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

Tetracaine Eye Drops

General Notices

Action and use

Local anaesthetic.

DEFINITION

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

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

Content of tetracaine hydrochloride, $C_{15}H_{24}N_2O_2$,HCl

92.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Dilute the eye drops with *water*, if necessary, to produce a solution containing 0.01% w/v of Tetracaine Hydrochloride. To 5 mL of this solution, add 15 mL of *buffer (acetate) solution pH 5.0* and add sufficient *water* to produce a solution containing 0.00003% w/v of Tetracaine Hydrochloride. The *light absorption*, Appendix II B, in the range 230 to 350 nm of this solution, exhibits a maximum only at 310 nm. The absorbance at 310 nm is about 0.35.
B. In the Assay, the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the principal peak in the chromatogram obtained with solution (2).

TESTS

Acidity

pH, 3.3 to 4.4, Appendix V L.

Related substances

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

(1) Dilute the eye drops, if necessary, with the mobile phase to produce a solution containing 0.5% w/v of Tetracaine Hydrochloride.
(2) Dilute 1 volume of solution (1) to 200 volumes with the mobile phase.
(3) 0.05% w/v of *4-(butylamino)benzoic acid* (impurity B) in *methanol*. To 1 volume of this solution, add 2 volumes of a solution of 1.0% w/v of *tetracaine hydrochloride BPCRS* in 0.01M *hydrochloric acid* and dilute to 100 volumes with the mobile phase.
(4) Dilute 1 volume of solution (2) to 5 volumes with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Hypersil GOLD C18 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 310 nm.
(f) Inject 20 µL of each solution.
(g) Allow the chromatography to proceed for 4 times the retention time of the principal peak.

MOBILE PHASE

1 volume of *perchloric acid*, 35 volumes of *stabiliser-free tetrahydrofuran* and 100 volumes of *water*. Adjust this solution to pH 3.0 with *ammonia*.

When the chromatograms are recorded under the prescribed conditions, the relative retentions with reference to tetracaine (retention time of about 4.5 minutes) are: impurity A, about 0.5 and impurity B, about 1.8.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to tetracaine and impurity B is at least 8.0.

LIMITS

Identify any peak in the chromatogram obtained with solution (1) due to impurity B using the chromatogram obtained with solution (3).

In the chromatogram obtained with solution (1):

the area of any peak corresponding to impurity B is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.5%);

the area of any other *secondary peak* is not greater than 0.4 times the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the sum of the areas of all *secondary peaks* is not greater than 3 times the area of the principal peak in the chromatogram obtained with solution (2) (1.5%)

Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4) (0.1%).

ASSAY

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

(1) Dilute a volume of the eye drops, if necessary, with the mobile phase to produce a solution containing 0.01% w/v of Tetracaine Hydrochloride.
(2) 0.01% w/v of *tetracaine hydrochloride BPCRS* in 0.01M *hydrochloric acid*.
(3) 0.01% w/v of *4-(butylamino)benzoic acid* in *methanol*. To 1 volume of this solution, add 2 volumes of solution (2) and dilute to 100 volumes with the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under the Related substances can be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to tetracaine and impurity B is at least 8.0.

DETERMINATION OF CONTENT

Calculate the content of $C_{15}H_{24}N_2O_2$,HCl in the eye drops using the declared content of $C_{15}H_{24}N_2O_2$,HCl in *tetracaine hydrochloride BPCRS*.

STORAGE

Tetracaine Eye Drops should be protected from light.

IMPURITIES

The impurities limited by the requirements of this monograph include impurities A and B listed under Tetracaine Hydrochloride.