Tetracaine Eye Drops

Tetracaine Preparations

**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, C₇H₁₂N₂O₂.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 make 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 octadecysilyl silica gel (5 µm) (Waters 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 tetrahydrofuran, stabiliser free and 100 volumes of water, adjusted to pH 3.0 with ammonia.

When the chromatograms are recorded under the prescribed conditions, the retention times relative to tetracaine (retention time of about 4.5 minutes) are: for 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 peaks 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).
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).
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).
Disregard any peak with an area less than the area of the principal peak in the chromatogram obtained with solution (4).

**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.

Notes: Draft revised monograph.
Updated Identification, Related substances and Assay tests.
CHROMATOGRAPHIC CONDITIONS
The 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 and tetracaine and impurity B is at least 8.0.

DETERMINATION OF CONTENT
Calculate the content of C₁₅H₂₄N₂O₂.HCl in the eye drops using the declared content of C₁₅H₂₄N₂O₂.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.