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Lidocaine Ointment

General Notices

Action and use

Local anaesthetic; Class I antiarrhythmic.

DEFINITION

Lidocaine Ointment contains Lidocaine in a suitable hydrophilic basis.

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

Content of lidocaine, $C_{14}H_{22}N_2O$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

Warm a quantity of the ointment containing about 25 mg of Lidocaine until the basis has melted, add 1 mL of *saturated sodium chloride solution* and 0.2 mL of 1M *sodium hydroxide* and cool. Add 5 mL of *ether*, shake vigorously for 1 minute and allow the layers to separate. Filter the ether layer through *anhydrous sodium sulfate* and evaporate the *ether* to dryness. Dissolve the residue in the minimum volume of *chloroform IR*, apply the solution directly to a *sodium chloride* disc and allow the solvent to evaporate. The *infrared absorption spectrum* of the resulting thin film, Appendix II A, is concordant with the *reference spectrum* of lidocaine *(RS 405)*.

2,6-Dimethylaniline

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dissolve a quantity of the ointment containing 50 mg of Lidocaine in the mobile phase, dilute to 50 mL with the mobile phase and dilute 1 volume of this solution to 10 volumes with the mobile phase.
(2) Dilute a 0.1% w/v solution of *2,6-dimethylaniline* in *methanol* with the mobile phase to produce a solution containing 0.04 µg per mL of 2,6-dimethylaniline.
(3) Mix equal volumes of a 0.01% w/v solution of *lidocaine BPCRS* in the mobile phase with a 0.005% w/v solution of *2,6-dimethylaniline* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 4.6 mm) packed with *octadecylsilyl silica gel for chromatography* (5 µm) (Apex ODS 2 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 0.8 mL per minute.
(d) Use an ambient column temperature.
(e) Use a detection wavelength of 230 nm.
(f) Inject 20 µL of each solution.

MOBILE PHASE

35 volumes of a phosphate buffer pH 8.0 prepared by adding a 0.408% w/v solution of *potassium dihydrogen orthophosphate* to a suitable volume of a 0.685% w/v solution of *dipotassium hydrogen orthophosphate* until pH 8.0 is attained and 65 volumes of *methanol*.

The chromatogram obtained with solution (3) shows a peak due to lidocaine and a peak due to 2,6-dimethylaniline with a retention time relative to lidocaine of about 0.5.

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 peak in the chromatogram obtained with solution (2) (400 ppm).

ASSAY

Carry out the method for *liquid chromatography*, Appendix III D, using the following solutions.

(1) Dissolve a quantity of the ointment containing 50 mg of Lidocaine in the mobile phase, dilute to 50 mL with the mobile phase and dilute 1 volume of this solution to 10 volumes with the mobile phase.
(2) 0.010% w/v of *lidocaine BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under 2,6-Dimethylaniline may be used.

DETERMINATION OF CONTENT

Calculate the content of $C_{14}H_{22}N_2O$ in the ointment using the declared content of $C_{14}H_{22}N_2O$ in *lidocaine BPCRS*.