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 (C₂₂H₃₂O₃), 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 Ultravioletvisible 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 (C₂₂H₃₂O₃)

= amount (mg) of Testosterone Propionate Reference Standard

 $\times \frac{A_{\rm T}}{A_{\rm S}}$

Containers and storage Containers—Hermetic containers.

Tetracaine Hydrochloride

塩酸テトラカイン

C₁₅H₂₄N₂O₂.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

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