

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 α - and β -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).

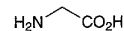
Containers and storage Containers—Tight containers.

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 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 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

spot from the sample solution are not more intense than the spot from the standard solution.

Loss on drying Not more than 0.30% (1 g, 105°C, 3 hours).

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

Assay Weigh accurately about 0.08 g of Glycine, previously dried, dissolve in 3 mL of formic acid, add 50 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

$$\begin{aligned} \text{Each mL of 0.1 mol/L perchloric acid VS} \\ = 7.507 \text{ mg of } \text{C}_2\text{H}_5\text{NO}_2 \end{aligned}$$

Containers and storage Containers—Well-closed containers.

Glycyrrhiza

Glycyrrhizae Radix

カンゾウ

Glycyrrhiza is the root and stolon, with (unpeeled) or without (peeled) the periderm, of *Glycyrrhiza uralensis* Fisher or *Glycyrrhiza glabra* Linné (*Leguminosae*).

It contains not less than 2.5% of glycyrrhizic acid ($\text{C}_{42}\text{H}_{62}\text{O}_{16}$: 822.93), calculated on the basis of dried material.

Description Nearly cylindrical pieces, 0.5–3.0 cm in diameter, over 1 m in length. Glycyrrhiza is externally dark brown to red-brown, longitudinally wrinkled, and often has lenticels, small buds and scaly leaves; peeled Glycyrrhiza is externally light yellow and fibrous. The transverse section reveals a rather clear border between phloem and xylem, and a radial structure which often has radiating splits; a pith in Glycyrrhiza originated from stolon, but no pith from root. Odor, slight; taste, sweet.

Under a microscope, the transverse section reveals several layers of yellow-brown cork layers, and 1- to 3-cellular layer of cork cortex inside the cork layer; the cortex exhibiting medullary rays and obliterated sieve portions radiated alternately; the phloem exhibiting groups of phloem fibers with thick but incompletely lignified walls and surrounded by crystal cells; peeled Glycyrrhiza some times lacks periderm and a part of phloem; the xylem exhibiting large yellow vessels and medullary rays in 3 to 10 rows radiated alternately; the vessels accompanied with xylem fibers surrounded by crystal cells, and with xylem parenchyma cells; the parenchymatous pithonily in Glycyrrhiza originated from stolon. The parenchyma cells contain starch grains and often solitary crystals of calcium oxalate.

Identification To 2.0 g of pulverized Glycyrrhiza add 10 mL of a mixture of ethanol (95) and water (7:3), heat by shaking on a water bath for 5 minutes, cool, filter, and use the filtrate as the sample solution. Separately, dissolve 5 mg of glycyrrhizic acid for thin-layer chromatography in 1 mL of a mixture of ethanol (95) and water (7:3), and use this solution as the standard solution. Perform the test with these so-

lutions as directed under the Thin-layer Chromatography. Spot 2 μL each of the sample solution and the standard solution on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (7:2:1) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): one spot among the spots from the sample solution and a dark purple spot from the standard solution show the same color tone and the same R_f value.

Loss on drying Not more than 12.0% (6 hours).

Total ash Not more than 7.0%.

Acid-insoluble ash Not more than 2.0%.

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

Assay Weigh accurately about 0.5 g of pulverized Glycyrrhiza in a glass-stoppered centrifuge tube, add 70 mL of dilute ethanol, shake for 15 minutes, centrifuge, and separate the supernatant liquid. To the residue add 25 ml of dilute ethanol, and proceed in the same manner. Combine all the extracts, add dilute ethanol to make exactly 100 ml, and use this solution as the sample solution. Separately, weigh accurately about 0.025 g of Glycyrrhizic Acid Reference Standard (separately determine the water content), dissolve in dilute ethanol to make exactly 100 mL, and use this solution as the standard solution. Pipet 20 μL each 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 peakareas, A_r and A_s , of glycyrrhizic acid of each solution.

$$\begin{aligned} \text{Amount (mg) of glycyrrhizic acid (C}_{42}\text{H}_{62}\text{O}_{16}) \\ = \text{amount (mg) of Glycyrrhizic Acid Reference} \\ \text{Standard, calculated on the anhydrous basis} \\ \times \frac{A_r}{A_s} \end{aligned}$$

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: Use a column 4 to 6 mm in inside diameter and 15 to 25 cm in length, packed with octadecylsilylated silica gel for liquid chromatography (5 to 10 μm in particle diameter).

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

Mobile phase: A mixture of diluted acetic acid (31) (1 in 15) and acetonitrile (3:2).

Flow rate: Adjust the flow rate so that the retention time of glycyrrhizic acid is about 10 minutes.

Selection of column: Dissolve 5 mg of Glycyrrhizic Acid Reference Standard and 1 mg of propyl parahydroxybenzoate in dilute ethanol to make 20 mL. Proceed with 20 μL of this solution under the above operating conditions. Use a column giving elution of glycyrrhizic acid and propyl parahydroxybenzoate in this order, and clearly dividing each peak.

System repeatability: Repeat the test 5 times with the standard solution under the above operating conditions: the relative standard deviation of the peak area of glycyrrhizic acid is not more than 1.5%.