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Cetylpyridinium Chloride Lozenges

DEFINITION

Cetylpyridinium Chloride Lozenges contain NLT 90.0% and NMT 125.0% of the labeled amount of cetylpyridinium chloride ($C_{21}H_{38}ClN \cdot H_2O$) in a suitable molded base.

IDENTIFICATION

• A.

Eluting solvent: Alcohol and 1.2 N hydrochloric acid (7:3)

Chromatographic column: Pack a pledget of fine glass wool in the base of a 10-mm × 200-mm chromatographic tube. Add styrene–divinylbenzene cation-exchange resin (strong acid form) to form a uniform column 12 cm in height, and top the column with a pledget of fine glass wool.

Standard solution: 5 µg/mL of [USP Cetylpyridinium Chloride RS](#) in *Eluting solvent*

Sample solution: Dissolve nominally 500 µg of cetylpyridinium chloride from NLT 20 finely powdered Lozenges in 50 mL of water.

Immediately transfer this solution to the *Chromatographic column*, and discard the eluate. Wash the column, successively, with 200 mL of water, 100 mL of alcohol, 100 mL of water, and 100 mL of 3 N hydrochloric acid. Discard the washings. Elute the column with 80 mL of *Eluting solvent*. Collect the eluate in a 100-mL volumetric flask, and dilute with the *Eluting solvent* to volume.

Instrumental conditions

(See [Ultraviolet-Visible Spectroscopy \(857\)](#).)

Mode: UV

Wavelength range: 225–300 nm

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*.

ASSAY

• PROCEDURE

0.004 M sodium lauryl sulfate: Dissolve 1.15 g of sodium lauryl sulfate in 500 mL of water. Add 2 mL of sulfuric acid, and dilute with water to 1000 mL.

Standardization of 0.004 M sodium lauryl sulfate: Determine the molarity of the solution as follows. To a glass-stoppered 100-mL cylinder transfer 10.0 mL of 0.004 M cetylpyridinium chloride (1.432 mg/mL of [USP Cetylpyridinium Chloride RS](#)). Add 5 mL of 2 N sulfuric acid, 20 mL of chloroform, and 1 mL of methyl yellow TS. Titrate with the sodium lauryl sulfate solution with frequent vigorous shaking until the chloroform layer acquires the first permanent orange-pink color.

Calculate the molarity, and restandardize before each use. [NOTE—Sulfuric acid is included in this solution to inhibit precipitate formation. If a precipitate forms under storage, discard the solution, and prepare and standardize a fresh solution of 0.004 M sodium lauryl sulfate.]

Sample solution: Nominally 0.1 mg/mL of cetylpyridinium chloride prepared as follows. Dissolve an accurately determined number of Lozenges (about 100) in about 400 mL of water in a 500-mL volumetric flask, and dilute with water to volume. Transfer a measured aliquot of this solution, equivalent to about 10 mg of cetylpyridinium chloride, to a glass-stoppered, 100-mL cylinder. Add 5 mL of 2 N sulfuric acid, 20 mL of chloroform, and 1 mL of methyl yellow TS. Insert the stopper, and shake until the chloroform layer develops a bright yellow color.

Analysis: Titrate with 0.004 M sodium lauryl sulfate, shaking thoroughly after each addition, until the chloroform layer develops the first permanent orange-pink color. Each mL of 0.004 M sodium lauryl sulfate is equivalent to 1.432 mg of cetylpyridinium chloride ($C_{21}H_{38}ClN \cdot H_2O$).

Acceptance criteria: 90.0%–125.0%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in well-closed containers.

• **USP REFERENCE STANDARDS (11).**
[USP Cetylpyridinium Chloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

We apologize for the inconvenience. The exact auxiliary information for this Documentary Standard is currently unavailable. Please contact Documentary Standards Support (stdsmonographs@usp.org) for assistance during this time.

Chromatographic Database Information: [Chromatographic Database](#)

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