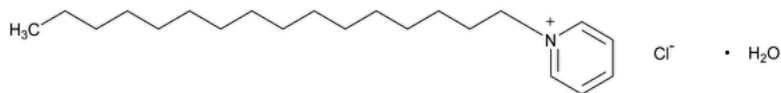


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Cetylpyridinium Chloride



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