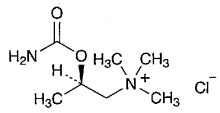
Selection of column: Proceed with 10 μL of the standard solution under the above operating conditions, and calculate the resolution. Use a column giving elution of betamethasone valerate and the internal standard in this order with the resolution between these peaks being not less than 5.

Containers and storage Containers—Tight containers.

Bethanechol Chloride

塩化ベタネコール



and enantiomer

$C_7H_{17}ClN_2O_2$: 196.68
N-[(*RS*)-2-(Carbamoyloxy)propyl]-*N*,*N*,*N*-trimethylammonium chloride [*590-63-6*]

Bethanechol Chloride, when dried, contains not less than 98.0% of $C_7H_{17}ClN_2O_2$, and not less than 17.7% and not more than 18.3% of chlorine (Cl: 35.45).

Description Bethanechol Chloride occurs as colorless or white crystals or a white, crystalline powder. It has a slight amine-like odor, and has a slight, saline taste.

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

It is hygroscopic.

Melting point: about 211°C or about 219°C

Identification (1) To 2 mL of a solution of Bethanechol Chloride (1 in 40) add 0.1 mL of a solution of cobalt (II) chloride hexahydrate (1 in 100), then add 0.1 mL of potassium hexacyanoferrate (II) TS: A green color is produced, and almost entirely fades within 10 minutes.

(2) To 1 mL of a solution of Bethanechol Chloride (1 in 100) add 0.1 mL of iodine TS: a brown precipitate is produced, and the solution shows a greenish brown color.

(3) A solution of Bethanechol Chloride (1 in 100) responds to the Qualitative Tests for chloride.

Purity Heavy metals—Proceed with 1.0 g of Bethanechol Chloride 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, 2 hours).

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

Assay (1) Bethanechol chloride—Weigh accurately about 0.4 g of Bethanechol Chloride, previously dried, dissolve in 2 mL of acetic acid (100), add 40 mL of acetic anhydride, and titrate with 0.1 mol/L perchloric acid VS until the color of the solution changes from purple through green to yellow-green (indicator: 2 drops of crystal violet TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L perchloric acid VS
= 19.668 mg of $C_7H_{17}ClN_2O_2$

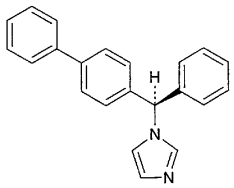
(2) Chlorine—Weigh accurately about 0.4 g of Bethanechol Chloride, previously dried, dissolve in 30 mL of water, and add exactly 40 mL of 0.1 mol/L silver nitrate VS. Then add 3 mL of nitric acid and 5 mL of nitrobenzene, shake vigorously for 2 to 3 minutes, and titrate the excess silver nitrate with 0.1 mol/L ammonium thiocyanate VS (indicator: 2 mL of ammonium iron (III) sulfate TS). Perform a blank determination.

Each mL of 0.1 mol/L silver nitrate VS = 3.5453 mg of Cl

Containers and storage Containers—Tight containers.

Bifonazole

ビホナゾール



and enantiomer

$C_{22}H_{18}N_2$: 310.39
1-[(*RS*)-(Biphenyl-4-yl)phenylmethyl]-1*H*-imidazole [*60628-96-8*]

Bifonazole, when dried, contains not less than 98.5% of $C_{22}H_{18}N_2$.

Description Bifonazole occurs as a white to pale yellow powder. It is odorless and tasteless.

It is freely soluble in dichloromethane, soluble in methanol, sparingly soluble in ethanol (95), slightly soluble in diethyl ether, and practically insoluble in water.

A solution of Bifonazole in methanol (1 in 100) does not show optical rotation.

Identification (1) Determine the absorption spectrum of a solution of Bifonazole in methanol (1 in 100,000) 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 Bifonazole, 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.

Melting point 147 - 151°C

Purity (1) Chloride—To 2.0 g of Bifonazole add 40 mL of water, warm for 5 minutes, and after cooling, filter. To 10 mL of the filtrate add 6 mL of dilute nitric acid and water to make 50 mL. Perform the test using this solution as the test solution. Prepare the control solution with 0.30 mL of 0.01 mol/L hydrochloric acid VS (not more than 0.021%).

(2) Sulfate—To 10 mL of the filtrate obtained in (1) add