5 (Cholesterol).

Purity Heavy metals 〈*1.07*〉—Proceed with 2.0 g of pulverized Antler Velvet according to Method 3, and perform the test. Prepare the control solution with 4.0 mL of Standard Lead Solution (not more than 20 ppm).

Loss on drying 〈*5.01*〉 Not more than 15.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 50.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 2.0%.

Containers and storage Containers—Well-closed containers.

ロクジョウ末

Powdered Antler Velvet

CERVI CORNU PANTOTRICHUM PULVERATUM

Powdered Antler velvet is the powder of Antler velvet in Non-JPS.

Description Powdered Antler velvet occurs as a grayish white to grayish brown or red-brown to dark brown powder.

Odor and taste are as directed in the Description under Antler velvet in Non-JPS.

Under a microscope 〈*5.01*〉, Powdered Antler velvet reveals fragments of colorless bone tissue with many lacunae of round, triangular and fusiform; in red-brown powder, many red-brown masses are observed solely or along with bone tissue; fragments of epidermis, dermis and periostea; between orthogonally oriented polarizing plates or prisms, occasionally coruscant granular masses in periostea; fragments of base of guard hair included in or attached to the cortex; septum of hair medulla usually reveals ladder like structures, no scale like structures; if any, very few.

Identification Proceed as directed in the Identification under Antler velvet in Non-JPS.

Purity Heavy metals 〈*1.07*〉—Proceed as directed in the Purity under Antler velvet in Non-JPS.

Loss on drying 〈*5.01*〉 Proceed as directed in the Loss on drying under Antler velvet in Non-JPS.

Total ash 〈*5.01*〉 Proceed as directed in the Total ash under Antler velvet in Non-JPS.

Extract content 〈*5.01*〉 Proceed as directed in Extract content under Antler velvet in Non-JPS.

Containers and storage Containers—Tight containers.

ワキョウカツ

Aralia Root

ARALIAE CORDATAE RADIX

Aralia Root is the root of *Aralia cordata* Thunberg (*Araliaceae*).

Description Curved, cylindrical to long conical, often without periderm; 5 - 15 cm in length, 0.5 - 1.5 cm in diameter; externally grayish brown, with numerous, longitudinal wrinkles, lenticels and rootlet scars scattered; outer surface grayish white in the root without periderm; light and slightly flexible in texture, easy to break; fractured surface slightly fibrous; under a magnifying glass, transversely cut surface reveals a brown ring near cambium, light brown in cortex, fine, brown points of oil canals in cortex.

Odor, characteristic; taste, slightly bitter.

Identification To 1 g of pulverized Aralia Root add 10 mL of methanol, shake for 5 minutes, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane, ethyl acetate and acetic acid (100) (30:10:1) to a distance of about 7 cm, and air-dry the plate. Spray evenly vanillin-sulfuric acid-ethanol TS for spraying on the plate, and heat at 105°C for 5 minutes: a purple spot is observed at an R_f value of about 0.5.

Total ash 〈*5.01*〉 Not more than 7.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.0%.

Containers and storage Containers—Well-closed containers.

ワコウホン

Osmorhiza Rhizome

OSMORHIZAE RHIZOMA

Osmorhiza Rhizome is the rhizome of *Osmorhiza aristata* Makino et Yabe (*Umbelliferae*).

Description Sympodially branching rhizome, 2 - 8 cm in length; branchlet cylindrical, 0.5 - 1.5 cm in diameter; orbicular hollow of stem scars or short stem residues on the apex; externally grayish brown to brown, with ring nodes, longitudinal wrinkles, numerous knob-like root residues; sometimes with a few short roots, 2 - 5 mm in diameter; light in texture, slightly easy to break.

Odor, characteristic; taste, slightly sweet at first, followed by a slightly acrid taste.

Identification To 0.5 g of pulverized Osmorhiza Rhizome add 5 mL of hexane, allow to stand for 15 minutes with occasional shaking, filter, and use the filtrate as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of hexane and ethyl acetate (4:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly the plate with dilute sulfuric acid, and heat at 105°C for 5 minutes: a red to red-purple spot is observed at an R_f value of about 0.5, and usually at the upper position close to the spot, another light blue spot is observed.

Total ash 〈*5.01*〉 Not more than 6.5%.

Acid-insoluble ash 〈*5.01*〉 Not more than 1.5%.

Containers and storage Containers—Well-closed containers.

ワニクジュヨウ

Boschniakia Herb

BOSCHNIAKIAE HERBA

Boschniakia Herb is the entire plant of *Boschniakia rossica* B. Fedtschenko (*Orobanchaceae*).

Description Flat and cylindrical, 3 - 30 cm in length, 2 - 8 cm in diameter; rhizome thick massive form, externally yellow-brown to blackish brown, densely covered with triangular scaly leaves; stems with ovoid or cylindrical spikes in the upper end; brittle in texture; a transverse section yellow-brown to blackish brown; vascular bundle arranged in a discontinuous circle.

Odorless; taste, slightly sweet, followed by a slight bitterness.

Under a microscope 〈*5.01*〉, a transverse section of middle part reveals a uni-layered epidermis coated with cuticle in the outermost layer; cortex composed of parenchyma and intercellular air spaces; beneath cortex, ellipse to oblong collateral bundles surrounded by bundle sheath, arranged in a discontinuous circle; pith composed of parenchyma and intercellular air spaces.

Identification To 1 g of pulverized Boschniakia Herb add 5 mL of water and 5 mL of 1-butanol, shake for 15 minutes, centrifuge, and use the 1-butanol layer as the sample solution. Perform the test with the sample solution as directed under Thin-layer Chromatography 〈*2.03*〉. Spot 5 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of ethyl acetate, methanol and water (20:3:2) to a distance of about 7 cm, and air-dry the plate. Spray evenly 2,6-dibromo-*N*-chloro-1,4-benzoquinone monoimine TS on the plate, and allow to stand in ammonia gas: a grayish green spot is observed at an R_f value of about 0.2 (Rosicaside B), and a blue spot is observed at an R_f value of about 0.3 (Boschnaloside).

Loss on drying 〈*5.01*〉 Not more than 23.0% (6 hours).

Total ash 〈*5.01*〉 Not more than 11.0%.

Acid-insoluble ash 〈*5.01*〉 Not more than 2.0%.

Extract content 〈*5.01*〉 Dilute ethanol-soluble extract: not less than 35.0%.

Containers and storage Containers—Well-closed containers.