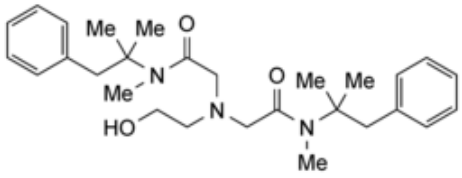
Edition: BP 2025 (Ph. Eur. 11.6 update)

Oxetacaine

General Notices



$C_{28}H_{41}N_3O_3$ 467.6 *126-27-6*

Action and use

Local anaesthetic.

DEFINITION

Oxetacaine is 2,2′-(2-hydroxyethylimino)bis[*N*-(α,α-dimethylphenethyl)-*N*-methylacetamide]. It contains not less than 99.0% and not more than 100.5% of $C_{28}H_{41}N_3O_3$, calculated with reference to the dried substance.

CHARACTERISTICS

A white or almost white powder.

Practically insoluble in water; freely soluble in methanol; soluble in ethyl acetate.

IDENTIFICATION

The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of oxetacaine *(RS 254)*.

TESTS

Melting point

100°C to 104°C, Appendix V A.

Related substances

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

(1) 10.0% w/v of the substance being examined.
(2) Dilute 1 volume of solution (1) to 200 volumes.
(3) Dilute 1 volume of solution (2) to 5 volumes.

CHROMATOGRAPHIC CONDITIONS

(a) Use a silica gel 60 precoated plate (Merck 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 it in a current of warm air and spray liberally with a solution containing 6% w/v of *ammonium thiocyanate* and 2% w/v of *cobalt(II) chloride*. Carefully remove excess solution by applying filter paper to the plate and allow the plate to dry in air for 10 minutes or until spots appear.

MOBILE PHASE

1 volume of 18M *ammonia*, 20 volumes of *absolute ethanol* and 79 volumes of *toluene*.

LIMITS

In the chromatogram obtained with solution (1):

any *secondary spot* is not more intense than the spot in the chromatogram obtained with solution (2) (0.5%);

not more than one *secondary spot* is more intense than the spot in the chromatogram obtained with solution (3) (0.1%).

Loss on drying

When dried at 60°C at a pressure not exceeding 0.7 kPa for 4 hours, loses not more than 0.5% of its weight. Use 1 g.

Sulfated ash

Not more than 0.1%, Appendix IX A.

ASSAY

Dissolve 1 g in 50 mL of *anhydrous acetic acid* and carry out Method I for *non-aqueous titration*, Appendix VIII A, determining the end-point potentiometrically. Each mL of *0.1M perchloric acid VS* is equivalent to 46.76 mg of $C_{28}H_{41}N_3O_3$.