



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

Lidocaine Injection

[General Notices](#)

Action and use

Local anaesthetic; Class I antiarrhythmic.

DEFINITION

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

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

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

95.0 to 105.0% of the stated amount.

IDENTIFICATION

- A. Make a volume containing 0.1 g 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\(III\) chloride](#) and shake for 2 minutes. A bluish-green precipitate is produced.
- B. To a volume containing 0.1 g of Lidocaine Hydrochloride 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](#).
- C. Yields the reactions characteristic of [chlorides](#), [Appendix VI](#).

2,6-Dimethylaniline

To a volume of the injection containing 25 mg of Lidocaine Hydrochloride Monohydrate add [water](#) if necessary to produce 10 mL, add 2M [sodium hydroxide](#) until the solution is just alkaline and extract with three 5 mL quantities of [chloroform](#). Dry the combined chloroform extracts over [anhydrous sodium sulfate](#), filter, wash with a further 5 mL of [chloroform](#) and evaporate the filtrate to dryness at a pressure of 2 kPa. Dissolve the residue in 2 mL of [methanol](#), add 1 mL of a 1% w/v solution of [4-dimethylaminobenzaldehyde](#) in [methanol](#) and 2 mL of [glacial acetic acid](#) and allow to stand at room temperature for 10 minutes. Any yellow colour produced is not more intense than the colour obtained by repeating the operation using 10 mL of a solution of [2,6-dimethylaniline](#) in [water](#) containing 1 µg per mL in place of the injection (400 ppm).

ASSAY

Make a quantity containing 0.1 g of Lidocaine Hydrochloride Monohydrate alkaline with 2M [sodium hydroxide](#) and extract with three 20 mL quantities of [chloroform](#), washing each extract with the same 10 mL of [water](#). Filter the washed extracts through a filter paper moistened with [chloroform](#) and wash the filter with 10 mL of [chloroform](#). Add the washings to the filtrate and carry out Method I for [non-aqueous titration](#), [Appendix VIII A](#), using [0.02M perchloric acid VS](#) as titrant and [crystal violet solution](#) as indicator. Each mL of [0.02M perchloric acid VS](#) is equivalent to 5.776 mg of $C_{14}H_{22}N_2O \cdot HCl \cdot H_2O$.

