

Glycerin

Glycerol

グリセリン

$C_3H_8O_3$: 92.09

Glycerin contains not less than 84% and not more than 87% of $C_3H_8O_3$ (by specific gravity).

Description Glycerin is a clear, colorless, viscous liquid. It is odorless and has a sweet taste.

It is miscible with water and with ethanol (95).

It is very slightly soluble in diethyl ether.

It is hygroscopic.

Identification Heat 2 to 3 drops of Glycerin with 0.5 g of potassium hydrogen sulfate: an odor of acrolein is perceptible.

Refractive index α_D^{20} : 1.449 – 1.454

Specific gravity d_{20}^{20} : 1.221 – 1.230

Purity (1) Color—Place 50 mL of Glycerin in a Nessler tube, and observe downward: the solution has no more color than the following control solution. Control solution: Place 0.40 mL of Ferric Chloride Colorimetric Stock Solution in a Nessler tube, and add water to make 50 mL.

(2) Acidity or alkalinity—To 2 mL of Glycerin add 8 mL of water and mix: the solution is neutral.

(3) Chloride—Take 10.0 g of Glycerin, and perform the test: Prepare the control solution with 0.30 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.001%).

(4) Sulfate—Take 10.0 g of Glycerin, and perform the test. Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.002%).

(5) Ammonium—To 5 mL of Glycerin add 5 mL of a solution of sodium hydroxide (1 in 10), and boil: the gas evolved does not change moistened red litmus paper to blue.

(6) Heavy metals—Proceed with 5.0 g of Glycerin according to Method 1, and perform the test: Prepare the control solution with 2.5 mL of Standard Lead Solution (not more than 5 ppm).

(7) Calcium—To 5 mL of the solution obtained in (2) add 3 drops of ammonium oxalate TS: the solution remains unchanged.

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

(9) Acrolein, glucose, and other reducing substances—To 1.0 g of Glycerin add 1 mL of ammonia TS, mix, and warm in a water bath at 60°C for 5 minutes: no yellow color is produced. Take the solution out of the water bath, add 3 drops of silver nitrate TS immediately, and allow to stand in a dark place for 5 minutes: the color of the solution does not change, and no turbidity is produced.

(10) Fatty acids and esters—Mix 50 g of Glycerin with 50 mL of freshly boiled and cooled water, add exactly 10 mL of 0.1 mol/L sodium hydroxide VS, boil the mixture for 15 minutes, cool, and titrate the excess sodium hydroxide with 0.1 mol/L hydrochloric acid VS: 0.1 mol/L sodium hydroxide VS consumed is not more than 3.0 mL (in-

dicator: 3 drops of phenolphthalein TS). Perform a blank determination.

(11) Readily carbonizable substances—To 5 mL of Glycerin add carefully 5 mL of sulfuric acid for readily carbonizable substances, mix gently at a temperature between 18°C and 20°C, and allow to stand for 1 hour between 15°C and 25°C: the solution has not more color than Matching Fluid H.

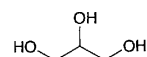
Residue on ignition Weigh accurately about 10 g of Glycerin in a tared crucible, heat to boiling, and fire to burn immediately. After cooling, moisten the residue with 1 to 2 drops of sulfuric acid, and ignite cautiously to constant mass: the mass of the residue is not more than 0.01%.

Containers and storage Containers—Tight containers.

Concentrated Glycerin

Concentrated Glycerol

濃グリセリン



$C_3H_8O_3$: 92.09

Propane-1,2,3-triol [56-81-5]

Concentrated Glycerin contains not less than 98.0% of glycerin ($C_3H_8O_3$) (by specific gravity).

Description Concentrated Glycerin is a clear, colorless and viscous liquid. It is odorless, and has a sweet taste.

It is miscible with water and with ethanol (95).

It is very slightly soluble in diethyl ether.

It is hygroscopic.

Identification Heat 2 to 3 drops of Concentrated Glycerin with 0.5 g of potassium hydrogen sulfate: the odor of acrolein is perceptible.

Refractive index n_D^{20} : Not less than 1.470.

Specific gravity d_{20}^{20} : Not less than 1.258.

Purity (1) Color—Place 50 mL of Concentrated Glycerin in a Nessler tube, and observe downward: the solution has no more color than the following control solution.

Control solution: Pipet 0.40 mL of Ferric Chloride Colorimetric Stock Solution into a Nessler tube, and add water to make 50 mL.

(2) Acidity or alkalinity—To 2 mL of Concentrated Glycerin add 8 mL of water and mix: the solution is neutral.

(3) Chloride—Take 10.0 g of Concentrated Glycerin, and perform the test. Prepare the control solution with 0.30 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.001%).

(4) Sulfate—Take 10.0 g of Concentrated Glycerin, and perform the test. Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.002%).

(5) Ammonium—To 5 mL of Concentrated Glycerin add 5 mL of a solution of sodium hydroxide (1 in 10), and boil: the gas evolved does not change moistened red litmus

paper to blue.

(6) Heavy metals—Proceed with 5.0 g of Concentrated Glycerin according to Method 1, and perform the test. Prepare the control solution with 2.5 mL of Standard Lead Solution (not more than 5 ppm).

(7) Calcium—To 5 mL of the solution obtained in (2) add 3 drops of ammonium oxalate TS: the solution remains unchanged.

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

(9) Acrolein, glucose, or other reducing substances—To 1.0 g of Concentrated Glycerin add 1 mL of ammonia TS, mix, and warm in a water bath at 60°C for 5 minutes: no yellow color is produced. Take the solution out of the water bath, add 3 drops of silver nitrate TS immediately, and allow to stand in a dark place for 5 minutes: the color of the solution does not change, and no turbidity is produced.

(10) Fatty acids and esters—Mix 50 g of Concentrated Glycerin with 50 mL of freshly boiled and cooled water, add 10 mL of 0.1 mol/L sodium hydroxide VS, accurately measured, boil the mixture for 15 minutes, cool, and titrate the excess sodium hydroxide with 0.1 mol/L hydrochloric acid VS: not more than 3.0 mL of 0.1 mol/L sodium hydroxide VS is consumed (indicator: 3 drops of phenolphthalein TS). Perform a blank determination.

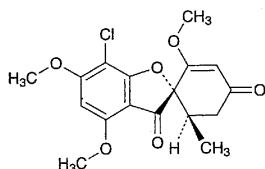
(11) Readily carbonizable substances—To 5 mL of Concentrated Glycerin add carefully 5 mL of sulfuric acid for readily carbonizable substances, mix gently at a temperature between 18°C and 20°C, and allow to stand for 1 hour between 15°C and 25°C: the solution has no more color than Matching Fluid H.

Residue on ignition Weigh accurately about 10 g of Concentrated Glycerin in a tared crucible, heat to boiling, and fire to burn immediately. Cool, moisten the residue with 1 to 2 drops of sulfuric acid, and ignite cautiously to constant mass: the mass of the residue is not more than 0.01%.

Containers and storage Containers—Tight containers.

Griseofulvin

グリセオフルビン



$C_{17}H_{17}ClO_6$: 352.77
(2*S*,4'*R*)-7-Chloro-2',4,6-trimethoxy-4'-methylspiro[benzo[*b*]furan-2(3*H*),3'-(cyclohex-1'-ene)]-3,6'-dione [126-07-8]

Griseofulvin conforms to the requirements of Griseofulvin in the Requirements for Antibiotic Products of Japan.

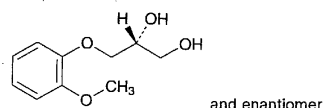
Description Griseofulvin occurs as white crystals or crystalline powder.

It is soluble in *N,N*-dimethylformamide, slightly soluble in methanol and in ethanol (95), and very slightly soluble in diethyl ether, and practically insoluble in water.

Guaifenesin

Guaiacol Glyceryl Ether

グアイフェネシン



$C_{10}H_{14}O_4$: 198.22
(*RS*)-3-(2-Methoxyphenoxy)propane-1,2-diol [93-14-1]

Guaifenesin, when dried, contains not less than 98.0% and not more than 102.0% of $C_{10}H_{14}O_4$.

Description Guaifenesin occurs as a white crystals or crystalline powder.

It is freely soluble in ethanol (95), and sparingly soluble in water.

A solution of ethanol (95) (1 in 20) shows no optical rotation.

Identification (1) Determine the absorption spectrum of a solution of Guaifenesin (1 in 50,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of a solution of Guaifenesin Reference Standard prepared in the same manner as the sample solution: both spectra exhibit similar intensities of absorption at the same wavelengths.

(2) Determine the infrared absorption spectrum of Guaifenesin, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of previously dried Guaifenesin Reference Standard: both spectra exhibit similar intensities of absorption at the same wave numbers.

Melting point 80 – 83°C

pH Dissolve 1.0 g of Guaifenesin in 100 mL of water: the pH of the solution is between 5.0 and 7.0.

Purity (1) Clarity and color of solution—Dissolve 0.20 g of Guaifenesin in 10 mL of water: the solution is clear and colorless.

(2) Chloride—Dissolve 0.7 g of Guaifenesin in 25 mL of water by warming. Cool, add 6 mL of dilute nitric acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 0.40 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.020%).

(3) Heavy metals—Dissolve 2.0 g of Guaifenesin in 25 mL of water by warming. Cool, add 2 mL of dilute acetic acid and water to make 50 mL, and perform the test using this solution as the test solution. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(4) Arsenic—Prepare the test solution with 1.0 g of