**Loss on drying** Not more than 0.5% (1 g, in vacuum at a pressure not exceeding 0.67 kPa, phosphorus (V) oxide, 50°C, 4 hours).

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

**Assay** Weigh accurately about 0.6 g of Benzethonium, previously dried, dissolve in 30 mL of N,N-dimethylformamide, and titrate with 0.1 mol/L tetramethylammonium hydroxide VS (indicator: 5 drops of thymol blue-dimethylformamide TS). Perform a blank determination, and make any necessary correction.

Each mL of 0.1 mol/L tetramethylammonium hydroxide VS = 42.41 mg of C13H23Br2O3

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

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**Benzethonium Chloride**

塩化ベンゼトンニウム

\[
\text{C}_{27}\text{H}_{42}\text{ClNNO}_2: 448.08
\]

N-Benzyl-N,N-dimethyl-N-2-[2-4-[1,1,3,3-tetramethylbutyl]phenoxyl]ethoxy]ethylammonium chloride

[121-54-0]

Benzethonium Chloride, when dried, contains not less than 97.0% of C27H42ClNNO2.

**Description** Benzethonium Chloride occurs as colorless or white crystals. It is odorless.

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

A solution of Benzethonium Chloride foams strongly when shaken.

**Identification** (1) Dissolve 0.2 g of Benzethonium Chloride in 1 mL of sulfuric acid, add 0.1 g of sodium nitrate, and heat for 5 minutes on a water bath. After cooling, add 10 mL of water and 0.5 g of zinc powder, heat for 5 minutes, cool, and filter: the filtrate responds to the Qualitative Tests for primary aromatic amines, developing a red color.

(2) To 2 mL of a solution of Benzethonium Chloride (1 in 1000) add a mixture of 0.2 mL of a solution of bromphenol blue (1 in 2000) and 0.5 mL of sodium hydroxide TS: a blue color develops. Add 4 mL of chloroform to this solution, and shake vigorously: the blue color shifts to the chloroform layer. Collect the chloroform layer, and add dropwise a solution sodium lauryl sulfate (1 in 1000) with stirring: the chloroform layer turns colorless.

(3) Determine the absorption spectrum of a solution of Benzethonium Chloride in 0.1 mol/L hydrochloric acid TS (1 in 5000) 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) To 1 mL of a solution of Benzethonium Chloride (1 in 100) add 2 mL of ethanol (95), 0.5 mL of dilute nitric acid and 1 mL of silver nitrate TS: a white precipitate is produced. This precipitate does not dissolve on addition of dilute nitric acid, but dissolved on addition of ammonia TS.

**Melting point** 158 – 164°C (after drying).

**Purity** Ammonium—Proceed as directed in the Purity under Benzalkonium Chloride.

**Loss on drying** Not more than 5.0% (1 g, 105°C, 4 hours).

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

**Assay** Weigh accurately about 0.2 g of Benzethonium Chloride, previously dried, dissolve in 75 mL of water, add diluted hydrochloric acid (1 in 2) dropwise to adjust the pH to 2.6–3.4, then add 1 drop of methyl orange TS, and titrate with 0.02 mol/L tetraphenylboron VS until the solution develops a red.

Each mL of 0.02 mol/L sodium tetraphenylboron VS = 8.962 mg of C27H42ClNNO2

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

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**Benzethonium Chloride Solution**

塩化ベンゼトンニウム液

Benzethonium Chloride Solution contains not less than 93% and not more than 107% of the labeled amount of benzethonium chloride (C27H42ClNNO2: 448.08).

**Method of preparation** Dissolve Benzethonium Chloride in Water or Purified Water.

**Description** Benzethonium Chloride Solution is a clear, colorless liquid. It is odorless.

It foams strongly when shaken.

**Identification** (1) Evaporate a volume of Benzethonium Chloride Solution, equivalent to 0.2 g of Benzethonium Chloride according to the labeled amount, on a water bath to dryness, and proceed with the residue as directed in the Identification (1) under Benzalkonium Chloride.

(2) To a volume of Benzethonium Chloride Solution, equivalent to 0.01 g of Benzethonium Chloride according to the labeled amount, add water to make 10 mL, proceed with 2 mL of this solution as directed in the Identification (2) under Benzalkonium Chloride.

(3) To a volume of Benzethonium Chloride Solution, equivalent to 1 g of Benzethonium Chloride according to the labeled amount, and add water or concentrate on a water bath to make 10 mL. To 1 mL of this solution add 0.1 mol/L hydrochloric acid TS to make 500 mL, and determine the absorption spectrum as directed under the Ultraviolet-visible Spectrophotometry: it exhibits maxima between 262 nm and 264 nm, between 268 nm and 270 nm, and between 274 nm and 276 nm.

(4) To a volume of Benzethonium Chloride Solution,