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.

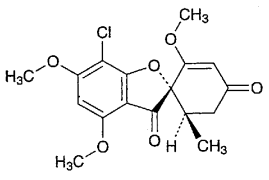
(11) Readily carbonizable substances—To 5 mL of Concentrated Glycerin add carefully 5 mL of sulfuric acid for readily carbonizable substances, mix gently at a temperature between 18°C and 20°C, and allow to stand for 1 hour between 15°C and 25°C: the solution has no more color than Matching Fluid H.

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.

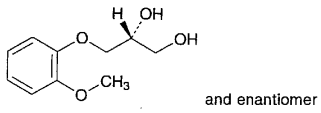
Description Griseofulvin occurs as white crystals or crystalline powder.

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 then 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

Guaifenesin according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(5) Free guaiacol—To 1.0 g of Guaifenesin add exactly 25 mL of water, dissolve by warming, cool, and use this solution as the sample solution. Separately, dissolve 0.100 g of guaiacol in water to make exactly 1000 mL. Pipet 3 mL of this solution, add exactly 22 mL of water, and use this solution as the standard solution. To each of the sample solution and the standard solution add 1.0 mL of potassium hexacyanoferrate (III) TS and 5.0 mL of a solution of 4-aminoantipyrine (1 in 200), and immediately after shaking for exactly 5 seconds add a solution of sodium hydrogen carbonate (1 in 1200) to make exactly 100 mL. Determine the absorbances of these solutions at 500 nm exactly 15 minutes after the addition of the 4-aminoantipyrine solution as directed under the Ultraviolet-visible Spectrophotometry, using a solution, prepared in the same manner with 25 mL of water, as the blank: the absorbance of the solution obtained from the sample solution is not greater than that from the standard solution.

(6) Related substances—Dissolve 1.0 g of Guaifenesin in 100 mL of ethanol (95), and use this solution as the sample solution. Pipet 1 mL of the sample solution, add water to make exactly 200 mL, 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 a mixture of diethyl ether, ethanol (95), and ammonia solution (28) (40:10:1) to a distance of about 10 cm, and air-dry the plate. Spray evenly 4-dimethylaminobenzaldehyde TS for spraying on the plate, and heat at 110°C for 10 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 0.5% (1 g, in vacuum, 60°C, 3 hours).

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

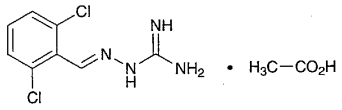
Assay Weigh accurately about 0.06 g of Guaifenesin and Guaifenesin Reference Standard, previously dried, and dissolve each then in water to make exactly 100 mL. Pipet 5 mL of these solutions, and add water to make exactly 100 mL, and use these solutions as the sample solution and the standard solution. Determine the absorbances, A_T and A_S, of the sample solution and the standard solution at 273 nm as directed under the Ultraviolet-visible Spectrophotometry.

$$\text{Amount (mg) of } C_{10}H_{14}O_4 = \text{amount (mg) of Guaifenesin Reference Standard} \times \frac{A_T}{A_S}$$

Containers and storage Containers—Tight containers.

Guanabenz Acetate

酢酸グアナベンズ



$C_8H_8Cl_2N_4.C_2H_4O_2$: 291.13

(*E*)-(2,6-Dichlorobenzylideneamino)guanidine monoacetate [*23256-50-0*]

Guanabenz Acetate, when dried, contains not less than 98.5% of $C_8H_8Cl_2N_4.C_2H_4O_2$.

Description Guanabenz Acetate occurs as white crystals or crystalline powder.

It is freely soluble in acetic acid (100), soluble in methanol and in ethanol (95), slightly soluble in water, and practically insoluble in diethyl ether.

It is gradually affected by light.

Melting point: about 190°C (with decomposition).

Identification **(1)** To 5 mL of a solution of Guanabenz Acetate (1 in 1000) add 0.5 mL of a diluted ethanol (95) (5 in 6) which contains 16 g of urea and 0.2 g of 1-naphthol in 100 mL, and add 1 mL of *N*-bromosuccinimide TS: a purple color develops.

(2) Determine the absorption spectrum of a solution of Guanabenz Acetate in methanol (1 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spectra exhibit similar intensities of absorption at the same wavelengths.

(3) Determine the infrared absorption spectrum of Guanabenz Acetate, 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.

(4) To 0.1 g of Guanabenz Acetate add 5 mL of water and 1 mL of ammonia TS, shake, filter, and neutralize the filtrate with dilute hydrochloric acid: the solution responds to the Qualitative Tests (3) for acetate.

Purity **(1)** Heavy metals—Proceed with 2.0 g of Guanabenz Acetate according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(2) Related substances—Conduct this procedure without exposure to daylight, using light-resistant vessels. Dissolve 0.05 g of Guanabenz Acetate in 5 mL of methanol, and use this solution as the sample solution. Pipet 1 mL of the sample solution, add methanol to make exactly 10 mL, then pipet 1 mL of this solution, add methanol 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 with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of chloroform, methanol and ammonia solution (28) (80:20:1) to a distance of about