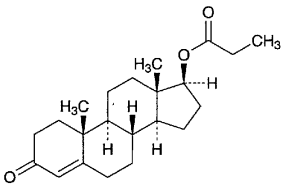
enanthate ($C_{26}H_{40}O_3$), and dissolve in chloroform to make exactly 25 mL. Pipet 3 mL of this solution, add chloroform to make exactly 50 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.025 g of Testosterone Propionate Reference Standard, proceed in the same manner as for the sample solution, and use this solution as the standard solution. Pipet 5 mL each of the sample solution and the standard solution, add exactly 10 mL of isoniazid TS, add methanol to make exactly 20 mL, and allow to stand for 45 minutes. Determine the absorbances, A_T and A_S, of these solutions at 380 nm, respectively, as directed under the Ultraviolet-visible Spectrophotometry, using a solution obtained by proceeding with 5 mL of chloroform as the blank.

Amount (mg) of testosterone enanthate ($C_{26}H_{40}O_3$)
= amount (mg) of Testosterone Propionate Reference Standard
$\times \frac{A_T}{A_S} \times 1.163$

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

Testosterone Propionate

プロピオン酸テストステロン



$C_{22}H_{32}O_3$: 344.49
3-Oxoandrost-4-en-17β-yl propionate [*57-85-2*]

Testosterone Propionate, when dried, contains not less than 97.0% and not more than 103.0% of $C_{22}H_{32}O_3$.

Description Testosterone Propionate occurs as white to pale yellow crystals or crystalline powder. It is odorless.

It is freely soluble in methanol, in ethanol (95), in 1,4-dioxane and in diethyl ether, and practically insoluble in water.

Identification **(1)** To 0.03 g of Testosterone Propionate add 2 mL of a solution of potassium hydroxide in ethanol (95) (1 in 100). Heat on a water bath under a reflux condenser for 1 hour. Cool, add 10 mL of water, and filter the precipitate by suction. Wash the precipitate with water until the washings become neutral, and dry in a desiccator (in vacuum, phosphorus (V) oxide) for 4 hours: the dried precipitate melts between 151°C and 157°C.

(2) To 0.02 g of Testosterone Propionate add 3.5 mL of a solution of 0.05 g of hydroxylammonium chloride and 0.05 g of anhydrous sodium acetate in 25 mL of methanol. Heat under a reflux condenser for 1 hour. Cool, add 15 mL of water, filter the precipitate, wash with water, and recrystallize from diluted methanol (7 in 10). Dry the crystals in a desiccator (in vacuum, phosphorus (V) oxide) for 4 hours: it melts between 167°C and 170°C.

Optical rotation $[\alpha]_D^{20}$: +83 - +90° (after drying, 0.1 g, 1,4-dioxane, 10 mL, 100 mm).

Melting point 118 - 123°C

Purity **(1)** Clarity and color of solution—Dissolve 0.5 g of Testosterone propionate in 10 mL of ethanol (95): the solution is clear and colorless.

(2) Other steroids—Dissolve 0.040 g of Testosterone Propionate in 2 mL of ethanol (95), and use this solution as the sample solution. Pipet 1 mL of this solution, add ethanol (95) to make exactly 100 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 chloroform and diethylamine (19:1) to a distance of about 15 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 0.5% (0.5 g, in vacuum, phosphorus (V) oxide, 4 hours).

Residue on ignition Not more than 0.1% (0.5 g).

Assay Weigh accurately about 0.01 g of Tetosterone Propionate, previously dried, and dissolve in methanol to make exactly 100 mL. To exactly 5 mL of this solution add methanol to make exactly 50 mL. Determine the absorbance A of this solution at the wavelength of maximum absorption at about 241 nm as directed under the Ultraviolet-visible Spectrophotometry.

Amount (mg) of testosterone propionate ($C_{22}H_{32}O_3$)
$= \frac{A}{495} \times 10{,}000$

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

Testosterone Propionate Injection

プロピオン酸テストステロン注射液

Testosterone Propionate Injection is an oily solution for injection. It contains not less than 90% and not more than 110% of the labeled amount of testosterone propionate ($C_{22}H_{32}O_3$: 344.49).

Method of preparation Prepare as directed under Injections, with Testosterone Propionate.

Description Testosterone Propionate Injection is a clear, colorless or pale yellow oily liquid.

Identification Measure a volume of Testosterone Propionate Injection, equivalent to 0.05 g of Testosterone Propionate according to the labeled amount, and transfer to a separator containing 40 mL of petroleum benzin. Shake well, then extract with three 20-mL portions of diluted

ethanol (99.5) (9 in 10). Combine the extracts, wash with 20 mL of petroleum benzin saturated with diluted ethanol (99.5) (9 in 10), and evaporate on a water bath to dryness. To the residue add 3 mL of semicarbazide acetate TS, and boil vigorously for 2 hours under a reflux condenser. After cooling, filter by suction, and collect the precipitate. Wash the precipitate on the filter with four 10-mL portions of petroleum benzin and four 5-mL portions of water, and dry at 105°C for 3 hours: it melts between 208°C and 217°C.

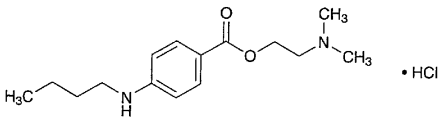
Assay Dissolve an accurately measured volume of Testosterone Propionate Injection, equivalent to about 0.05 g of testosterone propionate ($C_{22}H_{32}O_3$), in chloroform to make exactly 50 mL. Pipet 4 mL of this solution, dissolve in chloroform to make exactly 100 mL, and use this solution as the sample solution. Weigh accurately about 0.05 g of Testosterone Propionate 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, and treat each solution as follows: Add 10 mL of isoniazid TS, exactly measured, and methanol to make exactly 20 mL, and allow to stand for 45 minutes. 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 testosterone propionate ($C_{22}H_{32}O_3$)
= amount (mg) of Testosterone Propionate Reference Standard
$\times \frac{A_T}{A_S}$

Containers and storage Containers—Hermetic containers.

Tetracaine Hydrochloride

塩酸テトラカイン



$C_{15}H_{24}N_2O_2$.HCl: 300.82
2-(Dimethylamino)ethyl 4-(butylamino)benzoate monohydrochloride [*136-47-0*]

Tetracaine Hydrochloride, when dried, contains not less than 98.5% of $C_{15}H_{24}N_2O_2$.HCl.

Description Tetracaine Hydrochloride occurs as white crystals or crystalline powder. It is odorless, and has a slightly bitter taste followed by a sense of numbness on the tongue.

It is very soluble in formic acid, freely soluble in water, soluble in ethanol (95), sparingly soluble in ethanol (99.5), slightly soluble in acetic anhydride, and practically insoluble in diethyl ether.

A solution of Tetracaine Hydrochloride (1 in 10) is neutral.

Melting point: about 148°C

Identification (1) Dissolve 0.5 g of Tetracaine Hydrochloride in 50 mL of water, add 5 mL of ammonia TS, shake, and allow to stand in a cold place. Collect the precipitate, wash with water until the washings is neutral, and dry in a desiccator (silica gel) for 24 hours: it melts between 42°C and 44°C.

(2) Dissolve 0.1 g of Tetracaine Hydrochloride in 8 mL of water, and add 3 mL of ammonium thiocyanate TS: a crystalline precipitate is produced. Collect the precipitate, recrystallize from water, and dry at 80°C for 2 hours: it melts between 130°C and 132°C.

(3) Determine the absorption spectrum of a solution of Tetracaine Hydrochloride in ethanol (99.5) (1 in 200,000) 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.

(4) A solution of Tetracaine Hydrochloride (1 in 10) responds to the Qualitative Tests for chloride.

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

Loss on drying Not more than 1.0% (1 g, 105°C, 4 hours).

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

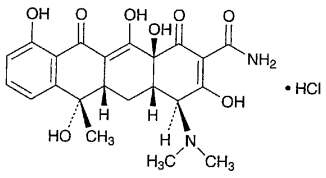
Assay Weigh accurately about 0.5 g of Tetracaine Hydrochloride, previously dried, dissolve in 2 mL of formic acid, add 80 mL of acetic anhydride, allow to stand at 30°C on a water bath for 15 minutes, cool, and titrate with 0.1 mol/L perchloric acid VS (potentiometric titration). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 30.083 mg of $C_{15}H_{24}N_2O_2$.HCl

Containers and storage Containers—Tight containers.

Tetracycline Hydrochloride

塩酸テトラサイクリン



$C_{22}H_{24}N_2O_8$.HCl: 480.90
(4*S*,4a*S*,5a*S*,6*S*,12a*S*)-4-Dimethylamino-1,4,4a,5,5a,6,11,12a-octahydro-3,6,10,12,12a-pentahydroxy-6-methyl-1,11-dioxonaphthacene-2-carboxamide monohydrochloride [*64-75-5*]