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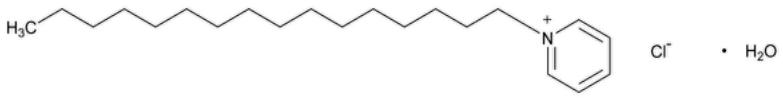
Cetylpyridinium Chloride



$C_{21}H_{38}ClN \cdot H_2O$ 358.00
$C_{21}H_{38}ClN$ 339.99

Pyridinium, 1-hexadecyl-, chloride, monohydrate;

1-Hexadecylpyridinium chloride monohydrate CAS RN®: 6004-24-6.

Anhydrous CAS RN®: 123-03-5.

DEFINITION

Cetylpyridinium Chloride contains NLT 98.0% and NMT 102.0% of cetylpyridinium chloride ($C_{21}H_{38}ClN$), calculated on the anhydrous basis.

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **C. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Chloride***

Sample solution: 2 mg/mL in water

Acceptance criteria: A 10-mL portion of 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**

Use 0.1% trifluoroacetic acid–rinsed glassware and silanized vials for all solutions containing cetylpyridinium chloride, as cetylpyridinium may react with the surface.

Solution A: Trifluoroacetic acid and water (1:999)

Solution B: Acetonitrile and trifluoroacetic acid (999:1)

Mobile phase: *Solution A* and *Solution B* (62.5:37.5)

Standard solution: 0.25 mg/mL of USP Cetylpyridinium Chloride RS in *Solution A*

Sample solution: 0.25 mg/mL of Cetylpyridinium Chloride in *Solution A*

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 258 nm

Column: 2.1-mm × 10-cm; 5-µm packing L78

Column temperature: 40°

Flow rate: 0.6 mL/min

Injection volume: 2 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cetylpyridinium chloride ($C_{21}H_{38}ClN$) in the portion of Cetylpyridinium Chloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Cetylpyridinium Chloride RS in the *Standard solution* (mg/mL)

C_U = concentration of Cetylpyridinium Chloride in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.2% on the anhydrous basis

Change to read:

• **Organic Impurities**

Use 0.1% trifluoroacetic acid–rinsed glassware and silanized vials for all solutions containing cetylpyridinium chloride, as cetylpyridinium may react with the surface.

Solution A, Solution B, Mobile phase, and **Chromatographic system:** Proceed as directed in the *Assay*.

▲**Sensitivity solution:** 1 µg/mL of USP Cetylpyridinium Chloride RS in *Solution A*▲ (USP 1-May-2021)

Standard solution: 2.5 µg/mL of USP Cetylpyridinium Chloride RS▲and 0.0125 mg/mL each of USP Myristylpyridinium Chloride RS and USP Stearylpyridinium Chloride RS▲ (USP 1-May-2021) in *Solution A*

Sample solution: 2.5 mg/mL of Cetylpyridinium Chloride in *Solution A*

System suitability

Samples: ▲*Sensitivity solution*▲ (USP 1-May-2021) and *Standard solution*

Suitability requirements

Relative standard deviation: NMT 2.0%,▲*Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*▲ (USP 1-May-2021)

Analysis

Samples: *Standard solution* and *Sample solution*

▲Calculate the percentage of myristylpyridinium chloride and stearylpyridinium chloride in the portion of Cetylpyridinium Chloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of myristylpyridinium or stearylpyridinium from the *Sample solution*

r_S = peak response of myristylpyridinium or stearylpyridinium from the *Standard solution*

C_S = concentration of USP Myristylpyridinium Chloride RS or USP Stearylpyridinium Chloride RS in the *Standard solution* (mg/mL)

C_U = concentration of Cetylpyridinium Chloride in the *Sample solution* (mg/mL)▲ (USP 1-May-2021)

Calculate the percentage of each unspecified impurity in the portion of Cetylpyridinium Chloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each unspecified impurity from the *Sample solution*

r_S = peak response of cetylpyridinium from the *Standard solution*

C_S = concentration of USP Cetylpyridinium Chloride RS in the *Standard solution* (mg/mL)

C_U = concentration of Cetylpyridinium Chloride in the *Sample solution* (mg/mL)

Acceptance criteria: ▲ See *Table 1*. The reporting threshold is 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Myristylpyridinium	0.53	0.45
Cetylpyridinium	1.0	—
Stearylpyridinium	2.1	0.15
Any unspecified impurity	—	0.1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Total impurities	—	1.0

▲ (USP 1-May-2021)

SPECIFIC TESTS

• **Acidity**

Sample: 500 mg

Analysis: Dissolve the *Sample* in 50 mL of water, add phenolphthalein TS, and titrate with 0.020 N sodium hydroxide.

Acceptance criteria: NMT 2.5 mL is required for neutralization.

• **Water Determination ⟨921⟩, *Method I*:** 4.5%–5.5%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers.

Change to read:

• **USP Reference Standards ⟨11⟩**

USP Cetylpyridinium Chloride RS

▲ USP Myristylpyridinium Chloride RS

1-Tetradecylpyridinium chloride.

$C_{19}H_{34}ClN$ 311.94

USP Stearylpyridinium Chloride RS

1-Octadecylpyridinium chloride.

$C_{23}H_{42}ClN$ 368.05▲ (USP 1-May-2021)

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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