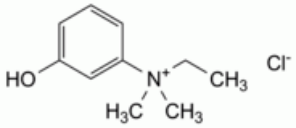
Edition: BP 2025 (Ph. Eur. 11.6 update)

Edrophonium Chloride

General Notices

(Ph. Eur. monograph 2106)



$C_{10}H_{16}ClNO$ 201.7 *116-38-1*

Action and use

Cholinesterase inhibitor.

Preparation

Edrophonium Injection

Ph Eur

DEFINITION

N-Ethyl-3-hydroxy-*N*,*N*-dimethylanilinium chloride.

Content

99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance

White or almost white, crystalline powder.

Solubility

Very soluble in water, freely soluble in ethanol (96 per cent), practically insoluble in methylene chloride.

IDENTIFICATION

A. Infrared absorption spectrophotometry (*2.2.24*).

Comparison *edrophonium chloride CRS*.

B. It gives reaction (a) of chlorides (*2.3.1*).

TESTS

Appearance of solution

The solution is clear (*2.2.1*) and colourless (*2.2.2, Method II*).

Dissolve 0.5 g in *water R* and dilute to 25 mL with the same solvent.

pH (*2.2.3*)

4.0 to 5.0.

Dissolve 1.0 g in *carbon dioxide-free water R* and dilute to 10.0 mL with the same solvent.

Related substances

Liquid chromatography (*2.2.29*).

Test solution Dissolve 50.0 mg in *water R* and dilute to 50.0 mL with the same solvent.

Reference solution (a) Dissolve 10.0 mg of *3-dimethylaminophenol R* in *acetonitrile R* and dilute to 10.0 mL with the same solvent.

Reference solution (b) Mix 1.0 mL of the test solution and 1.0 mL of reference solution (a) and dilute to 100.0 mL with *water R*. Dilute 10.0 mL of this solution to 100.0 mL with *water R*.

Column:

— *size*: *l* = 0.25 m, Ø = 4.6 mm,

— *stationary phase*: *styrene-divinylbenzene copolymer R* (8-10 µm).

Mobile phase Mix 10 volumes of *acetonitrile R* and 90 volumes of a 7.7 g/L solution of *tetramethylammonium bromide R* previously adjusted to pH 3.0 with *phosphoric acid R*.

Flow rate 1 mL/min.

Detection Spectrophotometer at 281 nm.

Injection 20 µL.

Run time Twice the retention time of edrophonium.

Relative retention With reference to edrophonium (retention time = about 3.8 min): impurity A = about 1.3.

System suitability Reference solution (b):

— *resolution*: minimum 2.0 between the peaks due to edrophonium and impurity A.

Limits:

— *impurity A*: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (b) (0.1 per cent),

— *any other impurity*: for each impurity, not more than the area of the peak due to edrophonium in the chromatogram obtained with reference solution (b) (0.1 per cent),

— *total*: not more than 5 times the area of the peak due to edrophonium in the chromatogram obtained with reference solution (b) (0.5 per cent),

— *disregard limit*: 0.5 times the area of the peak due to edrophonium in the chromatogram obtained with reference solution (b) (0.05 per cent).

Loss on drying (*2.2.32*)

Maximum 0.5 per cent, determined on 1.000 g by drying in a desiccator at a pressure not exceeding 0.7 kPa for 24 h.

Sulfated ash (*2.4.14*)

Maximum 0.1 per cent, determined on 1.0 g.

Bacterial endotoxins (*2.6.14*)

Less than 8.3 IU/mg.

ASSAY

Dissolve 0.150 g in 60 mL of a mixture of equal volumes of *acetic anhydride R* and *anhydrous acetic acid R*. Titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (*2.2.20*).

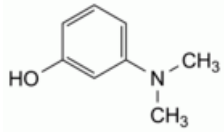
1 mL of *0.1 M perchloric acid* is equivalent to 20.17 mg of $C_{10}H_{16}ClNO$.

STORAGE

Protected from light.

IMPURITIES

Specified impurities *A.*



A. 3-(dimethylamino)phenol.