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

Mepivacaine Injection

General Notices

Action and use

Local anaesthetic.

DEFINITION

Mepivacaine Injection is a sterile solution of Mepivacaine Hydrochloride in Water for Injections.

The injection complies with the requirements stated under Parenteral Preparations and with the following requirements.

Content of mepivacaine hydrochloride, $C_{15}H_{22}N_2O_2$,HCl

95.0 to 105.0% of the stated amount.

IDENTIFICATION

A. Carry out the method for *thin-layer chromatography*, Appendix III A, using a *TLC silica gel F_{254} plate* and a mixture of 1 volume of 13.5M *ammonia*, 5 volumes of *methanol* and 100 volumes of *ether* as the mobile phase, but allowing the solvent front to ascend 12 cm above the line of application. Apply separately to the plate 10 µL of each of the following solutions. For solution (1) dilute a quantity of the injection with sufficient *ethanol (96%)* to produce a solution containing 0.4% w/v of Mepivacaine Hydrochloride. Solution (2) contains 0.4% w/v of *mepivacaine hydrochloride BPCRS* in *ethanol (96%)*. Solution (3) contains 0.4% w/v of each of *mepivacaine hydrochloride BPCRS* and *lidocaine hydrochloride BPCRS* in *ethanol (96%)*. After removal of the plate, allow it to dry in air and examine under *ultraviolet light (254 nm)*. The principal spot in the chromatogram obtained with solution (1) is similar in position and size to the principal spot in the chromatogram obtained with solution (2). The test is not valid unless the chromatogram obtained with solution (3) shows two clearly separated principal spots.
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).

TESTS

Acidity

pH, 4.5 to 6.0, Appendix V L.

2,6-Dimethylaniline

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. For solution (1) dilute a quantity of the injection containing 0.1 g of Mepivacaine Hydrochloride to 100 mL with the mobile phase. Solution (2) contains 0.0002% w/v of *2,6-dimethylaniline* in the mobile phase.

The chromatographic procedure described under Assay may be used.

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% of the content of mepivacaine hydrochloride).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. For solution (1) dilute a quantity of the injection containing 0.1 g of Mepivacaine Hydrochloride to 100 mL with the mobile phase and dilute 1 volume of this solution to 20 volumes with the mobile phase. Solution (2) contains 0.005% w/v of *mepivacaine hydrochloride BPCRS* in the mobile phase.

The chromatographic procedure may be carried out using (a) a stainless steel column (25 cm × 3.2 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Spherisorb ODS 1 is suitable), (b) as the mobile phase with a flow rate of 0.5 mL per minute a mixture of 1 volume of *triethylamine*, 400 volumes of *acetonitrile* and 600 volumes of a 0.2% w/v solution of *potassium dihydrogen orthophosphate*, the mixture adjusted to pH 4.0 with *orthophosphoric acid* and (c) a detection wavelength of 212 nm.

Calculate the content of $C_{15}H_{22}N_2O_2$,HCl in the injection using the declared content of $C_{15}H_{22}N_2O_2$,HCl in *mepivacaine hydrochloride BPCRS*.