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Lidocaine Injection

General Notices

Details for the public consultation of this monograph are as follows:

EAG/Panel/Working Party	Medicinal Chemicals 2
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Target Publication Date (subject to change)	BP 2028
Notes	Revised monograph If limits are too restrictive, please provide batch/stability data to demonstrate that an increase is required. **Content** revised expression of content. Please note that this amendment does not require a labelling change for established products. **Identification** tests A - C replaced with a single procedure. **2,6-Dimethylaniline** test deleted. **Related substances** new test added. **Assay** test revised, harmonised with new related substances test. **Labelling** section added. **Impurities** section added.

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 anhydrous lidocaine hydrochloride, $C_{14}H_{22}N_2O,HCl$

95.0 to 105.0% of the stated amount.

IDENTIFICATION

In the Assay, record the UV spectrum of the principal peak in the chromatograms obtained with solutions (1) and (2) with a diode array detector in the range of 210 to 400 nm.

The UV spectrum of the principal peak in the chromatogram obtained with solution (1) is concordant with that of the peak in the chromatogram obtained with solution (2);

the retention time of the principal peak in the chromatogram obtained with solution (1) is similar to that of the peak in the chromatogram obtained with solution (2).

TESTS

Related substances

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

(1) Dilute a volume of the injection with sufficient mobile phase, if necessary, to produce a solution containing the equivalent of 0.5% w/v of anhydrous lidocaine hydrochloride.
(2) Dilute 1 volume of solution (1) to 500 volumes.
(3) 0.0002% w/v of *2,6-dimethylaniline* (impurity A).
(4) 0.00005% w/v of *2,6-dimethylaniline* and 0.0005% w/v of *2-chloro-N-(2,6-dimethylphenyl)acetamide* (impurity H).

CHROMATOGRAPHIC CONDITIONS

(a) Use a stainless steel column (15 cm × 3.9 mm) packed with *end-capped polar-embedded octadecylsilyl amorphous organosilica polymer* (5 µm) (XTerra Shield RP18 is suitable).
(b) Use isocratic elution and the mobile phase described below.
(c) Use a flow rate of 1.0 mL per minute.
(d) Use a column temperature of 30°.
(e) Use a detection wavelength of 230 nm.
(f) Inject 20 µL of each solution.
(g) Allow the chromatography to proceed for 3 times the retention time of lidocaine.

MOBILE PHASE

30 volumes of *acetonitrile* and 70 volumes of 0.485% w/v of *potassium dihydrogen orthophosphate*, previously adjusted to pH 8.0 with 10M *sodium hydroxide*.

SYSTEM SUITABILITY

The test is not valid unless, in the chromatogram obtained with solution (3), the *resolution* between the peaks due to impurity H and impurity A is at least 1.5.

CALCULATION OF IMPURITIES

For impurity A, use the concentration of impurity A in solution (3).

For each unspecified impurity, use the concentration of anhydrous lidocaine hydrochloride in solution (2).

For the reporting threshold, use the concentration of anhydrous lidocaine hydrochloride in solution (2).

For peak identification, use solutions (3) and (4).

Lidocaine retention time: about 17 minutes.

Relative retentions: impurity H, about 0.35; impurity A, about 0.4.

LIMITS

— impurity A: not more than 0.04% (400 ppm);

— unspecified impurities: for each impurity, not more than 0.2%;

— total impurities: not more than 1.0%;

— reporting threshold, excluding impurity A: 0.1%.

ASSAY

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

(1) Dilute a volume of the injection with sufficient mobile phase, if necessary, to produce a solution containing the equivalent of 0.1% w/v of anhydrous lidocaine hydrochloride.
(2) 0.107% w/v of *lidocaine hydrochloride BPCRS* in the mobile phase.

CHROMATOGRAPHIC CONDITIONS

The chromatographic conditions described under Related substances should be used, excluding (g).

DETERMINATION OF CONTENT

Calculate the content of $C_{14}H_{22}N_2O$,HCl in the injection using the declared content of $C_{14}H_{22}N_2O$,HCl in *lidocaine hydrochloride BPCRS*. Each mg of $C_{14}H_{22}N_2O$,HCl, H_2O is equivalent to 0.9377 mg of $C_{14}H_{22}N_2O$,HCl.

LABELLING

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

IMPURITIES

The impurities limited by the requirements of this monograph include those listed under Lidocaine Hydrochloride Monohydrate.