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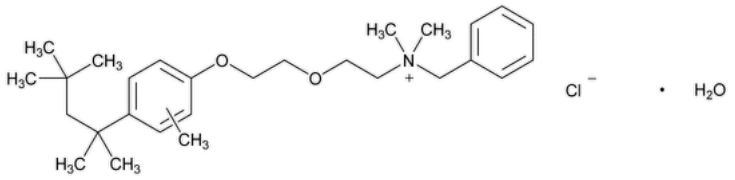
Methylbenzethonium Chloride



$C_{28}H_{44}ClNO_2 \cdot H_2O$ 480.12
$C_{28}H_{44}ClNO_2$ 462.12

Benzenemethanaminium, *N*,*N*-dimethyl-*N*-[2-[2-[methyl-4-(1,1,3,3-tetramethylbutyl)phenoxy]ethoxy]ethyl]-, chloride, monohydrate;

Benzyldimethyl[2-[2-[[4-(1,1,3,3-tetramethylbutyl)tolyl] oxy]ethoxy]ethyl]ammonium chloride monohydrate CAS RN®: 1320-44-1; UNII: WOA57K8S5V.

Anhydrous CAS RN®: 25155-18-4; UNII: 4XKK0M5H9M.

DEFINITION

Methylbenzethonium Chloride contains NLT 97.0% and NMT 103.0% of $C_{28}H_{44}ClNO_2$, calculated on the dried basis.

IDENTIFICATION

• **A. Procedure**

Analysis: To 1 mL of solution (1 in 100) add 2 mL of alcohol, 0.5 mL of 2 N nitric acid, and 1 mL of silver nitrate TS.

Acceptance criteria: A white precipitate, which is insoluble in 2 N nitric acid and soluble in 6 N ammonium hydroxide, is formed.

• **B. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: 197K**

ASSAY

Change to read:

• **Procedure**

Buffer: Dilute 20 mL of triethylamine with water to 1000 mL, and adjust the pH to 3.0 with phosphoric acid.

Mobile phase: Acetonitrile and *Buffer* (45:55)

Standard solution: 0.15 mg/mL of USP Methylbenzethonium Chloride RS in *Mobile phase*

System suitability solution: 0.15 mg/mL each of USP Benzethonium Chloride RS and USP Methylbenzethonium Chloride RS in *Mobile phase*

Sample solution: 0.15 mg/mL of methylbenzethonium chloride in *Mobile phase*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 15-cm; 5-µm packing L7

Column temperature: 40°

Flow rate: 1 mL/min

Injection size: 10 µL

Run time: 1.5 times the retention time of the methylbenzethonium peak

System suitability

Sample: *System suitability solution*

[Note—The relative retention times for benzethonium and methylbenzethonium are 0.7 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 5.0 between the benzethonium and methylbenzethonium peaks

Tailing factor: NMT 1.8 for the methylbenzethonium peak

Relative standard deviation: NMT 0.5% for the methylbenzethonium peak

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of methylbenzethonium chloride ($C_{28}H_{44}ClNO_2$ ▲▲ (ERR 1-Nov-2023)) in the portion of Methylbenzethonium Chloride taken:

Result = $(r_U/r_S) \times (C_S/C_U) \times 100$

r_U = peak response of methylbenzethonium from the *Sample solution*

r_S = peak response of methylbenzethonium from the *Standard solution*

C_S = concentration of USP Methylbenzethonium Chloride RS in the *Standard solution* (mg/mL)

C_U = concentration of Methylbenzethonium Chloride in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

SPECIFIC TESTS

• **Melting Range or Temperature ⟨741⟩:** 159°–163°, the specimen having been previously dried

• **Loss on Drying ⟨731⟩:** Dry a sample at 105° for 4 h: it loses NMT 5.0% of its weight.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards ⟨11⟩**

USP Benzethonium Chloride RS

USP Methylbenzethonium Chloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
METHYLBENZETHONIUM CHLORIDE	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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