



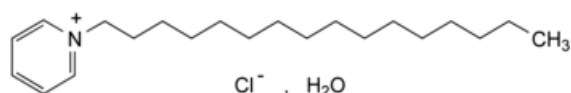
Edition: BP 2025 (Ph. Eur. 11.6 update)

## Cetylpyridinium Chloride



### [General Notices](#)

(Ph. Eur. monograph 0379)



C<sub>21</sub>H<sub>38</sub>ClN,H<sub>2</sub>O 358.0 6004-24-6

### Action and use

Antiseptic.

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## DEFINITION

Cetylpyridinium chloride contains not less than 96.0 per cent and not more than the equivalent of 101.0 per cent of 1-hexadecylpyridinium chloride, calculated with reference to the anhydrous substance.

## CHARACTERS

A white or almost white powder, slightly soapy to the touch, soluble in water and in ethanol (96 per cent). An aqueous solution froths copiously when shaken.

## IDENTIFICATION

First identification: B, D.

Second identification: A, C, D.

A. Dissolve 0.10 g in [water R](#) and dilute to 100.0 mL with the same solvent. Dilute 5.0 mL of this solution to 100.0 mL with [water R](#). Examined between 240 nm and 300 nm ([2.2.25](#)), the solution shows an absorption maximum at 259 nm and 2 shoulders at about 254 nm and at about 265 nm. The specific absorbance at the maximum is 126 to 134, calculated with reference to the anhydrous substance.

B. Examine by infrared absorption spectrophotometry ([2.2.24](#)), comparing with the spectrum obtained with [cetylpyridinium chloride CRS](#). Examine the substances in the solid state.

C. To 5 mL of [dilute sodium hydroxide solution R](#) add 0.1 mL of [bromophenol blue solution R1](#) and 5 mL of [chloroform R](#) and shake. The chloroform layer is colourless. Add 0.1 mL of solution S (see Tests) and shake. The chloroform layer becomes blue.

D. Solution S gives reaction (a) of chlorides ([2.3.1](#)).

## TESTS

### Solution S

Dissolve 1.0 g in [carbon dioxide-free water R](#) and dilute to 100 mL with the same solvent.

### Appearance of solution

Solution S is not more opalescent than reference suspension II ([2.2.1](#)) and is colourless ([2.2.2, Method II](#)).

### Acidity

To 50 mL of solution S add 0.1 mL of [phenolphthalein solution R](#). Not more than 2.5 mL of [0.02 M sodium hydroxide](#) is required to change the colour of the indicator.

### Amines and amine salts

Dissolve 5.0 g with heating in 20 mL of a mixture of 3 volumes of [1 M hydrochloric acid](#) and 97 volumes of [methanol R](#) and add 100 mL of [2-propanol R](#). Pass a stream of [nitrogen R](#) slowly through the solution. Gradually add 12.0 mL of [0.1 M tetrabutylammonium hydroxide](#) and record the potentiometric titration curve ([2.2.20](#)). If the curve shows 2 points of inflexion, the volume of titrant added between the two points is not greater than 5.0 mL. If the curve shows no point of inflexion, the substance to be examined does not comply with the test. If the curve shows one point of inflexion, repeat the test but add 3.0 mL of a 25.0 g/L solution of [dimethyldecylamine R](#) in [2-propanol R](#) before the titration. If the titration curve after the addition of 12.0 mL of the titrant shows only one point of inflexion, the substance to be examined does not comply with the test.

### Water ([2.5.12](#))

4.5 per cent to 5.5 per cent, determined on 0.300 g by the semi-micro determination of water.

### Sulfated ash ([2.4.14](#))

Not more than 0.2 per cent, determined on 1.0 g.

## ASSAY

Dissolve 2.00 g in [water R](#) and dilute to 100.0 mL with the same solvent. Transfer 25.0 mL of the solution to a separating funnel, add 25 mL of [chloroform R](#), 10 mL of [0.1 M sodium hydroxide](#) and 10.0 mL of a freshly prepared 50 g/L solution of [potassium iodide R](#). Shake well, allow to separate and discard the chloroform layer. Shake the aqueous layer with three quantities, each of 10 mL, of [chloroform R](#) and discard the chloroform layers. To the aqueous layer add 40 mL of [hydrochloric acid R](#), allow to cool and titrate with [0.05 M potassium iodate](#) until the deep-brown colour is almost discharged. Add 2 mL of [chloroform R](#) and continue the titration, shaking vigorously, until the chloroform layer no longer changes colour. Carry out a blank titration on a mixture of 10.0 mL of the freshly prepared 50 g/L solution of [potassium iodide R](#), 20 mL of [water R](#) and 40 mL of [hydrochloric acid R](#).

1 mL of [0.05 M potassium iodate](#) is equivalent to 34.0 mg of  $C_{21}H_{38}ClN$ .

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