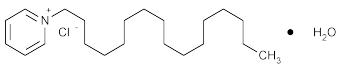
Cetylpyridinium Chloride



$C_{21}H_{38}ClN \cdot H_2O$ 358.00
Pyridinium, 1-hexadecyl-, chloride, monohydrate.
1-Hexadecylpyridinium chloride monohydrate [6004-24-6].
Anhydrous 339.99 [123-03-5].

» Cetylpyridinium Chloride contains not less than 99.0 percent and not more than 102.0 per cent of $C_{21}H_{38}ClN$, calculated on the anhydrous basis.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩**—**
USP Cetylpyridinium Chloride RS

Identification—

A: *Infrared Absorption* ⟨197K⟩.

B: *Ultraviolet Absorption* ⟨197U⟩—

Solution: 40 µg per mL.

Medium: water.

C: Dissolve 100 mg in 50 mL of water: a 10-mL portion of the solution responds to the tests for *Chloride* ⟨191⟩, except that a turbidity is produced, rather than a curdy white precipitate, when the silver nitrate TS is added.

Melting range, *Class I* ⟨741⟩: between 80° and 84°, the preliminary drying treatment being omitted.

Acidity—Dissolve 500 mg, accurately weighed, in 50 mL of water, add phenolphthalein TS, and titrate with 0.020 N sodium hydroxide: not more than 2.5 mL is required for neutralization.

Water, *Method I* ⟨921⟩: between 4.5% and 5.5%.

Residue on ignition ⟨281⟩: not more than 0.2%, calculated on the anhydrous basis.

Heavy metals, *Method II* ⟨231⟩: 0.002%.

Pyridine—Dissolve 1 g in 10 mL of sodium hydroxide solution (1 in 10) without heating: the odor of pyridine is not immediately perceptible.

Assay—Transfer about 200 mg of Cetylpyridinium Chloride, accurately weighed, to a glass-stoppered, 250-mL graduated cylinder containing 75 mL of water. 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), and titrate 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 6.800 mg of $C_{21}H_{38}ClN$.

Cetylpyridinium Chloride Lozenges

» Cetylpyridinium Chloride Lozenges contain not less than 90.0 per cent and not more than 125.0 percent of the labeled amount of $C_{21}H_{38}ClN \cdot H_2O$ in a suitable molded base.

Packaging and storage—Preserve in well-closed containers.

USP Reference standards ⟨11⟩**—**
USP Cetylpyridinium Chloride RS

Identification—

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.

Procedure—Weigh and finely powder not fewer than 20 Lozenges. Dissolve a portion of the powder, equivalent to about 500 µg of cetylpyridinium chloride, in about 50 mL of water, and immediately transfer this solution to the *Chromatographic column*. 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, and discard the washings. Elute the column with 80 mL of a solvent consisting of a mixture of 7 volumes of alcohol and 3 volumes of 1.2 N hydrochloric acid. Collect the eluate in a 100-mL volumetric flask, dilute with the eluting solvent to volume, and mix: the UV absorption spectrum of this solution, measured between 225 and 300 nm, exhibits maxima and minima at the same wavelengths as that of a solution of USP Cetylpyridinium Chloride RS , in the same medium at a concentration of 5 µg per mL, concomitantly measured.

Assay—

0.004 M Sodium lauryl sulfate—[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 *0.004 M Sodium lauryl sulfate* solution.] Dissolve 1.15 g of sodium laur yl sulfate in 500 mL of water, add 2 mL of sulfuric acid, dilute with water to 1000 mL, and mix. Determine the molarity of the solution as follows. T ransfer to a glass-stoppered, 100-mL cylinder 10.0 mL of 0.004 M cetylpyridinium chloride (1.432 mg of USP Cetylpyridinium Chloride RS per mL in water), add 5 mL of 2 N sulfuric acid, 20 mL of chloroform, and 1 mL of methyl yellow TS, and titrate with the sodium laur yl 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.

Procedure—Dissolve an accurately determined number (about 100) of Cetylpyridinium Chloride Lozenges in about 400 mL of water in a 500-mL volumetric flask, dilute with water to volume, and mix. T ransfer an accurately measured aliquot of this solution, equivalent to about 10 mg of cetylpyridinium chloride, to a glass-stoppered, 100-mL cylinder, and add 5 mL of 2 N sulfuric acid, 20 mL of chloroform, and 1 mL of methyl yellow TS. Insert the stopper, shake until the chloroform layer develops a bright yellow color, and 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 $C_{21}H_{38}ClN \cdot H_2O$.

Cetylpyridinium Chloride Topical Solution

» Cetylpyridinium Chloride T opical Solution contains not less than 95.0 per cent and not more than 105.0 per cent of the labeled amount of $C_{21}H_{38}ClN \cdot H_2O$.

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩**—**
USP Cetylpyridinium Chloride RS

Identification—

A: Dilute a volume of T opical Solution to a concentration of about 40 µg of cetylpyridinium chloride per mL: the UV absorption spectrum of the resulting solution exhibits maxima and minima at the same wavelengths as that of a similar solution of USP Cetylpyridinium Chloride RS , concomitantly measured.

B: Evaporate a volume of T opical Solution, equivalent to about 500 mg of cetylpyridinium chloride, on a steam bath to one-half of its original volume: the resulting solution meets the