

ethanol in a current of warm air, add 20 mL of water, and cool. Add a mixture of 10 mL of strong hydrogen peroxide and 40 mL of water, boil gently under a reflux condenser for 10 minutes, and filter rapidly after cooling. Wash the residue with two 10-mL portions of water, combine the washings with the filtrate, add 10 mL of dilute nitric acid and exactly 5 mL of 0.1 mol/L silver nitrate VS, and titrate the excess silver nitrate with 0.1 mol/L ammonium thiocyanate VS (indicator: 2 mL of ammonium iron (III) sulfate TS). Perform a blank determination: not more than 1.0 mL of 0.1 mol/L silver nitrate VS is consumed.

Assay Weigh accurately about 0.15 g of Dimercaprol into a glass-stoppered flask, dissolve in 10 mL of methanol, and titrate immediately with 0.05 mol/L iodine VS until a pale yellow color is produced. Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L iodine VS = 6.211 mg of $C_3H_8OS_2$

Containers and storage Containers—Tight containers.
Storage—Not exceeding 5°C.

Dimercaprol Injection

ジメルカプロール注射液

Dimercaprol Injection is an oily solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of dimercaprol ($C_3H_8OS_2$; 124.23).

Method of preparation Prepare as directed under Injections, with Dimercaprol. Benzyl Benzoate or Benzyl Alcohol may be added to increase the solubility.

Description Dimercaprol Injection is a clear, colorless to light yellow liquid. It has an unpleasant odor.

Identification (1) Measure a volume of Dimercaprol Injection, equivalent to 0.03 g of Dimercaprol according to the labeled amount, and proceed as directed in the Identification (1) and (2) under Dimercaprol, respectively.

(2) Measure a volume of Dimercaprol Injection, equivalent to 0.03 g of dimercaprol according to the labeled amount, add 20 mL of water, shake well, and proceed as directed in the Identification (3) under Dimercaprol.

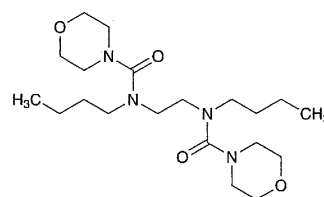
Assay Pipet a volume of Dimercaprol Injection, equivalent to about 0.2 g of dimercaprol ($C_3H_8OS_2$), into a flask, and rinse the pipet several times with a mixture of methanol and chloroform (3:1), adding the rinsings to the flask. Add a mixture of methanol and chloroform (3:1) to make 100 mL, and titrate with 0.05 mol/L iodine VS until a yellow color persists. Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L iodine VS = 6.211 mg of $C_3H_8OS_2$

Containers and storage Containers—Hermetic containers.
Storage—In a cold place.

Dimorpholamine

ジモルホラミン



$C_{20}H_{38}N_4O_4$: 398.54

N,N'-Ethylenebis(*N*-butylmorpholine-4-carboxamide)
[119-48-2]

Dimorpholamine, when dried, contains not less than 98.0% of $C_{20}H_{38}N_4O_4$.

Description Dimorpholamine is a white to light yellow, crystalline powder, mass or syrupy liquid. It has an amine-like, characteristic odor and a bitter taste.

It is very soluble in ethanol (95), in acetic anhydride, in diethyl ether and in nitrobenzene, and soluble in water.

The pH of a solution of Dimorpholamine (1 in 10) is between 6.0 and 7.0.

It is hygroscopic.

Identification (1) Dissolve 0.1 g of Dimorpholamine in 5 mL of water, and add 3 drops of Dragendorff's TS: an orange color is produced.

(2) To 1 g of Dimorpholamine add 10 mL of a solution of sodium hydroxide (1 in 10), and heat for 30 minutes on a water bath: the gas evolved does not change moistened red litmus paper to blue. Cool, and neutralize with dilute hydrochloric acid. Acidify 5 mL of this solution with dilute hydrochloric acid, boil, and pass the gas evolved through calcium hydroxide TS: a white precipitate is produced immediately.

(3) Dissolve 0.05 g of Dimorpholamine in 2 mL of hydrochloric acid, boil under a reflux condenser for 10 minutes, and evaporate on a water bath to dryness. Dissolve the residue in 1 mL of water, neutralize with sodium hydroxide TS, and add 0.2 mL of a solution of acetaldehyde (1 in 20), 0.1 mL of sodium pentacyanonitrosylferrate (III) TS and 0.5 mL of sodium carbonate TS: a blue color is produced.

(4) Determine the absorption spectrum of a solution of Dimorpholamine (1 in 50,000) 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.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Dimorpholamine in 50 mL of water: the solution is clear and colorless to pale yellow.

(2) Chloride—To 20 mL of the solution obtained in (1) add 6 mL of dilute nitric acid and water to make 50 mL. 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 0.036%).

(3) Sulfate—To 10 mL of the solution obtained in (1) add 1 mL of dilute hydrochloric acid and water to make 50 mL. Perform the test using this solution as the test solution.

Prepare the control solution with 0.40 mL of 0.005 mol/L sulfuric acid VS (not more than 0.096%).

(4) Heavy metals—Proceed with 2.0 g of Dimorpholamine 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).

Loss on drying Not more than 0.5% (1 g, in vacuum, phosphorus (V) oxide, 8 hours).

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

Assay Weigh accurately about 0.6 g of Dimorpholamine, previously dried, and dissolve in 10 mL of acetic anhydride and 40 mL of nitrobenzene. Titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from red through purple to blue-purple (indicator: 5 drops of neutral red TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 39.855 mg of C₂₀H₃₈N₄O₄

Containers and storage Containers—Tight containers.
Storage—Light-resistant.

Dimorpholamine Injection

ジモルホラミン注射液

Dimorpholamine Injection is an aqueous solution for injection. It contains not less than 95% and not more than 105% of the labeled amount of dimorpholamine (C₂₀H₃₈N₄O₄; 398.54).

Method of preparation Prepare as directed under Injections, with Dimorpholamine.

Description Dimorpholamine Injection is a clear, colorless liquid.

Identification (1) To a volume of Dimorpholamine Injection, equivalent to 0.1 g of Dimorpholamine according to the labeled amount, add 3 drops of Dragendorff's TS: an orange color develops.

(2) To a volume of Dimorpholamine Injection, equivalent to 0.05 g of Dimorpholamine according to the labeled amount, add 1 mL of dilute hydrochloric acid, and evaporate on a water bath to dryness. Dissolve this residue in 2 mL of hydrochloric acid, and proceed as directed in the Identification (3) under Dimorpholamine.

Assay Measure exactly a volume of Dimorpholamine Injection, equivalent to about 0.03 g of dimorpholamine (C₂₀H₃₈N₄O₄), and add water to make exactly 200 mL. Pipet 1 mL of this solution, shake with exactly 4 mL of the internal standard solution for 5 minutes, and use this solution as the sample solution. Separately, weigh accurately about 0.15 g of dimorpholamine for assay, previously dried in a desiccator (in vacuum, phosphorus (V) oxide) for 8 hours, and dissolve in water to make exactly 1000 mL. Pipet 1 mL of this solution, shake with exactly 4 mL of the internal standard solution for 5 minutes, and use this solution as the standard solution. Perform the test with 10 μm each of the sample solution and the standard solution as directed under the

Liquid Chromatography according to the following conditions, and calculate the ratios, Q_T and Q_S, of the peak area of dimorpholamine to that of the internal standard, respectively.

$$\begin{aligned} &\text{Amount (mg) of dimorpholamine (C}_{20}\text{H}_{38}\text{N}_4\text{O}_4) \\ &= \text{amount (mg) of dimorpholamine for assay} \\ &\quad \times \frac{Q_T}{Q_S} \times \frac{1}{5} \end{aligned}$$

Internal standard solution—A solution of butyl parahydroxybenzoate in acetonitrile (1 in 25,000).

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 216 nm).

Column: A stainless steel column about 4 mm in inside diameter and about 15 cm in length, packed with octadecylsilanized silica gel for liquid chromatography (5 μm in particle diameter).

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

Mobile phase: A mixture of water and acetonitrile (1:1).

Flow rate: Adjust the flow rate so that the retention time of dimorpholamine is about 4 minutes.

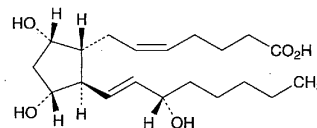
Selection of column: Proceed with 10 μL of the standard solution under the above operating conditions, and calculate the resolution. Use a column giving elution of dimorpholamine and the internal standard in this order with the resolution between these peaks being not less than 2.0.

Containers and storage Containers—Hermetic containers.

Dinoprost

Prostaglandin F_{2α}

ジノプロスト



C₂₀H₃₄O₅; 354.48

(5Z)-7-[(1R,2R,3R,5S)-3,5-Dihydroxy-2-[(1E,3S)-3-hydroxyoct-1-en-1-yl]cyclopentyl]hept-5-enoic acid [551-11-1]

Dinoprost contains not less than 98.5% of C₂₀H₃₄O₅, calculated on the anhydrous basis.

Description Dinoprost occurs as white, waxy masses or powder, or a clear, colorless to light yellow and viscous liquid. It is odorless.

It is very soluble in *N,N*-dimethylformamide, freely soluble in methanol, in ethanol (99.5) and in diethyl ether, and very slightly soluble in water.

Identification (1) To 5 mg of Dinoprost add 2 mL of sulfuric acid, and dissolve by shaking for 5 minutes: a dark red color develops. To this solution add 30 mL of sulfuric acid: an orange color develops with a green fluorescence.

(2) Dissolve 1 mg of Dinoprost in 50 mL of diluted sul-