Cetylpyridinium Chloride

C₂₁H₃₈ClN · H₂O  358.00
Pyridinium, 1-hexadecyl-, chloride, monohydrate.
1-Hexadecylypyridinium 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 percent of C₂₁H₃₈ClN, 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 1:10 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 bromphenol 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 bicarbonate until the 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 C₂₁H₃₈ClN.

Cetylpyridinium Chloride Topical Solution

Cetylpyridinium Chloride Topical Solution contains not less than 95.0% per cent and not more than 105.0% per cent of the labeled amount of C₂₁H₃₈ClN · H₂O.

Packaging and storage—Preserve in tight containers.

USP Reference standards (11)—
USP Cetylpyridinium Chloride RS

Identification—
A: Dilute a volume of Topical 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 Topical 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

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