



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

## Lidocaine Gel

### [General Notices](#)

### Action and use

Local anaesthetic; Class I antiarrhythmic.

## DEFINITION

Lidocaine Gel is a sterile solution of Lidocaine Hydrochloride Monohydrate in a suitable water-miscible basis.

*The gel complies with the requirements stated under Topical Semi-solid Preparations and with the following requirements.*

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

95.0 to 105.0% of the stated amount.

## IDENTIFICATION

To a quantity of the gel containing the equivalent of 80 mg of anhydrous lidocaine hydrochloride add 4 mL of [hydrochloric acid](#) and heat on a water bath for 10 minutes. Allow to cool, transfer to a separating funnel with the aid of 20 mL of [water](#), add 5M [sodium hydroxide](#) until precipitation is complete and extract with two 20-mL quantities of [chloroform](#). Filter the chloroform extracts through [anhydrous sodium sulfate](#) and evaporate the filtrate to dryness on a water bath using a current of nitrogen. The residue complies with the following tests.

- A. The [infrared absorption spectrum](#), [Appendix II A](#), is concordant with the *reference spectrum* of lidocaine ([RS 202](#)).
- B. Dissolve 20 mg in 1 mL of [ethanol \(96%\)](#), add 0.5 mL of a 10% w/v solution of *cobalt(II) chloride* and 0.5 mL of 5M [sodium hydroxide](#) and shake for 2 minutes. A bluish-green precipitate is produced.
- C. Dissolve 40 mg in 5 mL of a 1% w/v solution of [cetrimide](#) and add 1 mL of 5M [sodium hydroxide](#) and 1 mL of [bromine water](#). A yellow colour is produced.

## TESTS

### 2,6-Dimethylaniline

Mix a quantity of the gel containing the equivalent of 15 mg of anhydrous lidocaine hydrochloride with sufficient [water](#) to produce 3 mL using a rotary vortex mixer. To 2 mL of the resulting solution add 1 mL of a freshly prepared 1% w/v solution of 4-dimethyl-aminobenzaldehyde in [methanol](#), mix thoroughly using a rotary vortex mixer, add 2 mL of [glacial acetic acid](#) and allow to stand for 10 minutes. The yellow colour produced is not more intense than that obtained using a mixture of 2 mL of a solution of [2,6-dimethylaniline](#) in [methanol](#) containing 2 µg per mL in place of the solution of the gel.

### [Sterility](#)

Complies with the *test for* [sterility](#), [Appendix XVI A](#).

## ASSAY

Disperse a quantity containing the equivalent of 10 mg of anhydrous lidocaine hydrochloride in 20 mL of [water](#). Add 5 mL of [acetate buffer pH 2.8](#), 120 mL of [chloroform](#) and 5 mL of [dimethyl yellow and oracet blue 2R solution](#) and titrate with 0.005M [dioctyl sodium sulfosuccinate VS](#), swirling vigorously. Near the end point add the titrant dropwise and, after each addition, swirl vigorously, allow to separate and swirl gently for 5 seconds. The end point is indicated when the colour of the chloroform layer changes from green to pinkish-grey. Repeat the operation without the preparation being examined. The difference between the titrations represents the amount of dioctyl sodium sulfosuccinate required. Each mL of 0.005M [dioctyl sodium sulfosuccinate VS](#) is equivalent to 1.354 mg of  $C_{14}H_{22}N_2O \cdot HCl$ . Determine the [weight per mL](#) of the gel, [Appendix V G](#), and calculate the percentage of  $C_{14}H_{22}N_2O \cdot HCl$ , weight in volume.

## STORAGE

Lidocaine Gel should be stored in accordance with the manufacturer's instructions.

## LABELLING

The quantity of active ingredient is stated in terms of the equivalent amount of anhydrous lidocaine hydrochloride.