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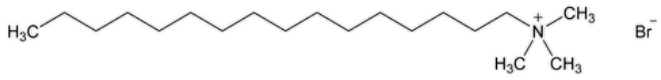
Cetrimonium Bromide



$C_{19}H_{42}BrN$ 364.45

Hexadecyltrimethylammonium bromide CAS RN®: 57-09-0.

DEFINITION

Cetrimonium Bromide contains NLT 96.0% and NMT 101.0% of hexadecyltrimethylammonium bromide, calculated as $C_{19}H_{42}BrN$, on the dried basis.

IDENTIFICATION

- **A. Ultraviolet Absorption**

  Sample solution: 10 mg/mL in alcohol

  Analytical wavelength: 260–280 nm

  Cell: 1 cm

  Acceptance criteria: After correcting for the blank, the absorbance is NMT 0.05.

- **B.**

  Sample solution: Dissolve 5 mg of Cetrimonium Bromide in 5 mL of phosphate buffer pH 8.0.

  Blank: 5 mL of phosphate buffer pH 8.0

  Analysis: Add a strip of methyl green–iodomercurate paper to the *Sample solution* and *Blank*.

  Acceptance criteria: After 5 min, the *Sample solution* shows a more intense greenish-blue color than the *Blank*.

- **C.**

  Sample: 2.0 g

  Analysis: Transfer the *Sample* to a 100-mL flask, and dissolve in and dilute with previously boiled and cooled water to volume.

  Acceptance criteria: The solution froths copiously when shaken.

- **D. Thin-Layer Chromatographic Identification Test ⟨201⟩**

  Solution A: 270 mg/mL of sodium acetate trihydrate

  Standard solution: 20 mg/mL of USP Cetrimonium Bromide RS

  Sample solution: 20 mg/mL of Cetrimonium Bromide

  Chromatographic system

  Developing solvent system: Methanol, acetone, and *Solution A* (45:20:35)

  Analysis

  Samples: *Standard solution* and *Sample solution*

  Proceed as directed in the chapter. Remove the plate from the developing chamber, and dry the plate in a current of hot air. Allow to cool. Expose the plate to iodine vapor, and examine in daylight.

  Acceptance criteria: The principal spot of the *Sample solution* is similar in position, color, and size to that of the *Standard solution*.

- **E. Identification Tests—General, *Bromide* ⟨191⟩:** A solution of it meets the requirements.

ASSAY

- **Procedure**

  Sample solution: 20 mg/mL of Cetrimorium Bromide

  Blank: Combine 10.0 mL of freshly prepared 50-mg/mL potassium iodide, 20 mL of water, and 40 mL of hydrochloric acid.

  Titrimetric system

  (See *Titrimetry* ⟨541⟩.)

  Mode: Residual titration

  Titrant: 0.05 M potassium iodate VS

  Analysis

  Samples: *Sample solution* and *Blank*

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Transfer 25.0 mL of the *Sample solution* to a separatory funnel, and add 25 mL of chloroform, 10 mL of 0.1 N sodium hydroxide VS, and 10.0 mL of a freshly prepared solution of potassium iodide (50 mg/mL). Shake well, allow to separate, and discard the chloroform layer. Wash the aqueous layer with three 10-mL portions of chloroform, and discard the washings. Transfer the aqueous layer to a stoppered conical flask, add 40 mL of hydrochloric acid, and allow to cool. Titrate with *Titrant* until the deep brown color is almost discharged. Add 2 mL of chloroform, and continue the titration, shaking vigorously, until the color of the chloroform layer no longer changes. Perform a blank determination. Each mL of *Titrant* is equivalent to 36.45 mg of Cetrimonium Bromide ($C_{19}H_{42}BrN$).

Acceptance criteria: 96.0%–101.0% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩**
Sample: 1.0 g
Acceptance criteria: NMT 0.5%

• **Limit of Amines and Amine Salts**
Sample: 5.0 g
Analysis: Dissolve the *Sample* in 30 mL of a mixture of methanol and 1 N hydrochloric acid VS (99:1), and add 100 mL of isopropyl alcohol. Pass a stream of nitrogen slowly through the solution. Gradually add 15.0 mL of 0.1 N tetrabutylammonium hydroxide VS, recording the potentiometric titration curve.
Acceptance criteria: If the curve shows two inflection points, the volume of titrant added between the two points is NMT 2.0 mL.

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total aerobic microbial count is NMT 10^3 cfu/g. The total combined molds and yeasts count is NMT 10^1 cfu/g.

• **Appearance of Solution**
Analysis: Transfer 2.0 g of Cetrimonium Bromide to a 100-mL flask, and dissolve in and dilute with previously boiled and cooled water to volume.
Acceptance criteria: The solution is clear and colorless.

• **Acidity or Alkalinity**
Sample solution: 50 mL of the solution obtained in the *Appearance of Solution* test
Analysis: To the *Sample solution* add 0.1 mL of bromocresol purple TS.
Acceptance criteria: NMT 0.1 mL of 0.1 N sodium hydroxide or 0.1 N hydrochloric acid is required to change the color of the indicator.

• **Loss on Drying ⟨731⟩**
Sample: 1.0 g
Analysis: Dry at 105° for 2 h.
Acceptance criteria: NMT 2.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. No storage requirements specified.

• **USP Reference Standards ⟨11⟩**
USP Cetrimonium Bromide RS

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

Topic/Question	Contact	Expert Committee
CETRIMONIUM BROMIDE	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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