($C_{21}H_{30}O_2$: 314.46).

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

Description Progesterone Injection is a clear, colorless to pale yellow, oily liquid.

Identification Transfer a volume of Progesterone Injection, equivalent to 0.02 g of progesterone according to the labeled amount, to a separator. Add 40 mL of hexane, and mix thoroughly, then extract with three 20-mL portions of diluted ethanol (99.5) (9 in 10). Evaporate the combined extracts on a water bath to dryness. Add 0.075 g of 2,4-dinitrophenylhydrazine and 30 mL of ethanol (95) to the residue, and boil for 15 minutes under a reflux condenser. Add 1 mL of hydrochloric acid, and heat for 15 minutes. Cool, and collect the precipitate on a glass filter (G4). Wash the precipitate with five 10-mL portions of hexane and three 5-mL portions of ethanol (95). Then wash with diluted hydrochloric acid (1 in 20) until the washings become colorless, and dry at 105°C for 3 hours: the residue melts between 269°C and 275°C.

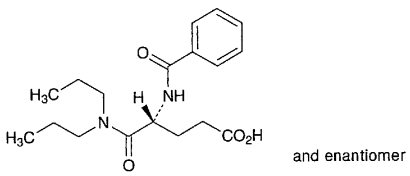
Assay Measure exactly a volume of Progesterone Injection, equivalent to about 0.05 g of progesterone ($C_{21}H_{30}O_2$), and dissolve in chloroform to make exactly 100 mL. To exactly measured 3 mL of this solution add chloroform to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.05 g of Progesterone Reference Standard, previously dried in a desiccator (in vacuum, phosphorus (V) oxide) for 4 hours, and prepare the standard solution in the same manner as directed for the preparation of the sample solution. Pipet 5 mL each of the sample solution and the standard solution, add exactly measured 10 mL of isoniazid TS and methanol to make exactly 20 mL, respectively. Allow to stand for 45 minutes, and perform the test with these solutions as directed under the Ultraviolet-visible Spectrophotometry, using a solution, prepared with 5 mL of chloroform in the same manner, as the blank. Determine the absorbances, A_T and A_S, of the subsequent solutions of the sample solution and the standard solution at 380 nm.

Amount (mg) of progesterone ($C_{21}H_{30}O_2$)
= amount (mg) of Progesterone Reference Standard
$\times \frac{A_T}{A_S}$

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

Proglumide

プログルミド



and enantiomer

$C_{18}H_{26}N_2O_4$: 334.41

(*RS*)-4-Benzoylamino-*N*,*N*-dipropylglutaramic acid
[*6620-60-6*]

Proglumide, when dried, contains not less than 98.5% of $C_{18}H_{26}N_2O_4$.

Description Proglumide occurs as white crystals or crystalline powder. It is freely soluble in methanol, soluble in ethanol (95), sparingly soluble in diethyl ether, and very slightly soluble in water.

A solution of Proglumide in methanol (1 in 10) shows no optical rotation.

Identification **(1)** Put 0.5 g of Proglumide in a round bottom tube, add 5 mL of hydrochloric acid, seal the tube, and heat the tube carefully at 120°C for 3 hours. After cooling, open the tube, filter the content to collect crystals separated out, wash the crystals with 50 mL of water, and dry at 100°C for 1 hour: the melting point of the crystals is between 121°C and 124°C.

(2) Determine the infrared absorption spectrum of Proglumide, 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.

Absorbance $E^{1\%}_{1cm}$ (225 nm): 384 - 414 (after drying, 4 mg, methanol, 250 mL)

Melting point 148 - 150°C

Purity **(1)** Heavy metals—Proceed with 1.0 g of Proglumide according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(2) Arsenic—To 1.0 g of Proglumide add 10 mL of a solution of magnesium nitrate hexahydrate in ethanol (95) (1 in 10) and 1.5 mL of hydrogen peroxide solution, burn the ethanol, and prepare the test solution according to Method 3, and perform the test using Apparatus B (not more than 2 ppm).

(3) Related substances—Dissolve 0.10 g of Proglumide 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 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 with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of cyclohexane, ethyl acetate, acetic acid (100) and methanol (50:18:5:4) to a distance of about 10 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): 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 0.10% (1 g, reduced pressure, phosphorus (V) oxide, 60°C, 3 hours).

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

Assay Weigh accurately about 0.16 g of Proglumide, previously dried, dissolve in 40 mL of methanol, add 10 mL of water, and titrate with 0.1 mol/L sodium hydroxide VS (potentiometric titration). Perform a blank determination,

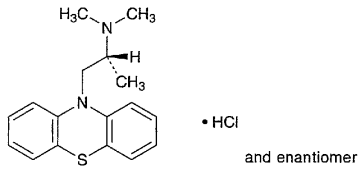
and make any necessary correction.

Each mL of 0.1 mol/L sodium hydroxide VS
= 33.442 mg of $C_{18}H_{26}N_2O_4$

Containers and storage Containers—Well-closed containers.

Promethazine Hydrochloride

塩酸プロメタジン



$C_{17}H_{20}N_2S.HCl$: 320.88
N,*N*-Dimethyl-*N*-[(*RS*)-1-methyl-2-(phenothiazin-10-yl)-ethyl]amine monohydrochloride [*58-33-3*]

Promethazine Hydrochloride, when dried, contains not less than 98.0% of $C_{17}H_{20}N_2S.HCl$.

Description Promethazine Hydrochloride occurs as a white to light yellow powder.

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

It is gradually colored by light.

A solution of Promethazine Hydrochloride (1 in 25) shows on optical rotation.

Melting point: about 223°C (with decomposition).

Identification **(1)** Determine the absorption spectrum of a solution of Promethazine Hydrochloride (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.

(2) Determine the infrared absorption spectrum of Promethazine Hydrochloride, 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.

(3) Dissolve 0.5 g of Promethazine Hydrochloride in 5 mL of water, add 2 mL of ammonia TS, and filter. To 5 mL of the filtrate add dilute nitric acid to make acidic: the solution responds to the Qualitative Tests (2) for chloride.

pH The pH of a solution of Promethazine Hydrochloride (1 in 10) is between 4.0 and 5.5.

Purity **(1)** Clarity and color of solution—Dissolve 1.0 g of Promethazine Hydrochloride in 10 mL of water, protecting from direct sunlight: the solution is clear and colorless.

(2) Heavy metals—Proceed with 1.0 g of Promethazine Hydrochloride according to Method 2, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(3) Related substances—Perform the test under the protection from sunlight. Dissolve 0.10 g of Promethazine Hydrochloride in exactly 5 mL of ethanol (95), and use this solution as the sample solution. Pipet 1 mL of the sample solution, add ethanol (95) to make exactly 200 mL, and use this solution as the standard solution (1). Separately, dissolve 0.020 g of isopromethazine hydrochloride for thin-layer chromatography in ethanol (95) to make exactly 100 mL, and use this solution as the standard solution (2). Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 10 μL each of the sample solution and the standard solutions (1) and (2) on a plate of silica gel with fluorescent indicator for thin-layer chromatography. Develop the plate with a mixture of methanol and diethylamine (19:1) to a distance of about 12 cm, and air-dry the plate. Examine under ultraviolet light (main wavelength: 254 nm): the spots from the sample solution corresponding to the spots from the standard solution (2) are not more intense than the spot from the standard solution (2), and any spot other than the principal spot from the sample solution is not more intense than the spot from the standard solution (1).

Loss on drying Not more than 0.5% (1 g, 105°C, 3 hours).

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

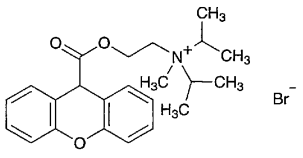
Assay Weigh accurately about 0.5 g of Promethazine Hydrochloride, previously dried, dissolve in 50 mL of a mixture of acetic anhydride and acetic acid (100) (7:3), and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 32.089 mg of $C_{17}H_{20}N_2S.HCl$

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

Propantheline Bromide

臭化プロパンテリン



$C_{23}H_{30}BrNO_3$: 448.39
N,*N*-Diisopropyl-*N*-methyl-*N*-[2-(xanthen-9-ylcarbonyloxy)ethyl]ammonium bromide [*50-34-0*]

Propantheline Bromide, when dried, contains not less than 98.0% and not more than 102.0% of $C_{23}H_{30}BrNO_3$.

Description Propantheline Bromide occurs as a white to yellowish white, crystalline powder. It is odorless and has a very bitter taste.

It is very soluble in water, in ethanol (95), in acetic acid (100) and in chloroform, soluble in acetic anhydride, and practically insoluble in diethyl ether.