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**

塩化ツボクラリン注射液

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<sub>2</sub>O: 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**  $\alpha_D^{20}$ : +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.

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<sub>2</sub>O), 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<sub>37</sub>H<sub>41</sub>ClN<sub>2</sub>O<sub>6</sub>.HCl.5H<sub>2</sub>O)

= amount (mg) of Tubocurarine Chloride Reference

Standard, calculated on the dried basis

$$\times \frac{A_{\rm T}}{A_{\rm S}} \times 1.1321$$

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

## **Tulobuterol Hydrochloride**

塩酸ツロブテロール

C<sub>12</sub>H<sub>18</sub>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  $C_{12}H_{18}CINO.HCl.$ 

**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 spectra 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