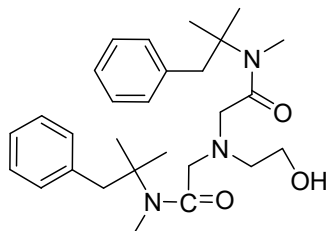


Oxetacaine



$C_{28}H_{41}N_3O_3$

Mol. Wt. 467.6

Oxetacaine is 2,2'-(2-hydroxyethylimino)bis[*N*-(α,α -dimethylphenethyl)-*N*-methylacetamide].

Oxetacaine contains not less than 99.0 per cent and not more than 100.5 per cent of $C_{28}H_{41}N_3O_3$ calculated on the dried basis.

Category. Local Anaesthetic.

Description. A white or almost white powder.

Identification

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *oxetacaine IPRS* or with the reference spectrum of oxetacaine.

Tests

Melting point (2.4.21). 100° to 104°.

Related substances. Determine by thin-layer chromatography (2.4.17), coating the plate with *silica gel G*.

Mobile phase. A mixture of 1 volume of 18 *M ammonia*, 20 volumes of *ethanol* and 79 volumes of *toluene*.

Test solution. Dissolve 1.0 g of the substance under examination in 10.0 ml of *ethyl acetate*.

Reference solution (a). Dilute 1.0 ml of the test solution to 200.0 ml with *ethyl acetate*.

Reference solution (b). Dilute 1.0 ml of reference solution (a) to 5.0 ml with *ethyl acetate*.

Apply to the plate 5 μ l of each solution. After development, dry the plate in warm air and spray with a solution containing 6 per cent w/v of *ammonium thiocyanate* and 2 per cent w/v of *cobalt (II) chloride*, allow to dry in air for 10 minutes. In the chromatogram obtained with the test solution, any secondary spot is not more intense than the spot in the chromatogram obtained with reference solution (a) (0.5 per cent) and not more than one secondary spot is more intense than the spot in the chromatogram obtained with reference solution (b) (0.1 per cent).

Heavy metals (2.3.13). 1.0 g complies with the limit test for heavy metals, Method B (20 ppm).

Sulphated ash (2.3.18). Not more than 0.1 per cent.

Loss on drying (2.4.19). Not more than 0.5 per cent, determined on 1.0 g by drying in an oven at 60°, at a pressure not exceeding 0.7 kPa for 4 hours.

Assay. Dissolve 1.0 g in 50 ml of *anhydrous glacial acetic acid*. Titrate with 0.1 *M perchloric acid*, determining the end-point potentiometrically (2.4.25). Carry out a blank titration.

1 ml of 0.1 *M perchloric acid* is equivalent to 0.04676 g $C_{28}H_{41}N_3O_3$.

2.4.26. Solubility

Oxetacaine. Freely soluble in *methanol*; soluble in *ethyl acetate*; practically insoluble in *water*.