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Cetylpyridinium Chloride Topical Solution

DEFINITION

Cetylpyridinium Chloride Topical Solution contains NLT 95.0% and NMT 105.0% of the labeled amount of cetylpyridinium chloride ($C_{21}H_{38}ClN \cdot H_2O$).

IDENTIFICATION

- **A.**

Standard solution: 40 µg/mL of USP Cetylpyridinium Chloride RS in water

Sample solution: 40 µg/mL of cetylpyridinium chloride from Topical Solution diluted with water

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as that of the *Standard solution*.

- **B.** **Identification Tests—General** ⟨191⟩, *Chloride*

Sample solution: Evaporate on a steam bath a volume of Topical Solution equivalent to 500 mg of cetylpyridinium chloride from Topical Solution to one-half of its original volume.

Acceptance criteria: The *Sample solution* meets the requirements of test *A*, except that when silver nitrate TS is added, turbidity is produced rather than a curdy white precipitate.

ASSAY

- **Procedure**

Sample solution: Add a volume of Topical Solution nominally equivalent to 150 mg of cetylpyridinium chloride to a glass-stoppered, 500-mL graduated cylinder. Add 10 mL of chloroform, 0.4 mL of bromophenol blue solution (1 in 2000), and 5 mL of a freshly prepared solution of sodium bicarbonate (4.2 in 1000).

Analysis: Titrate the *Sample solution* with 0.02 M sodium tetraphenylboron VS until the blue color disappears from the chloroform layer. Add the last portions of the sodium tetraphenylboron solution dropwise, agitating vigorously after each addition. Each mL of 0.02 M sodium tetraphenylboron is equivalent to 7.160 mg of cetylpyridinium chloride ($C_{21}H_{38}ClN \cdot H_2O$).

Acceptance criteria: 95.0%–105.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **USP Reference Standards** ⟨11⟩
  USP Cetylpyridinium Chloride RS

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

Topic/Question	Contact	Expert Committee
CETYLPYRIDINIUM CHLORIDE TOPICAL SOLUTION	Documentary Standards Support	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

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