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

Etamiphylline Injection

General Notices

Action and use

Non-selective phosphodiesterase inhibitor (xanthine); treatment of reversible airways obstruction.

DEFINITION

Etamiphylline Injection is a sterile solution of Etamiphylline Camsilate in Water for Injections.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of etamiphylline camsilate, $C_{13}H_{21}N_5O_2$,$C_{10}H_{16}O_4S$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Prepare a quantity of the residue as described in the Assay. The residue complies with the following tests.

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of etamiphylline *(RSV 19)*.

B. Yields the reactions characteristic of *xanthines*, Appendix VI.

TESTS

Acidity

pH, 3.9 to 5.4, Appendix V L.

Related substances

Carry out the method for *thin-layer chromatography*, Appendix III A, using the following solutions.

(1) Dilute the injection with sufficient *water* to produce a solution containing 3.5% w/v of Etamiphylline Camsilate.
(2) Dilute 1 volume of solution (1) to 500 volumes with *water*.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating *silica gel HF_{254}*.
(b) Use the mobile phase as described below.
(c) Apply 10 µl of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, allow it to dry in air and examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

1 volume of 13.5M *ammonia*, 20 volumes of *ethanol (96%)* and 80 volumes of *chloroform*.

LIMITS

Any *secondary spot* in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2) (0.2%).

ASSAY

To a volume containing 0.7 g of Etamiphylline Camsilate add 15 mL of *water*, make alkaline with 5M *ammonia* and extract with three 25-mL quantities of *chloroform*, washing each extract with the same 5-mL quantity of *water*. Evaporate the combined extracts to dryness, dissolve the residue in 25 mL of *water* and titrate with *0.05M sulfuric acid VS* using *bromocresol green solution* as indicator. Each mL of *0.05M sulfuric acid VS* is equivalent to 51.16 mg of $C_{13}H_{21}N_5O_2$,$C_{10}H_{16}O_4S$.