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

# Prilocaine Injection

General Notices

**Action and use**

Local anaesthetic.

## DEFINITION

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

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

**Content of prilocaine hydrochloride, $C_{13}H_{20}N_2O,HCl$**

95.0 to 105.0% of the stated amount.

## CHARACTERISTICS

A colourless solution.

## IDENTIFICATION

A. To a volume containing 0.1 g of Prilocaine Hydrochloride add 2M *sodium hydroxide* until the solution is about pH 11. Add 20 mL of *ethyl acetate*, shake, allow the layers to separate, dry the organic layer over *anhydrous calcium chloride* at a pressure of 2 kPa, filter and evaporate the filtrate to dryness under reduced pressure. The *infrared absorption spectrum* of the oily residue, Appendix II A, is concordant with the *reference spectrum* of prilocaine (*RS 284*).
B. In the Assay, the principal peak in the chromatogram obtained with solution (3) has the same retention time as the peak due to prilocaine in the chromatogram obtained with solution (1).

## TESTS

**Acidity**

pH, 5.0 to 7.0, Appendix V L.

**Aromatic amines**

To 1 mL of the injection, diluted if necessary to contain 0.05% w/v of Prilocaine Hydrochloride, add 1 mL of a 1% w/v solution of *4-dimethylaminobenzaldehyde* in *methanol* and 2 mL of *glacial acetic acid*. Shake and allow to stand for 10 minutes. Measure the *absorbance* of the solution at 430 nm, Appendix II B, using *water* in the reference cell. The absorbance is not more intense than that produced in a solution prepared at the same time and in the same manner but using 1 mL of a solution in *water* containing 5 µg per mL of o-*toluidine hydrochloride* (0.75%, calculated as *o*-toluidine).

## ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions. Solution (1) contains 0.01% w/v of *prilocaine hydrochloride BPCRS* in the mobile phase. For solution (2) dilute the injection with the mobile phase to produce a solution containing 0.01% w/v of Prilocaine Hydrochloride.

The chromatographic procedure may be carried out using (a) a stainless steel column (15 cm × 4.6 mm) packed with *end-capped octadecylsilyl silica gel for chromatography* (5 µm) (Spherisorb ODS 2 is suitable), (b) a mixture of 30 volumes of 0.05M *mixed phosphate buffer pH 8* and 70 volumes of *methanol* as the mobile phase with a flow rate of 1 mL per minute and (c) a detection wavelength of 240 nm.

Calculate the content of $C_{13}H_{20}N_2O$,HCl in the injection using the declared content of $C_{13}H_{20}N_2O$,HCl in *prilocaine hydrochloride BPCRS*.