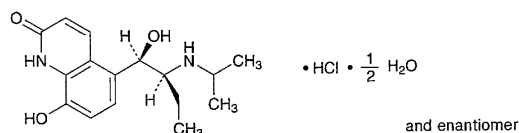


Each mL of 0.05 mol/L potassium iodate VS
= 8.592 mg of $C_{12}H_{19}N_3O \cdot HCl$

Containers and storage Containers—Tight containers.

Procaterol Hydrochloride

塩酸プロカテロール



$C_{16}H_{22}N_2O_3 \cdot HCl \cdot \frac{1}{2}H_2O$: 335.83
8-Hydroxy-5-[(1*RS*,2*SR*)-1-hydroxy-2-isopropylaminobutyl]quinolin-2(1*H*)-one
monohydrochloride hemihydrate [62929-91-3, anhydride]

Procaterol Hydrochloride contains not less than 98.5% of $C_{16}H_{22}N_2O_3 \cdot HCl$ (mol. wt.: 326.82), calculated on the anhydrous basis.

Description Procaterol Hydrochloride occurs as white to pale yellowish white crystals or crystalline powder.

It is soluble in water, in formic acid and in methanol, slightly soluble in ethanol (95), and practically insoluble in diethyl ether.

The pH of a solution of Procaterol Hydrochloride (1 in 100) is between 4.0 and 5.0.

It is gradually colored by light.

Melting point: about 195°C (with decomposition).

The solution of Procaterol Hydrochloride (1 in 20) shows no optical rotation.

Identification (1) Determine the absorption spectrum of a solution of Procaterol Hydrochloride (7 in 1,000,000) 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 Procaterol Hydrochloride 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 Procaterol Hydrochloride (1 in 50) responds to the Qualitative Tests for chloride.

Purity (1) Clarity and color of solution—Dissolve 1.0 g of Procaterol Hydrochloride in 30 mL of water: the solution is clear, and has no more color than the following control solution.

Control solution: To 3.0 mL of Ferric Chloride Stock CS add water to make 50 mL.

(2) Heavy metals—Proceed with 2.0 g of Procaterol Hydrochloride according to Method 2, 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 0.10 g of Procaterol Hydrochloride in 100 mL of diluted methanol (1 in 2), and

use this solution as the sample solution. Pipet 1 mL of the sample solution, add diluted methanol (1 in 2) to make exactly 100 mL, and use this solution as the standard solution. Perform the test with 2 μ L each of the sample solution and the standard solution as directed under the Liquid Chromatography according to the following conditions. Determine each peak area of these solutions by the automatic integration method: the total area of the peaks other than procaterol from the sample solution is not larger than the peak area of procaterol from the standard solution.

Operating conditions—

Detector: An ultraviolet absorption photometer (wavelength: 254 nm).

Column: A stainless steel column about 4 mm in inside diameter and about 25 cm in length, packed with octadecylsilylated silica gel for liquid chromatography (5 μ m in particle diameter).

Column temperature: A constant temperature of about 40°C.

Mobile phase: Dissolve 0.87 g of sodium 1-pentanesulfonate in 1000 mL of water. To 760 mL of this solution add 230 mL of methanol and 10 mL of glacial acetic acid.

Flow rate: Adjust the flow rate so that the retention time of procaterol is about 15 minutes.

Selection of column: Dissolve 0.020 g each of Procaterol Hydrochloride and threoprocaterol hydrochloride in 100 mL of diluted methanol (1 in 2). To 15 mL of this solution add diluted methanol (1 in 2) to make 100 mL. Proceed with 2 μ L of this solution under the above operating conditions, and calculate the resolution. Use a column giving elution of procaterol and threoprocaterol in this order with the resolution of these peaks being not less than 3.

Detection sensitivity: Adjust the detection sensitivity so that the peak height of procaterol obtained from 2 μ L of the standard solution is not less than 10 mm.

Time span of measurement: 2.5 times as long as the retention time of procaterol after the solvent peak.

Water 2.5 – 3.3% (0.5 g, direct titration).

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

Assay Weigh accurately about 0.25 g of Procaterol Hydrochloride, add 2 mL of formic acid, dissolve by warming, and add exactly 15 mL of 0.1 mol/L perchloric acid VS. Add 1 mL of acetic anhydride, heat on a water bath for 30 minutes, cool, add 60 mL of acetic anhydride, and titrate the excess perchloric acid with 0.1 mol/L sodium acetate VS (potentiometric titration). Perform a blank determination.

Each mL of 0.1 mol/L perchloric acid VS
= 32.682 mg of $C_{16}H_{22}N_2O_3 \cdot HCl$

Containers and storage Containers—Well-closed containers.

Storage—Light-resistant.