control solution with 2.0 mL of Standard Lead Solution (not more than 20 ppm).

(6) Arsenic—Dissolve 1.0 g of L-Tryptophan in 3 mL of 1 mol/L hydrochloric acid TS and 2 mL of water by heating, and perform the test with this solution as the test solution using Apparatus B (not more than 2 ppm).

(7) Other amino acids—Dissolve 0.30 g of L-Tryptophan in 1 mL of 1 mol/L hydrochloric acid TS, add water to make 50 mL, and use this solution as the sample solution. Pipet 1 mL of the sample solution, and add water to make exactly 50 mL. Pipet 5 mL of this solution, add water to make exactly 20 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Spot 5 μL each of the sample solution and the standard solution on a plate of silica gel for thin-layer chromatography. Develop the plate with a mixture of 1-butanol, water and acetic acid (100) (3:1:1) to a distance of about 10 cm, and dry the plate at 80°C for 30 minutes. Spray evenly a solution of ninhydrin in acetone (1 in 50) on the plate, and heat at 80°C for 5 minutes: 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 0.30% (1 g, 105°C, 3 hours).

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

Assay Weigh accurately about 0.2 g of L-Tryptophan, previously dried, dissolve in 3 mL of formic acid, add 50 mL of acetic acid (100), 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
= 20.423 mg of $C_{11}H_{12}N_2O_2$

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

Tubocurarine Chloride

Tubocurarine Hydrochloride

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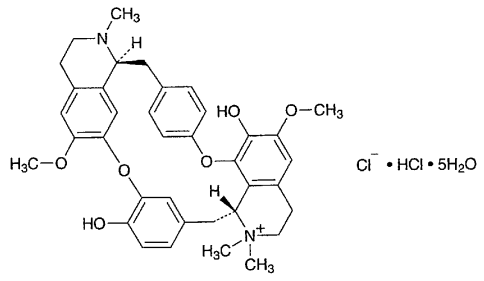

$C_{37}H_{41}ClN_2O_6.HCl.5H_2O$: 771.72
7′,12′-Dihydroxy-6,6′-dimethoxy-2,2′,2′-trimethyltubocuraranium chloride monohydrochloride pentahydrate [*41354-45-4*]

Tubocurarine Chloride contains not less than 98.0% of $C_{37}H_{41}ClN_2O_6.HCl$ (mol. wt.: 681.65), calculated on the dried basis.

Description Tubocurarine Chloride occurs as white crystals or crystalline powder. It is odorless.

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

The pH of a solution of Tubocurarine chloride (1 in 100) is between 4.0 and 6.0.

Melting point: about 270°C (with decomposition).

Identification **(1)** To 20 mL of a solution of Tubocurarine Chloride (1 in 2000) add 0.2 mL of sulfuric acid and 2 mL of a solution of potassium iodate (1 in 100), shake, and heat on a water bath for 30 minutes: a yellow color is produced.

(2) To 1 mL of a solution of Tubocurarine Chloride (1 in 100) add 1 mL of a solution of Reinecke salt (1 in 25): a red precipitate is formed.

(3) Determine the absorption spectrum of a solution of Tubocurarine Chloride (3 in 100,000) as directed under the Ultraviolet-visible Spectrophotometry, and compare the spectrum with the Reference Spectrum or the spectrum of a solution of Tubocurarine Chloride Reference Standard prepared in the same manner as the sample solution: both spectra exhibit similar intensities of absorption at the same wavelengths.

(4) A solution of Tubocurarine Chloride (1 in 50) responds to the Qualitative Tests (2) for chloride.

Optical rotation $[\alpha]_D^{20}$: +210 - +220° (0.1 g, calculated on the dried basis, water, 10 mL, after allowing to stand for 3 hours, 100 mm).

Purity **(1)** Clarity and color of solution—Dissolve 0.10 g of Tubocurarine Chloride in 10 mL of ethanol (95): the solution is clear and colorless.

(2) Chloroform-soluble substances—Weigh accurately about 0.2 g of Tubocurarine Chloride, calculated on the dried basis, add 200 mL of water and 1 mL of a saturated solution of sodium hydrogen carbonate, and extract with three 20-mL portions of chloroform. Combine the chloroform extracts, wash with 10 mL of water, filter the chloroform solution through absorbent cotton into a tared beaker, wash the absorbent cotton with two 5-mL portions of chloroform, and combine the filtrate and the washings. Evaporate the chloroform on a water bath, and dry the residue at 105°C for 1 hour: the mass of the residue is not more than 2.0% of the mass of Tubocurarine Chloride taken. Add 10 mL of water to the residue: the residue does not dissolve. Add 1 mL of hydrochloric acid, and stir: the residue dissolves.

Loss on drying 9 - 12% (0.5 g, in vacuum, phosphorus (V) oxide, 105°C, 4 hours).

Residue on ignition Not more than 0.25% (0.5 g).

Assay Weigh accurately about 0.5 g of Tubocurarine Chloride, add 20 mL of acetic acid (100), and dissolve by warming on a water bath. After cooling, add 60 mL of acetic anhydride, 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
= 34.083 mg of $C_{37}H_{41}ClN_2O_6.HCl$

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

Tubocurarine Chloride Injection

Tubocurarine Hydrochloride Injection

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Tubocurarine Chloride Injection is an aqueous solution for injection. It contains not less than 93% and not more than 107% of the labeled amount of tubocurarine chloride ($C_{37}H_{41}ClN_2O_6.HCl.5H_2O$: 771.72).

Method of preparation Prepare as directed under Injections, with Tubocurarine Chloride.

Description Tubocurarine Chloride Injection is a clear, colorless liquid.

Identification (1) To a volume of Tubocurarine Chloride Injection, equivalent to 0.01 g of Tubocurarine Chloride according to the labeled amount, add water to make 20 mL, and proceed as directed in the Identification (1) under Tubocurarine Chloride.

(2) Proceed with a volume of Tubocurarine Chloride Injection, equivalent to 3 mg of Tubocurarine Chloride according to the labeled amount, as directed in the Identification (2) under Tubocurarine Chloride.

(3) To a volume of Tubocurarine Chloride Injection, equivalent to 3 mg of Tubocurarine Chloride according to the labeled amount, add water to make 100 mL, and determine the absorption spectrum of the solution as directed under the Ultraviolet-visible Spectrophotometry: it exhibits a maximum between 279 nm and 281 nm, and a minimum between 253 nm and 257 nm.

Optical rotation α_D^{20}: +0.35 - +0.42° (200 mm), calculated with reference to the value of solution containing 1 mg of Tubocurarine Chloride per ml, according to the labeled amount of Tubocurarine Chloride Injection.

pH 3.0 - 6.0

Assay Measure exactly a volume of Tubocurarine Chloride Injection, equivalent to about 0.015 g of tubocurarine chloride ($C_{37}H_{41}ClN_2O_6.HCl.5H_2O$), add water to make exactly 500 mL, and use this solution as the sample solution. Separately, weigh accurately about 0.015 g of Tubocurarine Chloride Reference Standard (previously dry in the same manner as directed under Tubocurarine Chloride, and weigh to determine the loss on drying), dissolve in water to make exactly 500 mL, and use this solution as the standard solution. Determine the absorbances, A_T and A_S, of the sample solution and the standard solution at 280 nm as directed under the Ultraviolet-visible Spectrophotometry, respectively.

Amount (mg) of tubocurarine chloride ($C_{37}H_{41}ClN_2O_6.HCl.5H_2O$)
= amount (mg) of Tubocurarine Chloride Reference Standard, calculated on the dried basis

$$\times \frac{A_T}{A_S} \times 1.1321$$

Containers and storage Containers—Hermetic containers.
Storage—Light-resistant, and under Nitrogen atmosphere.

Tulobuterol Hydrochloride

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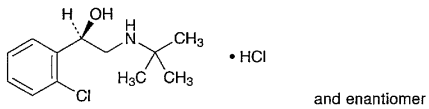

and enantiomer

$C_{12}H_{18}ClNO.HCl$: 264.19
(*RS*)-2-*tert*-Butylamino-1-(2-chlorophenyl)ethanol monohydrochloride [*56776-01-3*]

Tulobuterol Hydrochloride, when dried, contains not less than 98.5% of $C_{12}H_{18}ClNO.HCl$.

Description Tulobuterol Hydrochloride occurs as white crystals or crystalline powder.

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

A solution of Tulobuterol Hydrochloride (1 in 20) shows no optical rotation.

Melting point: about 163°C

Identification (1) Determine the absorption spectrum of a solution of Tulobuterol Hydrochloride (1 in 2500) 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 Tulobuterol Hydrochloride, previously dried, as directed in the potassium bromide disk method under the Infrared Spectrophotometry, and compare the spectrum with the Reference Spectrum: both spctra exhibit similar intensities of absorption at the same wave numbers.

(3) A solution of Tulobuterol Hydrochloride (1 in 20) responds to the Qualitative Tests for chloride.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Tulobuterol Hydrochloride in 10 mL of water: the solution is clear and colorless.

(2) Heavy metals—Proceed with 2.0 g of Tulobuterol Hydrochloride according to Method 1, and perform the test. Prepare the control solution with 2.0 mL of Standard Lead Solution (not more than 10 ppm).

(3) Related substances—Dissolve 0.30 g of Tulobuterol Hydrochloride 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 50 mL, and use this solution as the standard solution. Perform the test with these solutions as directed under the Thin-layer Chromatography. Use a