

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  $\mu$ L 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  $\alpha$ -BHC,  $\beta$ -BHC,  $\gamma$ -BHC,  $\delta$ -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  $\alpha$ -BHC,  $\beta$ -BHC,  $\gamma$ -BHC,  $\delta$ -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 Powdered Ginseng

Content (ppm) of total BHC's  
= content (ppm) of  $\alpha$ -BHC + content (ppm) of  $\beta$ -BHC + content (ppm) of  $\gamma$ -BHC + content (ppm) of  $\delta$ -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  $\mu$ m.

Column temperature: Maintain the temperature at 60°C for 2 minutes after injection, program to increase the temper-

ature 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  $\mu$ L 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.

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

**Total ash** Not more than 4.2%.

**Acid-insoluble ash** Not more than 0.5%.

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

**Containers and storage** Containers—Tight containers.

## Glehnia Root

### *Glehniae Radix cum Rhizoma*

ハマボウフウ

*Glehnia* Root is the root and rhizome of *Glehnia littoralis* Fr. Schmidt ex Miquel (*Umbelliferae*).

**Description** Cylindrical to long conical root or rhizome, 10–20 cm in length, 0.5–1.5 cm in diameter; externally light yellow-brown to red-brown. Rhizome short, with fine ring nodes; roots having longitudinal wrinkles and numerous, dark red-brown, warty protrusions or transversely elongated protuberances. Brittle and easily breakable. A transverse section white and powdery, and under a magnifying glass, oil canals scattered as brown dots. Odor, slight; taste, slightly sweet.

**Total ash** Not more than 6.0%.

**Acid-insoluble ash** Not more than 1.5%.

## Glycerin and Potash Solution

グリセリンカリ液

#### Method of preparation

|                         |                       |
|-------------------------|-----------------------|
| Potassium Hydroxide     | 3 g                   |
| Glycerin                | 200 mL                |
| Ethanol                 | 250 mL                |
| Aromatic substance      | a suitable quantity   |
| Water or Purified Water | a sufficient quantity |
| To make 1000 mL         |                       |

Dissolve Potassium Hydroxide in a portion of Water or Purified Water, add Glycerin, Ethanol, a suitable quantity of

aromatic substance and another portion of Water or Purified Water to volume, and filter. Concentrated Glycerin may be used in place of Glycerin.

**Description** Glycerin and Potash Solution is a clear, colorless liquid, having an aromatic odor.

The pH of a solution of Glycerin and Potash Solution (1 in 5) is about 12.

Specific gravity  $d_{20}^{20}$ : about 1.02

**Identification (1)** A solution of Glycerin and Potash Solution (1 in 2) is alkaline (potassium hydroxide).

(2) Place 10 mL of a solution of Glycerin and Potash Solution (1 in 10) in a glass-stoppered test tube, add 2 mL of sodium hydroxide TS and 1 mL of copper (II) sulfate TS, and shake: a blue color is produced (glycerin).

(3) Glycerin and Potash Solution responds to the Qualitative Tests for potassium salt.

**Containers and storage** Containers—Tight containers.

## Glyceryl Monostearate

モノステアリン酸グリセリン

Glyceryl Monostearate is a mixture of  $\alpha$ - and  $\beta$ -glyceryl monostearate and other fatty acid esters of glycerin.

**Description** Glyceryl Monostearate occurs as white to light yellow, waxy masses, thin flakes, or granules. It has a characteristic odor and taste.

It is very soluble in hot ethanol (95), soluble in chloroform, sparingly soluble in diethyl ether, and practically insoluble in water and in ethanol (95).

It is slowly affected by light.

**Identification (1)** Heat 0.2 g of Glyceryl Monostearate with 0.5 g of potassium hydrogen sulfate until thoroughly charred: the irritative odor of acrolein is perceptible.

(2) Dissolve 0.1 g of Glyceryl Monostearate in 2 mL of ethanol (95) by warming, heat with 5 mL of dilute sulfuric acid in a water bath for 30 minutes, and cool: a white to yellow solid is produced. This separated solid dissolves when shaken with 3 mL of diethyl ether.

**Melting point** Not below 55°C (Method 2).

**Acid value** Not more than 15.

**Saponification value** 157 – 170

**Iodine value** Not more than 3.0. Use chloroform instead of cyclohexane.

**Purity** Acidity or alkalinity—To 1.0 g of Glyceryl Monostearate add 20 mL of boiling water, and cool with swirling: the solution is neutral.

**Residue on ignition** Not more than 0.10% (1 g).

**Containers and storage** Containers—Tight containers.

Storage—Light-resistant.

## Glycine

### Aminoacetic Acid

グリシン



$\text{C}_2\text{H}_5\text{NO}_2$ : 75.07

Aminoacetic acid [56-40-6]

Glycine, when dried, contains not less than 98.5% of  $\text{C}_2\text{H}_5\text{NO}_2$ .

**Description** Glycine occurs as white crystals or crystalline powder. It is odorless. It has a sweet taste.

It is freely soluble in water and in formic acid, and practically insoluble in ethanol (95).

**Identification** Determine the infrared absorption spectrum of Glycine, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wave numbers. If any difference appears between the spectra, dissolve Glycine in water, evaporate the water to dryness, and repeat the test with the residue.

**pH** Dissolve 1.0 g of Glycine in 20 mL of water: the pH of the solution is between 5.6 and 6.6.

**Purity (1)** Clarity and color of solution—Dissolve 1.0 g of Glycine in 10 mL of water: the solution is clear and colorless.

(2) Chloride—Perform the test with 0.5 g of Glycine. Prepare the control solution with 0.30 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.021%).

(3) Sulfate—Perform the test with 0.6 g of Glycine. Prepare the control solution with 0.35 mL of 0.005 mol/L sulfuric acid VS (not more than 0.028%).

(4) Ammonium—Perform the test using 0.25 g of Glycine. Prepare the control solution with 5.0 mL of Standard Ammonium Solution (not more than 0.02%).

(5) Heavy metals—Proceed with 1.0 g of Glycine according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(6) Arsenic—Prepare the test solution with 1.0 g of Glycine according to Method 1, and perform the test using Apparatus B (not more than 2 ppm).

(7) Other amino acids—Dissolve 0.10 g of Glycine in 25 mL of water and use this solution as the sample solution. Pipet 1 mL of the sample solution, add water to make exactly 50 mL. Pipet 5 mL of this solution, add water to make exactly 20 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5  $\mu\text{L}$  each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (3:1:1) to a distance of about 10 cm, and dry the plate at 80°C for 30 minutes. Spray evenly a solution of ninhydrin in acetone (1 in 50), and heat at 80°C for 5 minutes: the spots other than the principal