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

Oxybuprocaine Eye Drops

General Notices

Action and use

Local anaesthetic.

DEFINITION

Oxybuprocaine Eye Drops are a sterile solution of Oxybuprocaine Hydrochloride in Purified Water.

The eye drops comply with the requirements stated under Eye Preparations and with the following requirements.

Content of oxybuprocaine hydrochloride, $C_{17}H_{28}N_2O_3$,HCl

90.0 to 110.0% of the stated amount.

IDENTIFICATION

A. To a quantity of the eye drops containing 0.4% w/v of Oxybuprocaine Hydrochloride add 0.5 mL of 2M *hydrochloric acid* and 0.5 mL of a 10% w/v solution of *sodium nitrite* and mix. Add a solution prepared by dissolving 0.2 g of *2-naphthol* in the minimum volume of 18M *ammonia*; a red precipitate is produced.
B. In the Assay, the chromatogram obtained with solution (1) shows a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2).
C. Yield reaction A characteristic of *chlorides*, Appendix VI.

TESTS

Acidity

pH, 3.5 to 4.3, Appendix V L.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dilute a volume of the eye drops with sufficient of the mobile phase to produce a solution containing 0.016% w/v of Oxybuprocaine Hydrochloride.
(2) Dilute 1 volume of solution (1) to 100 volumes with the mobile phase.
(3) Mix 1 volume of solution (1) with 1 volume of a 4% w/v solution of *sodium hydroxide* and allow to stand for 20 minutes. Add 1 volume of 2M *orthophosphoric acid*, dilute to 100 volumes with the mobile phase and dilute 1 volume of the final solution to 4 volumes with the mobile phase (generation of 4-amino-3-butoxybenzoic acid).

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Assay may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution factor* between the two principal peaks is at least 2.0.

LIMITS

In the chromatogram obtained with solution (1):

the sum of the areas of any *secondary peaks* is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (3%).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dilute a suitable volume of the eye drops with sufficient of the mobile phase to produce a solution containing 0.016% w/v of Oxybuprocaine Hydrochloride.
(2) 0.016% w/v of *oxybuprocaine hydrochloride BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil ODS is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 235 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

40 volumes of *acetonitrile* containing 0.1% v/v of *diethylamine* and 60 volumes of a 0.75% w/v solution of *ammonium acetate* which has been adjusted to pH 5.0 with *glacial acetic acid*.

DETERMINATION OF CONTENT

Calculate the content of $C_{17}H_{28}N_2O_3$,HCl in the eye drops using the declared content of $C_{17}H_{28}N_2O_3$,HCl in *oxybuprocaine hydrochloride BPCRS*.

STORAGE

Oxybuprocaine Eye Drops should be protected from light. They should not be allowed to freeze.