



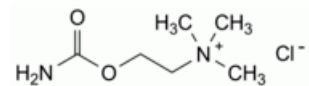
Edition: BP 2025 (Ph. Eur. 11.6 update)

Carbachol



General Notices

(Ph. Eur. monograph 1971)



C₆H₁₅ClN₂O₂ 182.7 51-83-2

Action and use

Cholinoceptor agonist.

Ph Eur

DEFINITION

2-(Carbamoyloxy)-N,N,N-trimethylethanaminium chloride.

Content

99.0 per cent to 101.5 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, crystalline, hygroscopic powder.

Solubility

Very soluble in water, sparingly soluble in ethanol (96 per cent), practically insoluble in acetone.

IDENTIFICATION

First identification: A, C.

Second identification: B, C.

A. Infrared absorption spectrophotometry ([2.2.24](#)).

Comparison [carbachol CRS](#).

B. Examine the chromatograms obtained in the test for related substances.

Results The principal spot in the chromatogram obtained with test solution (b) is similar in position, colour and size to the principal spot in the chromatogram obtained with reference solution (a).

C. 0.5 mL of solution S (see Tests) gives reaction (a) of chlorides ([2.3.1](#)).

TESTS

Solution S

Dissolve 2.5 g in [carbon dioxide-free water R](#) and dilute to 25 mL with the same solvent.

Appearance of solution

Solution S is clear ([2.2.1](#)) and colourless ([2.2.2, Method II](#)).

Acidity or alkalinity

To 2.0 mL of solution S, add 0.05 mL of [methyl red mixed solution R](#). Not more than 0.2 mL of [0.01 M hydrochloric acid](#) or [0.01 M sodium hydroxide](#) is required to change the colour of the indicator.

Related substances

Thin-layer chromatography ([2.2.27](#)).

Prepare the solutions immediately before use.

Test solution (a) Dissolve 0.20 g of the substance to be examined in [methanol R](#) and dilute to 5.0 mL with the same solvent.

Test solution (b) Dilute 2.0 mL of test solution (a) to 20.0 mL with [methanol R](#).

Reference solution (a) Dissolve 20 mg of [carbachol CRS](#) in [methanol R](#) and dilute to 5.0 mL with the same solvent.

Reference solution (b) Dissolve 8 mg of [choline chloride R](#) and 8 mg of [acetylcholine chloride CRS](#) in [methanol R](#) and dilute to 10.0 mL with the same solvent. Dilute 5.0 mL to 10.0 mL with [methanol R](#).

Plate [cellulose for chromatography R](#) as the coating substance.

Mobile phase [water R](#), [methanol R](#) (10:90 V/V).

Application 10 µL.

Development Over 2/3 of the plate.

Detection Spray with [potassium iodobismuthate solution R3](#).

System suitability The chromatogram obtained with reference solution (b) shows 2 clearly separated spots.

Limits In the chromatogram obtained with test solution (a):

— *any impurity*: any spot, apart from the principal spot, is not more intense than one or other of the 2 principal spots in the chromatogram obtained with reference solution (b) (1 per cent). Compare the spots with the spot of the most appropriate colour in the chromatogram obtained with reference solution (b).

[Loss on drying \(2.2.32\)](#)

Maximum 1.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 2 h.

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

ASSAY

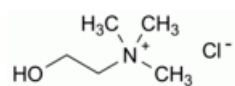
Dissolve 0.150 g in a mixture of 10 mL of [anhydrous acetic acid R](#) and 40 mL of [acetic anhydride R](#). Titrate with [0.1 M perchloric acid](#). Determine the end-point potentiometrically ([2.2.20](#)).

1 mL of [0.1 M perchloric acid](#) is equivalent to 18.27 mg of $C_6H_{15}ClN_2O_2$.

STORAGE

In an airtight container, protected from light.

IMPURITIES



A. 2-hydroxy-*N,N,N*-trimethylethanaminium chloride (choline chloride).

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