

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 C<sub>20</sub>H<sub>38</sub>N<sub>4</sub>O<sub>4</sub>

**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 (C<sub>20</sub>H<sub>38</sub>N<sub>4</sub>O<sub>4</sub>: 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 (C<sub>20</sub>H<sub>38</sub>N<sub>4</sub>O<sub>4</sub>), 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<sub>T</sub> and Q<sub>S</sub>, of the peak area of dimorpholamine to that of the internal standard, respectively.

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

**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.

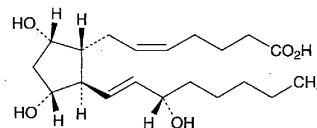
**Selection of column:** Proceed with 10 μL of the standard solution under the above operating conditions, and calculate the resolution. Use a column giving elution of dimorpholamine and the internal standard in this order with the resolution between these peaks being not less than 2.0.

**Containers and storage** Containers—Hermetic containers.

## Dinoprost

### Prostaglandin F<sub>2α</sub>

ジノプロスト



C<sub>20</sub>H<sub>34</sub>O<sub>5</sub>: 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 C<sub>20</sub>H<sub>34</sub>O<sub>5</sub>, 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-