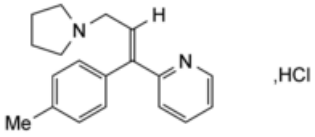
Edition: BP 2025 (Ph. Eur. 11.6 update)

Triprolidine Hydrochloride

General Notices



$C_{19}H_{22}N_2,HCl,H_2O$ 332.9 *6138-79-0*

Action and use

Histamine H_1 receptor antagonist; antihistamine.

Preparation

Triprolidine Tablets

DEFINITION

Triprolidine Hydrochloride is (*E*)-2-(3-pyrrolidin-1-yl-1-*p*-tolylprop1-enyl)pyridine hydrochloride monohydrate. It contains not less than 98.5% and not more than 101.0% of $C_{19}H_{22}N_2,HCl$, calculated with reference to the anhydrous substance.

CHARACTERISTICS

A white, crystalline powder.

Freely soluble in *water*; freely soluble in *ethanol (96%)* and practically insoluble in *ether*.

IDENTIFICATION

A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of triprolidine hydrochloride *(RS 356)*.
B. Yields reaction A characteristic of *chlorides*, Appendix VI.

TESTS

Related substances

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

(1) 1.0% w/v of the substance being examined.
(2) 0.020% w/v of Z-*triprolidine hydrochloride BPCRS*.

(3) 0.010% w/v of the substance being examined.

CHROMATOGRAPHIC CONDITIONS

(a) Use as the coating silica gel F_{254} (Merck silica gel 60 F_{254} plates are suitable).
(b) Use the mobile phase as described below.
(c) Apply 5 µL of each solution.
(d) Develop the plate to 15 cm.
(e) After removal of the plate, dry in air, examine under *ultraviolet light (254 nm)*.

MOBILE PHASE

Equal volumes of *butan-2-one* and *dimethylformamide*.

LIMITS

In the chromatogram obtained with solution (1):

any spot corresponding to *Z*-triprolidine is not more intense than the spot in the chromatogram obtained with solution (2);

and any other *secondary spot* is not more intense than the spot in the chromatogram obtained with solution (3).

Sulfated ash

Not more than 0.1%, Appendix IX A.

Water

4.5 to 6.0% w/w, Appendix IX C. Use 0.4 g.

ASSAY

Carry out Method I for *non-aqueous titration*, Appendix VIII A, using 0.25 g dissolved in a mixture of 50 mL of *anhydrous acetic acid* and 0.5 mL of *acetic anhydride* and *crystal violet solution* as indicator. Each mL of *0.1M perchloric acid VS* is equivalent to 15.74 mg of $C_{19}H_{22}N_2,HCl$.