Residue on ignition Not more than 0.30% (1 g).

Assay (1) Diphenhydramine—Weigh accurately about 0.5 g of Dimenhydrinate, previously dried, transfer to a 250-mL separator, and add 50 mL of water, 3 mL of ammonia TS and 10 g of sodium chloride. Extract with six 15-mL portions of diethyl ether with shaking, combine the diethyl ether extracts, and wash the combined diethyl ether extracts with three 50-mL portions of water. To the diethyl ether extracts add exactly 25 mL of 0.05 mol/L sulfuric acid VS, and add 25 mL of water. Shake thoroughly, and evaporate the diethyl ether gently. Cool, and titrate the excess sulfuric acid with 0.1 mol/L sodium hydroxide VS (indicator: 3 drops of methyl red TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.05 mol/L sulfuric acid VS
= 25.536 mg of $C_{17}H_{21}NO$

(2) 8-Chlorotheophylline—Weigh accurately about 0.8 g of Dimenhydrinate, previously dried, transfer to a 200-mL volumetric flask, add 50 mL of water, 3 mL of ammonia TS and 6 mL of a solution of ammonium nitrate (1 in 10), and heat on a water bath for 5 minutes. Add exactly 25 mL of 0.1 mol/L silver nitrate VS, heat on a water bath for 15 minutes with occasional shaking, cool, and add water to make exactly 200 mL. Allow to stand overnight to settle the precipitate, and filter through a dry filter paper, discarding the first 20 mL of the filtrate. Measure exactly 100 mL of the subsequent filtrate, acidify with nitric acid, add 3 mL of nitric acid, 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, and make any necessary correction.

Each mL of 0.1 mol/L silver nitrate VS
= 21.461 mg of $C_7H_7ClN_4O_2$

Containers and storage Containers—Well-closed containers.

Dimenhydrinate Tablets

ジメンヒドリナート錠

Dimenhydrinate Tablets contain not less than 95% and not more than 105% of the labeled amount of dimenhydrinate ($C_{17}H_{21}NO.C_7H_7ClN_4O_2$: 469.96).

Method of preparation Prepare as directed under Tablets, with Dimenhydrinate.

Identification (1) Triturate a quanity of powdered Dimenhydrinate Tablets, equivalent to 0.5 g of Dimenhydrinate according to the labeled amount, with 25 mL of warm ethanol (95), and filter. Dilute the filtrate with 40 mL of water, and filter again. Use the filtrate as the sample solution. Transfer 30 mL of the sample solution to a separator, and proceed as directed in the Identification (1) under Dimenhydrinate.

(2) With 30 mL of the sample solution obtained in (1), proceed as directed in the Identification (2), (3) and (4) under Dimenhydrinate.

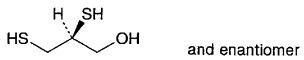
Assay Weigh accurately, and powder not less than 20 Dimenhydrinate Tablets. Weigh accurately a portion of the powder, equivalent to about 0.5 g of dimenhydrinate ($C_{17}H_{21}NO.C_7H_7ClN_4O_2$), transfer to a flask, add 40 mL of ethanol (95), and heat with swirling on a water bath until the solution just boils. Continue to heat for 30 seconds, and filter through a glass filter (G4). Wash the filter with warm ethanol (95), transfer the filtrate and washings to a flask, and evaporate the ethanol on a water bath to make 5 mL. Add 50 mL of water, 3 mL of ammonia TS and 6 mL of a solution of ammonium nitrate (1 in 10), heat the mixture on a water bath for 5 minutes, add exactly 25 mL of 0.1 mol/L silver nitrate VS, and heat on a water bath for 15 minutes with occasional shaking. Transfer the mixture to a 200-mL volumetric flask, using water to rinse the flask, cool, add water to make exactly 200 mL, and proceed as directed in the Assay (2) under Dimenhydrinate.

Each mL of 0.1 mol/L silver nitrate VS
= 47.00 mg of $C_{17}H_{21}NO.C_7H_7ClN_4O_2$

Containers and storage Containers—Well-closed containers.

Dimercaprol

ジメルカプロール



and enantiomer

$C_3H_8OS_2$: 124.23
(*RS*)-2,3-Disulfanylpropan-1-ol [*59-52-9*]

Dimercaprol contains not less than 98.5% and not more than 101.5% of $C_3H_8OS_2$.

Description Dimercaprol is a colorless to pale yellow liquid. It has a mercaptan-like, disagreeable odor.

It is miscible with methanol, with ethanol (95), and with diethyl ether.

It is soluble in peanut oil, and sparingly soluble in water.

Identification (1) Add 1 drop of Dimercaprol to a mixture of 1 drop of a solution of cobalt (II) chloride hexahydrate (1 in 200) and 5 mL of water: a yellow-brown color develops.

(2) Add 1 drop of Dimercaprol to a mixture of 1 drop of a solution of iron (II) sulfate heptahydrate (1 in 200) and 5 mL of water: a red color develops.

(3) Dissolve 1 drop of Dimercaprol in 20 mL of water, add 1 mL of a solution of sodium hydroxide (1 in 10), and shake. Add 0.2 mL of sodium pentacyanonitrosylferrate (III) TS, and shake: a purple color develops immediately, and changes to green on standing.

Refractive index n_D^{20}: 1.570 - 1.575

Specific gravity d_{20}^{20}: 1.238 - 1.248

Purity (1) Clarity and color of solution—Dissolve 1.0 mL of Dimercaprol in 20 mL of peanut oil: the solution is clear and colorless to pale yellow.

(2) Bromide—To 2.0 g of Dimercaprol add 25 mL of dilute potassium hydroxide-ethanol TS, and heat in a water bath under a reflux condenser for 2 hours. Evaporate the

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.

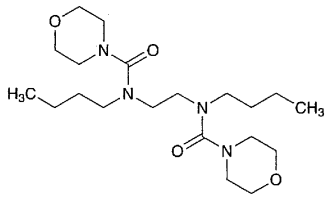
Assay Pipet a volume of Dimercaprol Injection, equivalent to about 0.2 g of dimercaprol ($C_3H_8OS_2$), into a flask, and rinse the pipet several times with a mixture of methanol and chloroform (3:1), adding the rinsings to the flask. Add a mixture of methanol and chloroform (3:1) to make 100 mL, and 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.