hairs; furthermore, multicellular glandular hairs, epidermis with stomata, fragments of palisade tissue, rosette aggregates of calcium oxalate, and starch grains. Fiber is thick-walled, with somewhat distinct pits; unicellular hair shows small point-like protrusions on the surface; palisade tissue consisting of circular parenchyma cells in surface view, each cell containing one rosette aggregate of calcium oxalate which is about 20 μm in diameter. Starch grains consisting of simple grains but rarely of 2-compound grains, ovoid to spherical, 5 - 30 μm in diameter, with distinct hilum.

Identification Boil 0.1 g of Powdered Geranium Herb with 10 mL of water, filter, and to the filtrate add 1 drop of iron (III) chloride TS: a dark blue color develops.

Purity Foreign matter—Under a microscope, Powdered Geranium Herb reveals no stone cells.

Total ash Not more than 10.0%.

Acid-insoluble ash Not more than 1.5%.

Extract content Dilute ethanol-soluble extract: not less than 15.0%.

Ginger

Zingiberis Rhizoma

ショウキョウ

Ginger is the rhizome of *Zingiber officinale* Roscoe (*Zingiberaceae*).

Description Irregularly compressed and often branched massive rhizome or a part of it; the branched parts are slightly curved ovoid or oblong-ovoid, 2 - 4 cm in length, and 1 - 2 cm in diameter; external surface grayish white to light grayish brown, and often with white powder; fractured surface is somewhat fibrous, powdery, light yellowish brown; under a magnifying glass, a transverse section reveals cortex and stele distinctly divided; vascular bundles and secretes scattered all over the surface as small dark brown dots. Odor, characteristic; taste, extremely pungent.

Identification To 2 g of pulverized Ginger add 5 mL of acetone, shake for 3 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of [6]-gingerol for thin-layer chromatography in 1 mL of acetone, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. 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, acetone and acetic acid (100) (10:7:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly the plate with 2,4-dinitrophenylhydrazine TS, and heat at 105°C for 10 minutes: one of the spots from the sample solution and a brown spot from the standard solution shows the same color tone and *R*f value.

Total ash Not more than 8.0%

Powdered Ginger

Zingiberis Rhizoma Pulveratum

ショウキョウ末

Powdered Ginger is the powder of Ginger.

Description Powdered Ginger occurs as a light grayish brown to light grayish yellow powder. It has a characteristic odor and an extremely pungent taste.

Under a microscope, Powdered Ginger reveals mainly starch grains and parenchyma cells containing them; also, parenchyma cells containing yellow-brown to dark brown resinous substances or single crystals of calcium oxalate; fragments of fibers with distinct pits; fragments of spiral, ring and reticulate vessels, and rarely fragments of cork tissue; starch grains composed of simple, compound or half-compound grains, spherical, ovoid or globular, with abaxial hilum, usually 20 - 30 μm in long axis.

Identification To 2 g of Powdered Ginger add 5 mL of acetone, shake for 3 minutes, filter, and use the filtrate as the sample solution. Separately, dissolve 1 mg of [6]-gingerol for thin-layer chromatography in 1 ml of acetone, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. 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, acetone and acetic acid (100) (10:7:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly the platewith 2,4-dinitrophenylhydrazine TS, and heat at 105°C for 10 minutes: one of the spots from the sample solution and a brown spot from the standard solution shows the same color tone and *R*f value.

Purity Foreign matter—Under a microscope, Powdered Ginger does not show stone cells, lignified parenchyma cells and other foreign matter.

Total ash Not more than 8.0%.

Containers and storage Containers—Tight containers.

Ginseng

Ginseng Radix

ニンジン

Ginseng is the root of *Panax ginseng* C. A. Meyer (*Panax schinseng* Nees) (*Araliaceae*), from which rootlets have been removed, or the root has been quickly passed through hot water.

Description Thin and long cylindrical to fusiform root, often branching 2 to 5 lateral roots from the middle; 5 - 20 cm in length, main root 0.5 - 3 cm in diameter; externally light yellow-brown to light grayish brown, with longitudinal wrinkles and scars of rootlets; sometimes crown somewhat constricted and with short remains of rhizome; fractured surface practically flat, light yellow-brown in color, and brown

in the neighborhood of the cambium. Odor, characteristic; taste, at first slightly sweet, followed by a slight bitterness.

Identification (1) On a section of Ginseng add dilute iodine TS dropwise: a dark blue color is produced on the surface.

(2) To 2.0 g of pulverized Ginseng add 20 mL of methanol, boil gently under a reflux condenser on a water bath for 15 minutes, cool, filter, and use the filtrate 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 the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with the lower layer of a mixture of chloroform, methanol and water (13:7:2) to a distance of about 10 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat at 110°C for 5 minutes: one of the spots from the sample solution and a red-purple spot from the standard solution show the same color tone and the same *Rf* value.

Purity (1) Foreign matter—The amount of stems and other foreign matter contained in Ginseng does not exceed 2.0%.

(2) Heavy metals—Proceed with 1.0 g of pulverized Ginseng according to Method 4, and perform the test. Prepare the control solution with 1.5 mL of Standard Lead Solution (not more than 15 ppm).

(3) Arsenic—Prepare the test solution with 1.0 g of pulverized Ginseng according to Method 4, and perform the test using Apparatus B (not more than 2 ppm).

(4) Total BHC's and total DDT's—Sodium chloride, anhydrous sodium sulfate and synthetic magnesium silicate for column chromatography used in this procedure are used after drying by heating at about 130°C for more than 12 hours and cooling in a desiccator (silica gel). Chromatographic column is prepared as follows: Place 20 g of synthetic magnesium silicate for column chromatography in a 200-mL flask, add 50 mL of hexane for Purity of crude drug, shake vigorously, and immediately pour the mixture into a chromatographic tube about 2 cm in inside diameter and about 30 cm in length. Drip until the depth of hexane layer at the upper part is about 5 cm, introduce 8 g of anhydrous sodium sulfate from the top, and further drip until a small quantity of hexane is left at the upper part.

Weigh accurately about 5 g of pulverized Ginseng, place in a glass-stoppered centrifuge tube, add 30 mL of a mixture of acetone for Purity of crude drug and water (5:2), stopper tightly, shake for 15 minutes, centrifuge, and separate the supernatant liquid. Repeat the same procedure twice with the residue using two 30-mL portions of a mixture of acetone for Purity of crude drug and water (5:2). Combine all the supernatant liquids, and evaporate in a vacuum at a temperature not higher than 40°C until the order of acetone is faint. Transfer the evaporated solution to a separator containing 100 mL of sodium chloride TS, and shake twice with two 50-mL portions of hexane for Purity of crude drug for 5 minutes each. Combine the hexane solutions, transfer to a separator containing 50 mL of sodium chloride TS, and shake for 5 minutes. Take the hexane layer, dry over 30 g of anhydrous sodium sulfate, and filter. Wash the residue on the filter paper with 20 mL of hexane for Purity of crude drug. Combine the filtrate and the washings, and evaporate in a vacuum at a temperature not higher than 40°C to about 5 mL. Transfer this solution to the chromatographic column and allow to pass with 300 mL of a mixture of hexane for Purity of crude drug and diethyl ether for Purity of crude drug (17:3) at a rate of not more than 5 mL per minute. After evaporating the eluate in a vacuum at a temperature not higher than 40°C, add hexane for Purity of crude drug to make exactly 5 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g each of α-BHC, β-BHC, γ-BHC, δ-BHC, *o,p'*-DDT, *p,p'*-DDT, *p,p'*-DDD and *p,p'*-DDE, dissolve in 5 mL of acetone for Purity of crude drug and add hexane for Purity of crude drug to make exactly 100 mL. Pipet 10 mL of this solution, and add hexane for Purity of crude drug to make exactly 100 mL. Pipet 1 mL of this solution, add hexane for Purity of crude drug to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 1 μL each of the sample solution and the standard solution as directed under Gas Chromatography according to the following conditions, and determine the peak areas corresponding to α-BHC, β-BHC, γ-BHC, δ-BHC, *o,p'*-DDT, *p,p'*-DDT, *p,p'*-DDD and *p,p'*-DDE from each solution, A_{TA} and A_{SA}; A_{TB} and A_{SB}; A_{TC} and A_{SC}; A_{TD} and A_{SD}; A_{TE} and A_{SE}; A_{TF} and A_{SF}; A_{TG} and A_{SG}; A_{TH} and A_{SH}. Calculate the content of each of α-BHC, β-BHC, γ-BHC, δ-BHC, *o,p'*-DDT, *p,p'*-DDT, *p,p'*-DDD and *p,p'*-DDE by means of the following equations, and determine the content of total BHC's and that of total DDT's: the content of total BHC's and that of total DDT's are each not more than 0.2 ppm.

Content (ppm) of α-BHC

$$= \frac{\text{amount (g) of } \alpha\text{-BHC}}{W} \times \frac{A_{TA}}{A_{SA}} \times 50$$

Content (ppm) of β-BHC

$$= \frac{\text{amount (g) of } \beta\text{-BHC}}{W} \times \frac{A_{TB}}{A_{SB}} \times 50$$

Content (ppm) of γ-BHC

$$= \frac{\text{amount (g) of } \gamma\text{-BHC}}{W} \times \frac{A_{TC}}{A_{SC}} \times 50$$

Content (ppm) of δ-BHC

$$= \frac{\text{amount (g) of } \delta\text{-BHC}}{W} \times \frac{A_{TD}}{A_{SD}} \times 50$$

Content (ppm) of *o,p'*-DDT

$$= \frac{\text{amount (g) of } o,p'\text{-DDT}}{W} \times \frac{A_{TE}}{A_{SE}} \times 50$$

Content (ppm) of *p,p'*-DDT

$$= \frac{\text{amount (g) of } p,p'\text{-DDT}}{W} \times \frac{A_{TF}}{A_{SF}} \times 50$$

Content (ppm) of *p,p'*-DDD

$$= \frac{\text{amount (g) of } p,p'\text{-DDD}}{W} \times \frac{A_{TG}}{A_{SG}} \times 50$$

Content (ppm) of *p,p'*-DDE

$$= \frac{\text{amount (g) of } p,p'\text{-DDE}}{W} \times \frac{A_{TH}}{A_{SH}} \times 50$$

W: Amount (g) of pulverized Ginseng

Content (ppm) of total BHC's
= content (ppm) of α-BHC + content (ppm) of β-BHC + content (ppm) of γ-BHC + content (ppm) of δ-BHC

Content (ppm) of total DDT's
= content (ppm) of *o,p'*-DDT + content (ppm) of *p,p'*-DDT + content (ppm) of *p,p'*-DDD + content (ppm) of *p,p'*-DDE

Operating conditions—
Detector: An electron capture detector
Sample injection system: A splitless injection system
Column: A fused silica capillary column about 0.3 mm in inside diameter and about 30 m in length, coated the inside wall with 7% cyanopropyl-7% phenylmethylsilicone polymer for gas chromatography in a thickness of 0.25 to 1.0 μm.
Column temperature: Maintain the temperature at 60°C for 2 minutes after injection, program to increase the temperature at a rate of 10°C per minute to 200°C, and then program to increase the temperature at a rate of 2°C per minute to 260°C.
Carrier gas: Helium
Flow rate: Adjust the flow rate so that the retention times of the objective compounds are between 10 and 30 minutes.
Selection of column: Proceed with 1 μL of the standard solution under the above operating conditions. Use a column clearly separating each peak.
System repeatability: Repeat the test 6 times with the standard solution under the above operating conditions: the relative standard deviation of the peak area is not more than 10% for any objective compound.

Total ash Not more than 4.2%.

Extract content Dilute ethanol-soluble extract: not less than 14.0%.

Powdered Ginseng

Ginseng Radix Pulverata

ニンジン末

Powdered Ginseng is the powder of Ginseng.

Description Powdered Ginseng occurs as a light yellowish white to light yellowish-brown powder. It has characteristic odor and is a slight sweet taste followed by a slight bitterness.

Under a microscope, Powdered Ginseng reveals round to rectangular parenchyma cells containing starch grains, occasionally gelatinized starch, vessels, secretory cell, sclerenchyma cell, big and thin-walled cork cell; crystals of calcium oxalate and starch. Vessel are reticulate vessel, 45 μm in diameter; scalariform vessel and spiral vessel, 15 to 40 μm in diameter. Secretory cell containing a mass of yellow glistened contents; rosette aggregate of calcium oxalate, 20 to 50 μm in diameter, and 1 to 5 μm in diameter, rarely 10 μm, in diameter. Starch grains are observed in simple grain and 2 to 4-compound grain, simple grain, 3 to 15 μm in diameter.

Identification To 2.0 g of Powdered Ginseng add 20 mL of methanol, boil gently under a reflux condenser on a water bath for 15 minutes, cool, filter, and use the filtrate 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. Spot 10 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with the lower layer of a mixture of chloroform, methanol and water (13:7:2) to a distance of about 10 cm, and air-dry the plate. Spray evenly dilute sulfuric acid on the plate, and heat at 110°C for 5 minutes: one of the spots from the sample solution and a red-purple spot from the standard solution show the same color tone and the same *Rf* value.

Purity (1) Heavy metals—Proceed with 1.0 g of Powdered Ginseng according to Method 4, and perform the test. Prepare the control solution with 1.5 mL of Standard Lead Solution (not more than 15 ppm).

(2) Arsenic—Prepare the test solution with 1.0 g of Powdered Ginseng according to Method 4, and perform the test using Apparatus B (not more than 2 ppm).

(3) Total BHC's and total DDT's—Sodium chloride, anhydrous sodium sulfate and synthetic magnesium silicate for column chromatography used in this procedure are used after drying by heating at about 130°C for more than 12 hours and cooling in a desiccator (silica gel). Chromatographic column is prepared as follows: Place 20 g of synthetic magnesium silicate for column chromatography in a 200-mL flask, add 50 mL of hexane for Purity of crude drug, shake vigorously, and immediately pour the mixture into a chromatographic tube about 2 cm in inside diameter and about 30 cm in length. Drip until the depth of hexane layer at the upper part is about 5 cm, introduce 8 g of anhydrous sodium sulfate from the top, and further drip until a small quantity of hexane is left at the upper part.

Weigh accurately about 5 g of Powdered Ginseng, place in a glass-stoppered centrifuge tube, add 30 mL of a mixture of acetone for Purity of crude drug and water (5:2), stopper tightly, shake for 15 minutes, centrifuge, and separate the supernatant liquid. Repeat the same procedure twice with the residue using two 30-mL portions of a mixture of acetone for Purity of crude drug and water (5:2). Combine all the supernatant liquids, and evaporate in a vacuum at a temperature not higher than 40°C until the order of acetone is faint. Transfer the evaporated solution to a separator containing 100 mL of sodium chloride TS, and shake twice with two 50-mL portions of hexane for Purity of crude drug for 5 minutes each. Combine the hexane solutions, transfer to a separator containing 50 mL of sodium chloride TS, and shake for 5 minutes. Take the hexane layer, dry over 30 g of anhydrous sodium sulfate, and filter. Wash the residue on the filter paper with 20 mL of hexane for Purity of crude drug. Combine the filtrate and the washings, and evaporate in a vacuum at a temperature not higher than 40°C to about 5 mL. Transfer this solution to the chromatographic column and allow to pass with 300 mL of a mixture of hexane for Purity of crude drug and diethyl ether for Purity of crude drug (17:3) at a rate of not more than 5 mL per minute. After evaporating the eluate in a vacuum at a temperature not higher than 40°C, add hexane for Purity of crude drug to make exactly 5 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.01 g each of α-BHC, β-BHC, γ-BHC, δ-BHC, *o,p'*-DDT, *p,p'*-DDT, *p,p'*-DDD and *p,p'*-DDE, dissolve in 5 mL of acetone for Purity of crude drug and add hexane for Purity of crude drug to make exactly 100 mL. Pipet 10 mL of this solution, and add hexane for Purity of crude drug to make exactly 100 mL.