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Lidocaine Hydrochloride Injection

» Lidocaine Hydrochloride Injection is a sterile solution of Lidocaine Hydrochloride in Water for Injection, or a sterile solution prepared from Lidocaine with the aid of Hydrochloric Acid in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of lidocaine hydrochloride ($C_{14}H_{22}N_2O \cdot HCl$).

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass. Injection may be packaged in 50-mL multiple-dose containers.

Labeling—Injections that are of such concentration that they are not intended for direct injection into tissues are labeled to indicate that they are to be diluted prior to administration.

USP REFERENCE STANDARDS (11).—
[USP Lidocaine RS](#)

Identification—Place in a separator a volume of Injection equivalent to about 300 mg of lidocaine hydrochloride, and extract with four 15-mL portions of chloroform, discarding the chloroform extracts. Add 2 mL of 2 N sodium hydroxide to the aqueous solution remaining in the separator, and extract with four 15-mL portions of chloroform. Combine the chloroform extracts, and evaporate with the aid of a current of warm air to dryness. Dissolve the crystals so obtained in solvent hexane, evaporate with the aid of warm air, and dry the residue in vacuum over silica gel for 24 hours: the residue so obtained responds to [Identification](#) test A under [Lidocaine](#).

BACTERIAL ENDOTOXINS TEST (85).—It contains not more than 1.1 USP Endotoxin Units per mg of lidocaine hydrochloride.

pH (791): between 5.0 and 7.0.

PARTICULATE MATTER IN INJECTIONS (788): meets the requirements for small-volume injections.

Other requirements—It meets the requirements under [Injections and Implanted Drug Products](#) (1).

Assay—Proceed with Injection as directed in the [Assay for lidocaine hydrochloride](#) under [Lidocaine Hydrochloride and Epinephrine Injection](#).

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
LIDOCAINE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

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