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.

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

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

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

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

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

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

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

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

W: Amount (g) of pulverized Red 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 4.5%.

Extract content Dilute ethanol-soluble extract: not less than 18.0%.

Rehmannia Root

Rehmanniae Radix

ジオウ

Rehmannia Root is the root of *Rehmannia glutinosa* Liboschitz var. *purpurea* Makino or *Rehmania glutinosa* Liboschitz (*Scrophulariaceae*), with or without the application of steaming.

Description Thin and long, usually, fusiform root, 5 - 10 cm in length, 0.5 - 1.5 cm in diameter, often broken or markedly deformed in shape; externally yellow-brown to blackish brown, with deep, longitudinal wrinkles and constrictions; soft in texture and mucous; cross section yellow-brown to blackish brown, and cortex darker than xylem in color; pith hardly observable. Odor, characteristic; taste, slightly sweet at first, followed by a slight bitterness.

Under a microscope, a transverse section reveals 7 to 15 layers of cork; cortex composed entirely of parenchyma cells; outer region of cortex with scattered cells containing brown secretes; xylem practically filled with parenchyma; vessels radially lined, mainly reticulate vessels.

Total ash Not more than 6.0%.

Acid-insoluble ash Not more than 2.5%.

Rhubarb

Rhei Rhizoma

ダイオウ

Rhubarb is usually the rhizome of *Rheum palmatum* Linné, *Rheum tanguticum* Maximowicz, *Rheum officinale* Baillon, *Rheum coreanum* Nakai or their interspecific hybrids (*Polygonaceae*).

It contains not less than 0.25% of sennosides *A*, calculated on the basis of dried material.

Description Ovoid, oblong-ovoid or cylindrical rhizome, often cut crosswise or longitudinally, 4 - 10 cm in diameter, 5 - 15 cm in length. In the case of Rhubarb without most part of cortex, the outer surface is flat and smooth, yellow-brown to light brown in color, and sometimes exhibiting white, fine reticulations; thick and hard in texture. In the case of Rhubarb with cork layer, externally dark brown or reddish black, and with coarse wrinkles; rough and brittle in texture. The fractured surface of Rhubarb is not fibrous; transverse section grayish brown, light grayish brown or brown in color, having patterns of dark brown tissue complicated with white and light brown tissues; near the cambium, the patterns often radiate, and in pith, consist of whirls of tissues radiated from the center of a small brown circle 1 - 3 mm in diameter and arranged in a ring or scattered irregularly. Odor, characteristic; taste, slightly astringent and bitter; when chewed, gritty between the teeth, and coloring the saliva yellow.

Under a microscope, the transverse section reveals mostly parenchyma cells; small abnormal cambium-rings scattered here and there in the pith; the cambium-rings produce phloem inside and xylem outside, accompanied with 2 to 4 rows of medullary rays containing brown-colored substances, and the rays run radiately from the center of the ring towards the outside forming whirls of tissues; parenchyma cells contain starch grains, brown-colored substances or crystal druses of calcium oxalate.

Identification To 2.0 g of pulverized Rhubarb add 40 mL of a mixture of tetrahydrofuran and water (7:3), shake for 30 minutes, and centrifuge. Transfer the supernatant liquid to a separator, add 13 g of sodium chloride, and shake for 30 minutes. Separate the water layer with undissolved sodium chloride, and adjust the pH to 1.5 by adding 1 mol/L hydrochloric acid TS. Transfer this solution to another separator, add 30 mL of tetrahydrofuran, shake for 10 minutes, separate the tetrahydrofuran layer, and use this solution as the sample solution. Separately, dissolve 1 mg of sennoside A for thin-layer chromatography in 4 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 the Thin-layer Chromatography. Spot 40 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography at 10 mm along the initial line. Develop the plate with a mixture of ethyl acetate, 1-propanol, water and acetic acid (100) (40:40:30:1) to a distance of about 15 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 365 nm): one of the spots from the sample solution and a red fluorescent spot from the standard solution show the same color tone and *R*f value.

Purity Raponticin—To 0.5 g of pulverized Rhubarb add 10 mL of ethanol (95), heat on a water bath with a reflux condenser for 10 minutes, and filter. Perform the test as directed under the Thin-layer Chromatography, using the filtrate as the sample solution. Spot 10 μL of the sample solution on a plate of silica gel for thin-layer chromatography. Develop the chromatogram with a mixture of isopropyl ether, 1-butanol and methanol (26:7:7) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength 365 nm): no spot with blue-purple fluorescence is observed at an *R*f value between 0.3 and 0.6, though a bluish white fluorescence may appear.

Loss on drying Not more than 13.0% (6 hours).

Total ash Not more than 13.0%.

Extract content Dilute ethanol-soluble extract: not less than 30.0%.

Component determination Weigh accurately about 0.5 g of pulverized Rhubarb, add exactly 50 mL of a solution of sodium hydrogen carbonate (1 in 1000), shake for 30 minutes, filter, and use the filtrate as the sample solution. Separately, weigh accurately about 0.01 g of sennoside A for component determination, previously dried in a desiccator (in vacuum at a pressure not exceeding 0.67 kPa, phosphorous (V) oxide) for not less than 12 hours, dissolve in a solution of sodium hydrogen carbonate (1 in 1000) to make exactly 50 mL. Pipet 5 mL of this solution, add a solution of sodium hydrogen carbonate (1 in 1000) to make exactly 20 mL and use this solution as the standard solution. Pipet 10 μL of the sample solution and the standard solution, and perform the test as directed under the Liquid Chromatography according to the following conditions. Determine the peak areas, A_T and A_S, of sennoside A in each solution.

$$\text{Amount (mg) of sennoside A} = \text{amount (mg) of sennoside A for component determination} \times \frac{A_T}{A_S} \times 0.25$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 340 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 to 10 μm in particle diameter).

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

Mobile phase: A mixture of diluted acetic acid (100) (1 in 80) and acetonitrile (4:1).

Flow rate: Adjust the flow rate so that the retention time of sennoside A is about 15 minutes.

Selection of column: Dissolve 1 mg each of sennoside A for component determination and naringin for thin-layer chromatography in a solution of sodium hydrogen carbonate (1 in 1000) to make 10 mL. Proceed with 20 μL of this solu-