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

Lidocaine Intraocular Injection

General Notices

NOTE: *This monograph has been developed to cover unlicensed formulations.*

Action and use

Intraocular anaesthetic.

DEFINITION

Lidocaine Intraocular Injection is a sterile, isotonic solution of Lidocaine Hydrochloride Monohydrate in a suitable diluent. It is supplied as a ready-to-use solution.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements. Where appropriate, the injection also complies with the requirements stated under Unlicensed Medicines.

Content of lidocaine hydrochloride monohydrate, $C_{14}H_{22}N_2O,HCl,H_2O$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Make a volume of the injection containing 10 mg of Lidocaine Hydrochloride Monohydrate alkaline with 5M *sodium hydroxide*; filter, wash the residue with *water*, dissolve it in 1 mL of *ethanol (96%)*, add 0.5 mL of a 10% w/v solution of *cobalt(II) chloride* and shake for 2 minutes. A bluish-green precipitate is produced.
B. To a volume of the injection containing 10 mg of Lidocaine Hydrochloride Monohydrate add 10 mL of *picric acid solution R1*. The *melting point* of the precipitate, after washing with *water* and drying at 105°, is about 229°, Appendix V A.

TESTS

Acidity or alkalinity

pH, 6.0 to 7.0, Appendix V L.

Osmolality

The osmolality of the injection is 270 to 330 mosmol/kg, Appendix V N.

Related substances

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in a buffer prepared by dissolving 2.72 g of *potassium dihydrogen orthophosphate* and 1.01 g of *sodium heptanesulfonate* in 1000 mL of *water* and adjusting the pH to 3.0 with *orthophosphoric acid* (solution A).

(1) Dilute a volume of the injection to contain 0.2% w/v of Lidocaine Hydrochloride Monohydrate.
(2) 0.0004% w/v of *2,6-dimethylaniline*.
(3) Dilute 1 volume of solution (1) to 100 volumes and further dilute 1 volume to 5 volumes.
(4) Mix 1 volume of a 0.2% w/v solution of *lidocaine hydrochloride BPCRS* with 5 volumes of solution (2) and dilute to 10 volumes.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (25 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Luna 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 263 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

30 volumes of *acetonitrile* and 70 volumes of solution A.

SYSTEM SUITABILITY

The test is not valid unless the chromatogram obtained with solution (4) shows a peak due to lidocaine (retention time about 6 minutes) and a peak due to 2,6-dimethylaniline with a retention relative to lidocaine of about 2.35.

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to 2,6-dimethylaniline is not greater than the area of the principal peak in the chromatogram obtained with solution (2) (0.2%);

the area of any other *secondary peak* is not greater than the area of the principal peak in the chromatogram obtained with solution (3) (0.2%);

the sum of the areas of all the *secondary peaks* is not greater than 10 times the area of the principal peak in the chromatogram obtained with solution (3) (2.0%).

Disregard any peak with an area less than 0.25 times the area of the principal peak in the chromatogram obtained with solution (3) (0.05%).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions in solution A described under Related substances.

(1) Dilute a volume of the injection to contain 0.2% w/v of Lidocaine Hydrochloride Monohydrate.
(2) 0.2% w/v of *lidocaine hydrochloride BPCRS*.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances may be used.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (2), the *column efficiency*, determined on the peak due to lidocaine is at least 2000 *theoretical plates*.

DETERMINATION OF CONTENT

Calculate the content of $C_{14}H_{22}N_2O,HCl,H_2O$ in the injection using the declared content of $C_{14}H_{22}N_2O,HCl,H_2O$ in *lidocaine hydrochloride BPCRS*.

IMPURITIES

The impurities limited by the requirements of this monograph include 2,6-dimethylaniline.