Melting point: 50 - 54°C

Purity—Dissolve 0.032 g of dibenzyl in methanol to make exactly 50 mL, and use this solution as the sample solution. Perform the test with 20  $\mu$ L of the sample solution as directed under the Liquid Chromatography according to the operating conditions in the Assay under Vinblastine Sulfate for Injection: any peak other than the principal peak does not appear. Adjust the detection sensitivity so that the peak height of dibenzyl obtained from 20  $\mu$ L of the solution prepared by adding methanol to 10 mL of the sample solution to make 20 mL, is 3 to 5 cm, and the time span of measurement is about 1.2 times as long as the retention time of dibenzyl after the solvent peak.

- **2,6-Dibromo-***N***-chloro-1,4-benzoquinone monoimine** C<sub>6</sub>H<sub>2</sub>Br<sub>2</sub>:ClNO [K 8491, Special class]
- **2,6-Dibromo-***N***-chloro-1,4-benzoquinone monoimine TS** Dissolve 0.5 g of 2,6-dibromo-*N*-chloro-1,4-benzoquinone monoimine in methanol to make 100 mL.
- **2,6-Dibromo-***N***-chloro-1,4-benzoquinone monoimine TS, dilute** Dissolve 0.2 g of 2,6-dibromo-*N*-chloro-1,4-benzoquinone monoimine in methanol to make 100 mL.
- **2,6-Dibromoquinone chlorimide** See **2,6**-dibromo-*N*-chloro-1, **4**-benzoquinone monoimine.
- **2,6-Dibromoquinone chlorimide TS** See 2,6-dibromo-*N*-chloro-1, 4-benzoquinone monoimine TS.

**Dibucaine hydrochloride**  $C_{20}H_{29}N_3O_2$ .HCl [Same as the namesake monograph]

Dibutyl ether C<sub>8</sub>H<sub>18</sub>O Clear colorless liquid.

**Di-n-butyl phthalate**  $C_6H_4(COOC_4H_9)_2$  Clear colorless liquid.

Purity Related substances—Dissolve 0.5 g of di-n-butyl phthalate in 50 mL of methanol, and use this solution as the sample solution. Perform the test with  $10\,\mu\text{L}$  of the sample solution as directed in the Assay under Nicardipine Hydrochloride Injection, and determine the peak area by the automatic integration method. Calculate the amount of di-n-butyl phthalate by the area percentage method: the amount of di-n-butyl phthalate is not less than 98.0%, and no peak appears at the same position as nicardipine. Adjust the detection sensitivity so that the peak height of di-n-butyl phthalate obtained from  $10\,\mu\text{L}$  of the sample solution is 50 to 100% of the full scale, and measure about 2 times as long as the retention time of di-n-butyl phthalate after the solvent peak.

**1,2-Dichloroethane** ClCH<sub>2</sub>CH<sub>2</sub>Cl [K 8465, Special class]

**Dichlorofluorescein**  $C_{20}H_{10}Cl_2O_5$  [K 8466: 1972, Special class]

**Dichlorofluorescein TS** Dissolve 0.1~g of dichlorofluorescein in 60~mL of ethanol (95), add 2.5~mL of 0.1~mol/L sodium hydroxide VS, and dilute with water to make 100~mL.

- **2,6-Dichloroindophenol sodium dihydrate**  $C_{12}H_6Cl_2NNaO_2.2H_2O$  [K 8469, Special class]
- **2,6-Dichloroindophenol sodium TS** Add 0.1 g of 2,6-dichloroindophenol sodium dihydrate to 100 mL of water, warm, and filter. Use within 3 days.

**2,6-Dichloroindophenol sodium TS for titration** See the monograph Ascorbic Acid Powder.

Dichloromethane CH<sub>2</sub>Cl<sub>2</sub> [K 8161, Special class]

- **2,6-Dichlorophenol-indophenol sodium** See 2,6-dichloroindophenol sodium dihydrate.
- **2,6-Dichlorophenol-indophenol sodium TS** See 2,6-dichloroindophenol sodium TS.
- **2,6-Dichlorophenol-indophenol sodium TS for titration**See 2,6-dichloroindophenol sodium TS for titration.

N,N'-Dicyclohexylcarbodiimide  $C_6H_{11}N=C=NC_6H_{11}$  Colorless or white crystals or crystalline mass. Dissolves in ethanol (95), but decomposes in water to produce a white precipitate.

Melting point: 35 - 36°C

N,N'-Dicyclohexylcarbodiimide-dehydrated ethanol TS See N,N'-dicyclohexylcarbodiimide-ethanol (99.5) TS.

N,N'-Dicyclohexylcarbodiimide-ethanol (99.5) TS Dissolve 6 g of N,N'-dicyclohexylcarbodiimide in ethanol (99.5) to make 100 mL.

Storage—Preserve in tight containers, in a cold place.

**Dicyclohexyl phthalate**  $C_6H_4(COOC_6H_{11})_2$  A white, crystalline powder.

Melting point: 63 - 66°C

Purity Clarity and color of solution—Dissolve 1.0 g of dicyclohexyl phthalate in 20 mL of ethanol (95): the solution is clear and colorless.

## Dicyclohexylurea for thin-layer chromatography

 $C_6H_{11}NHCONHC_6H_5$  A white crystalline powder. Odorless. Very slightly soluble in N,N-dimethylformamide and in acetone, and practically insoluble in water.

Purity Related substances—Dissolve 0.04 g of dicyclohexylurea for thin-layer chromatography in a mixture of N,N-dimethylformamide and acetone (1:1) to make exactly 50 mL. Proceed with this solution as directed in the Purity (5) Related substances, Dicyclohexylurea, under Acetohexamide: any spot other than the principal spot at the Rf value of about 0.8 does not appear.

**Diethanolamine**  $C_4H_{11}NO_2$  Colorless viscous liquid. *Melting point*: 27 – 30°C *Water*: less than 0.1%.

**Diethanolamine hydrochloride**  $C_4H_{11}NO_2$ .HCl A pale yellow liquid.

Refractive index  $n_D^{20}$ : 1.515 – 1.519

Specific gravity  $d_{20}^{20}$ : 1.259 – 1.263

Water: less than 0.1%.

**Diethylamine**  $(C_2H_5)_2NH$  A clear, colorless liquid, having an amine-like odor. Miscible with water and with ethanol (95). The solution in water is alkaline, and readily absorbs carbon dioxide in air.

Specific gravity  $d_4^{10}$ : 0.702 - 0.708

Distilling range: 54 - 58°C; not less than 96 vol%.

Content: not less than 99.0%. Assay—Weigh accurately about 1.5 g of diethylamine in a flask containing exactly 30 mL of 0.5 mol/L sulfuric acid VS, and titrate the excess of sulfuric acid with 1 mol/L sodium hydroxide VS (indicator: 2 drops of methyl red TS). Perform a blank determination.

Each mL of 0.5 mol/L sulfuric acid VS = 73.14 mg of  $(C_2H_5)_2NH$ 

Diethylaminoethyl cellulose for column chromatography Prepared for column chromatography.

**Diethylene glycol** HO(CH<sub>2</sub>CH<sub>2</sub>O)<sub>2</sub>H Colorless and odorless liquid. Miscible with water and with ethanol (95).

Specific gravity  $d_{20}^{20}$ : 1.118 – 1.120

**Diethylene glycol adipinate for gas chromatography** Prepared for gas chromatography.

**Diethylene glycol dimethyl ether** (CH<sub>3</sub>OCH<sub>2</sub>CH<sub>2</sub>)<sub>2</sub>O Clear and colorless liquid, miscible with water.

Specific gravity d<sub>4</sub><sup>20</sup>: 0.940 - 0.950

Distilling range: 158 - 160°C, not less than 95 vol%.

## Diethylene glycol monoethyl ether

 $C_2H_5(OCH_2CH_2)_2OH$  [2-(2-ethoxyethoxy)ethanol] Clear, colorless liquid, of which boiling point is about 203 °C. It freely mixed with water.

Refractive index  $n_D^{20}$ : 1.425 – 1.429

Specific gravity d<sub>20</sub><sup>20</sup>: 0.990 – 0.995

Acid (as CH<sub>3</sub>COOH): less than 0.01%.

Diethylene glycol monoethyl ether for water determination See the Water Determination under the General Tests, Processes and Apparatus.

Diethylene glycol succinate ester for gas chromatography Prepared for gas chromatography.

Diethylene glycol succinate polyester for gas chromatography Prepared for gas chromatography.

Diethyl ether C<sub>2</sub>H<sub>5</sub>OC<sub>2</sub>H<sub>5</sub> [K 8103, Special class]

Diethyl ether, dehydrated  $C_2H_5OC_2H_5$  [K 8103, Special class. The water content is not more than 0.01%.]

Diethyl ether for purity of crude drug [K 8103, Special class] Use diethyl ether meeting the following additional specification. Evaporate 300.0 mL of diethyl ether for purity of crude drug in vacuum at a temperature not higher than 40°C, add the diethyl ether to make exactly 1 mL, and use this solution as the sample solution. Separately, dissolve 2.0 mg of  $\gamma$ -BHC in hexane for purity of crude drug to make exactly 100 mL. Pipet 1 mL of this solution, and add hexane for purity of crude drug to make exactly 100 mL. Pipet 2 mL of this solution, add hexane for purity of crude drug to make exactly 100 mL, and use this solution as the standard solution I. Perform the test with 1  $\mu$ L each of the sample solution and the standard solution I as directed under the Gas Chromatography according to the following operating conditions, and determine each peak area by the automatic integration method: the total area of peaks other than the solvent peak from the sample solution is not larger than the peak area of  $\gamma$ -BHC from the standard solution I. Operating conditions

Proceed the operating conditions in the Purity (3) under Powdered Ginseng except detection sensitivity and time span of measurement.

Detection sensitivity: Pipet 1 mL of the standard solution I, add hexane for purity of crude drug to make exactly 20 mL, and use this solution as the standard solution II. Adjust the detection sensitivity so that the peak area of  $\gamma$ -BHC obtained from 1  $\mu$ L of the standard solution II can be meas-

ured by the automatic integration method, and the peak height of  $\gamma$ -BHC from 1  $\mu$ L of the standard solution I is about 20% of the full scale.

Time span of measurement: About three times as long as the retention time of  $\gamma$ -BHC after the peak of solvent.

N,N-Diethyl-N'-1-naphthylethylenediamine oxalate  $C_{18}H_{24}N_2O_4$  [K 8694: 1992, Special class]

N,N-Diethyl-N'-1-naphthylethylenediamine oxalate-acetone TS Dissolve 1 g of N,N-Diethyl-N'-1-naphthylethylenediamine oxalate in 100 mL of a mixture of acetone and water (1:1). Prepare before use.

N,N-Diethyl-N'-1-naphthylethylenediamine oxalate TS Dissolve 1 g of N,N-Diethyl-N'-1-naphthylethylenediamine oxalate in water to make 1000 mL.

Diethyl phthalate  $C_6H_4(COOC_2H_5)_2$  A colorless, clear liquid.

*Refractive index*  $n_D^{20}$ : 1.500 – 1.505

Purity Related substances—To 1 mL of diethyl phthalate add a solution of tetra n-heptylammonium bromide in a mixture of water, acetonitrile and methanol (137:80:23) (2 in 625) to make 100 mL. To 6 mL of this solution add a solution of tetra n-heptylammonium bromide in a mixture of water, acetonitrile and methanol (137:80:23) (2 in 625) to make 50 mL, and use this solution as the sample solution. Perform the test with 10  $\mu$ L of the sample solution as directed in the assay under Cefetamet Pivoxil Hydrochloride: any peaks other than peaks of diethyl phthalate and the solvent are not observed.

**Diethyl terephthalate**  $C_6H_4(COOC_2H_5)_2$  White to pale brownish white, crystalline or mass.

Melting point: 44 - 46°C

Content: not less than 99%. Assay—Dissolve 100 mg of diethyl terephthalate in 10 mL of methanol. Perform the test with  $2 \mu L$  of this solution as directed under the Gas Chromatography according to the following conditions, and determine the area of each peak by the automatic integration method.

Content = 
$$\frac{\text{peak area of diethyl terephthalate}}{\text{total of all peak areas}} \times 100$$

Operating conditions

Detector: Hydrogen flame-ionization detector.

Column: A glass tube 4 mm in inside diameter and 2 m in length, packed with Shimalite W(AW, DMCS) coated with SE-30 in 10% (177 – 250  $\mu$ m in particle diameter).

Column temperature: A constant temperature of about  $200^{\circ}$ C

Carrier gas: Helium

Flow rate: Adjust the flow rate so that the retention time of diethyl terephthalate is between 6 and 7 minutes.

Time span of measurement: About 5 times as long as the retention time of diethyl terephthalate after the solvent peak.

Digitonin C<sub>56</sub>H<sub>92</sub>O<sub>29</sub> [K 8452, Special class]

## Dihydrocodeine phosphate for assay

 $C_{18}H_{23}NO_3.H_3PO_4$  [Same as the monograph Dihydrocodeine Phosphate. It contains not less than 99.0% of dihydrocodeine phosphate ( $C_{18}H_{23}NO_3.H_3PO_4$ ), calculated on the dried basis.

Dihydroergocristine mesilate for thin-layer chromatography  $C_{35}H_{41}N_5O_5$ .  $CH_4O_3S$  A pale yellowish white powder. Freely soluble in methanol, in ethanol (95) and in chloroform, soluble in acetonitrile, sparingly soluble in water, and practically insoluble in diethyl ether.

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

Purity Related substances—Dissolve 0.006 g of dihydroergocristine mesilate for thin-layer chromatography in exact 100 mL of a mixture of chloroform and methanol (9:1), and perform the test with  $5 \mu$ L of this solution as directed in the Purity (3) under Dihydroergotoxine Mesilate: any spot other than the principal spot at the Rf value around 0.4 does not appear.

**2,4-Dihydroxybenzoic acid**  $C_7H_6O_4$  White to pale brown powder.

Purity Clarity of solution—Dissolve 1.0 g of 2,4-di-hydroxybenzoic acid in 20 mL of ethanol (95): the solution is clear.

Content: not less than 95%. Assay—Weigh accurately about 1 g of 2,4-dihydroxybenzoic acid, dissolve in 50 mL of ethanol (95) and 50 mL of water, and titrate with 0.1 mol/L sodium hydroxide VS.

Each mL of 0.1 mol/L sodium hydroxide VS = 15.412 mg of  $C_7H_6O_4$ 

**Diltiazem hydrochloride**  $C_{22}H_{26}N_2O_4S.HCl$  [Same as the namesake monograph]

Dilute acetic acid See acetic acid, dilute.

Dilute bismuth subnitrate-potassium iodide TS for spray Dissolve 10 g of L-tartaric acid in 50 mL of water, and add 5 mL of bismuth subnitrate TS.

**Dilute bromophenol blue TS** See bromophenol blue TS, dilute.

Diluted ethanol See ethanol, diluted.

Dilute ethanol See ethanol, dilute.

**Dilute ferric ammonium sulfate TS** See ammonium iron (III) sulfate TS, dilute.

Dilute ferric chloride TS See iron (III) chloride TS, dilute.

Dilute hydrochloric acid See hydrochloric acid, dilute.

**Dilute hydrogen peroxide TS** See hydrogen peroxide TS, dilute.

Dilute iodine TS See iodine TS, dilute.

Dilute iron-phenol TS See iron-phenol TS, dilute.

Dilute lead subacetate TS See lead subacetate TS, dilute.

Dilute methyl red TS See methyl red TS, dilute.

Dilute nitric acid See nitric acid, dilute.

Dilute p-dimethylaminobenzaldehyde-ferric chloride TS See 4-dimethylaminobenzaldehyde-iron (III) chloride TS, dilute.

**Dilute potassium hydroxide-ethanol TS** See potassium hydroxide-ethanol TS, dilute.

**Dilute sodium hydroxide TS** See sodium hydroxide TS, dilute.

Dilute sulfuric acid See sulfuric acid, dilute.

Dilute thymol blue TS See thymol blue TS, dilute.

**Dilute vanadium pentoxide TS** See vanadium (V) oxide TS, dilute.

**Dilute 4-dimethylaminobenzaldehyde-iron (III) chloride TS** See 4-dimethylaminobenzaldehyde-iron (III) chloride
TS, dilute.

**Dimedon**  $C_8H_{12}O_2$  White to pale yellow, crystalline powder.

Melting point: 145-149°C

**Dimethylamine** (CH<sub>3</sub>)<sub>2</sub>NH Colorless, clear liquid, having amine-like, characteristic odor. It is miscible with water and with ethanol (99.5). It is alkaline.

*Specific gravity*  $d_{20}^{20}$ : 0.85 – 0.93

Content: 38.0 – 45.0%. Assay—Weigh accurately about 1.0 g of dimethylamine, transfer to a flask containing exactly 20 mL of 0.5 mol/L sulfuric acid VS, and titrate the excess sulfuric acid with 1 mol/L sodium hydroxide VS (indicator: 2 drops of methyl red TS). Perform a blank determination in the same manner.

Each mL of 0.5 mol/L sulfuric acid VS = 45.08 mg of (CH<sub>3</sub>)<sub>2</sub>NH

*p*-Dimethylaminobenzaldehyde See 4-dimethylaminobenzaldehyde.

**4-Dimethylaminobenzaldehyde** (CH<sub>3</sub>)<sub>2</sub>NC<sub>6</sub>H<sub>4</sub>CHO [K 8496, *p*-Dimethylaminobenzaldechyde, Special class]

*p*-Dimethylaminobenzaldehyde-ferric chloride TS See 4-dimethylaminobenzaldehyde-iron (III) chloride TS.

*p*-Dimethylaminobenzaldehyde-ferric chloride TS, dilute See 4-dimethylaminobenzaldehyde-iron (III) chloride TS, dilute.

p-Dimethylaminobenzaldehyde-hydrochloric acid TS See 4-dimethylaminobenzaldehyde-hydrochloric acid TS.

**4-Dimethylaminobenzaldehyde-hydrochloric acid TS** Dissolve 1.0 g of 4-dimethylaminobenzaldehyde in 50 mL of hydrochloric acid while cooling, and add 50 mL of ethanol (95).

**4-Dimethylaminobenzaldehyde-iron** (III) chloride TS Dissolve 0.125 g of 4-dimethylaminobenzaldehyde in a cold mixture of 65 mL of sulfuric acid and 35 mL of water, then add 0.05 mL of iron (III) chloride TS. Use within 7 days.

4-Dimethylaminobenzaldehyde-iron (III) chloride TS, dilute To 80 mL of water add carefully 100 mL of 4-dimethylaminobenzaldehyde-iron (III) chloride TS and 0.15 mL of iron (III) chloride TS, while cooling with ice.

*p*-Dimethylaminobenzaldehyde TS See 4-dimethylaminobenzaldehyde TS.

**4-Dimethylaminobenzaldehyde TS** Dissolve 10 g of 4-dimethylaminobenzaldehyde in a cold mixture of 90 mL of sulfuric acid and 10 mL of water. Prepare before use.

*p*-Dimethylaminobenzaldehyde TS for spraying See 4-dimethylaminobenzaldehyde TS for spraying.

**4-Dimethylaminobenzaldehyde TS for spraying**Dissolve 1.0 g of 4-dimethylaminobenzaldehyde in 20 mL of dilute sulfuric acid. Prepare before use.

*p*-Dimethylaminobenzylidene rhodanine See 4-dimethylaminobenzylidene rhodanine.

**4-Dimethylaminobenzylidene rhodanine** C<sub>12</sub>H<sub>12</sub>N<sub>2</sub>OS<sub>2</sub> [K 8495, Special class]

*p*-Dimethylaminobenzylidene rhodanine TS See 4-dimethylaminobenzylidene rhodanine TS.

**4-Dimethylaminobenzylidene rhodanine TS** Dissolve 0.02 g of 4-dimethylaminobenzylidene rhodanine in acetone to make 100 mL.

*p*-Dimethylaminocinnamaldehyde See 4-dimethylaminocinnamaldehyde.

**4-Dimethylaminocinnamaldehyde**  $C_{11}H_{13}NO$  Orange crystals or crystalline powder, having a characteristic odor. Freely soluble in dilute hydrochloric acid, sparingly soluble in ethanol (95) and in diethyl ether, and practically insoluble in water.

Melting point: 140 - 142°C

Purity Clarity of solution—Dissolve 0.2 g of 4-dimethylaminocinnamaldehyde in 20 mL of ethanol (95): the solution is clear.

Loss on drying: not more than 0.5% (1 g, 105°C, 2 hours). Residue on ignition: not more than 0.10% (1 g).

Nitrogen content: 7.8 - 8.1% (105°C, 2 hours, after drying, according to the Nitrogen Determination).

**p-Dimethylaminocinnamaldehyde TS** See 4-dimethylaminocinnamaldehyde TS.

**4-Dimethylaminocinnamaldehyde TS** Before use, add 1 mL of acetic acid (100) to 10 mL of a solution of 4-dimethylaminocinnamaldehyde in ethanol (95) (1 in 2000).

**Dimethylaminophenol** (CH<sub>3</sub>)<sub>2</sub>NC<sub>6</sub>H<sub>4</sub>OH Dark purple, crystals or crystalline mass.

Melting point: 85°C

Dimethylaminopropylsilanized silica gel for liquid chromatography Prepared for liquid chromatography.

**Dimethylaniline** See N,N-dimethylaniline.

N, N-Dimethylaniline  $C_6H_5N(CH_3)_2$  [K 8493: 1980, First class]

**Dimethylformamide** See N,N-dimethylformamide.

N, N-Dimethylformamide HCON(CH<sub>3</sub>)<sub>2</sub> [K 8500, Special class]

N,N-Dimethylformamide for liquid chromatography [K 8500, N,N-Dimethylformamide, Special class] Read absorbance as directed under the Ultraviolet-visible Spectrophotometry (in a 1-cm cell, using water as the blank): the absorbance is not more than 0.60 at 270 nm, not more than 0.15 at 280 nm, and not more than 0.05 at 300 nm.

Dimethylglyoxime C<sub>4</sub>H<sub>8</sub>N<sub>2</sub>O<sub>2</sub> [K 8498, Special class]

Dimethylglyoxime-thiosemicarbazide TS Solution A: Dissolve 0.5 g of dimethylglyoxime in hydrochloric acid to make 100 mL. Prepare before use. Solution B: Dissolve 0.1 g of thiosemicarbazide in 50 mL of water with the acid of warming if necessary, and add diluted hydrochloric acid (1 in 2) to make 100 mL. Prepare before use.

Mix 10 mL each of solution A and solution B, add diluted hydrochloric acid (1 in 2) to make 100 mL, and allow the mixture to stand for 1 hour. Use within 24 hours.

**Dimethylglyoxime TS** Dissolve 1 g of dimethylglyoxime in ethanol (95) to make 100 mL.

Dimethyl malonate  $C_5H_8O_4$  Clear, colorless or pale yellow liquid.

Specific gravity  $d_4^{20}$ : 1.152 – 1.162

Water: not more than 0.3%.

Residue on ignition: not more than 0.1%.

N,N-Dimethyl-n-octylamine  $C_{10}H_{23}N$  Colorless liquid. Refractive index  $n_D^{20}$ : 1.424

Dimethyl phthalate  $C_{16}H_{22}O_4$  Colorless, clear liquid, having a slight aroma.

*Refractive index*  $n_D^{20}$ : 1.491 – 1.493

Purity—To 6.0 mL of a solution of Dimethyl phthalate in isooctane (1 in 100) add a solution of n-amyl alcohol in hexane (3 in 1000) to make 50 mL, and perform the test with 10  $\mu$ L of this solution as directed under the Liquid Chromatography according to the conditions described in the Assay under Ergocalciferol or Cholecalciferol: any peak other than the principal peak does not appear.

*N*, *N*-Dimethyl-*p*-phenylenediamine dichloride H<sub>2</sub>NC<sub>6</sub>H<sub>4</sub>N(CH<sub>3</sub>)<sub>2</sub>.2HCl [K 8193, *N*,*N*-Dimethyl-*p*-phenyl enediammonium dichloride, Special class]

N,N-Dimethyl-p-phenylenediamine hydrochloride See N, N-dimethyl-p-phenylenediamine dichloride.

Dimethylsilanized silica gel with fluorescent indicator for thin-layer chromatography Dimethylsilanized silica gel for thin-layer chromatography to which a fluorescent indicator is added.

Dimethylsulfoxide (CH<sub>3</sub>)<sub>2</sub>SO [K 9702, Special class]

Dimethylsulfoxide for ultraviolet-visible spectrophotometry Colorless crystals or clear colorless liquid, having a characteristic odor. It is highly hygroscopic.

Congealing point: not less than 18.3°C.

Purity—Read absorbance of dimethylsulfoxide for ultraviolet-visible spectrophotometry, immediately after saturating with nitrogen, using water as the blank as directed under the Ultraviolet-visible Spectrophotometry: its value is not more than 0.20 at 270 nm, not more than 0.09 at 275 nm, not more than 0.06 at 280 nm, and not more than 0.015 at 300 nm. It exhibits no characteristic absorption between 260 nm and 350 nm.

Water content: not more than 0.1%.

2,6-Dimethyl-4-(2-nitrosophenyl)3,5-pyridinedicarboxylic acid dimethyl ester for thin-layer chromatography  $C_{17}H_{16}N_2O_5$  Irradiate xenon light at 50,000 lux of illumination for 8 hours to a methanol solution of nifedipine (1 in 100), and evaporate the methanol on a water bath. Recrystallize the residue 4 times from 1-propanol, and dry in a desiccator (in vacuum, phosphorus pentoxide). Pale blue crystals. Very soluble in chloroform, freely soluble in acetone, and practically insoluble in water.

Melting point: 93 - 95°C

Content: not less than 99.0%. Assay—Weigh accurately about 0.4 g of 2,6-dimethyl-4-(2-nitrosophenyl)-3,5-pyridinedicarboxylic acid dimethyl ester for thin-layer chromatography, dissolve in 70 mL of acetic acid (100), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination in the same manner.