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Lidocaine Hydrochloride and Dextrose Injection

» Lidocaine Hydrochloride and Dextrose Injection is a sterile solution of Lidocaine Hydrochloride and Dextrose in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amounts of lidocaine hydrochloride ($C_{14}H_{22}N_2O \cdot HCl$) and dextrose ($C_6H_{12}O_6 \cdot H_2O$).

Packaging and storage—Preserve in single-dose glass or plastic containers. Glass containers are preferably of Type I or Type II glass.

USP Reference standards ⟨11⟩—
USP Lidocaine RS

Identification—

A: Place in a separator a volume of Injection equivalent to about 300 mg of lidocaine hydrochloride, add 2 mL of 2 N sodium hydroxide, 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*.

B: Add a few drops of a solution (1 in 20) to 5 mL of hot alkaline cupric tartrate TS. A copious red precipitate of cuprous oxide is formed.

Bacterial Endotoxins Test ⟨85⟩—It contains not more than 1.1 USP Endotoxin Units per mg of lidocaine hydrochloride.

pH ⟨791⟩**:** between 3.0 and 7.0.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Change to read:

Assay for lidocaine hydrochloride—Proceed with Injection as directed in the *Assay for lidocaine hydrochloride* under *Lidocaine* ▲*Hydrochloride*▲ *(ERR 1-Mar-2023)* *and Epinephrine Injection*.

Assay for dextrose—Determine the angular rotation of Injection in a suitable polarimeter tube (see *Optical Rotation* ⟨781⟩). Calculate the percentage (g per 100 mL) of dextrose ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Injection taken by the formula:

$$(100/52.9)(198.17/180.16)AR$$

in which 100 is the percentage; 52.9 is the midpoint of the specific rotation range for anhydrous dextrose, in degrees; 198.17 and 180.16 are the molecular weights for dextrose monohydrate and anhydrous dextrose, respectively; *A* is 100 mm divided by the length of the polarimeter tube, in mm; and *R* is the observed rotation, in degrees.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
LIDOCAINE HYDROCHLORIDE AND DEXTROSE INJECTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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