Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-034DB8B8-0C5D-4999-8910-9DF7E6532133_3_en-US
DOI: https://doi.org/10.31003/USPNF_M10502_03_01
DOI Ref: k870t

Bupivacaine Hydrochloride in Dextrose Injection

» Bupivacaine Hydrochloride in Dextrose Injection is a sterile solution of Bupivacaine Hydrochloride and Dextrose in Water for Injection. It contains not less than 93.0 percent and not more than 107.0 percent of the labeled amounts of bupivacaine hydrochloride ($C_{18}H_{28}N_2O \cdot HCl$) and dextrose ($C_6H_{12}O_6$). It contains no preservative.

Packaging and storage—Preserve in single-dose containers, preferably of Type I glass.

USP Reference standards ⟨11⟩—
USP Bupivacaine Hydrochloride RS
USP Dextrose RS

Identification—

A: *Thin-Layer Chromatographic Identification Test ⟨201⟩*—

Adsorbent: chromatographic silica gel mixture; 0.25 mm.

Developing solvent: mixture of butyl alcohol, water, dehydrated alcohol, and glacial acetic acid (6:2:1:1).

Test preparation: Bupivacaine Hydrochloride in Dextrose Injection.

Standard preparations A, B, and *C*—Separately prepare (*A*) a solution of USP Bupivacaine Hydrochloride RS in water, (*B*) a solution of USP Dextrose RS in water, and (*C*) a solution of USP Bupivacaine Hydrochloride RS in (*B*) to obtain solutions having concentrations corresponding to the labeled concentrations of bupivacaine hydrochloride and dextrose in the Injection.

Naphthalenediol reagent—Dissolve 20 mg of 1,3-naphthalenediol in 10 mL of dehydrated alcohol containing 0.2 mL of sulfuric acid.

Iodoplatinate reagent—Mix equal volumes of platinic chloride solution (3 in 1000) and potassium iodide solution (6 in 100).

Procedure—Separately apply 10 µL each of the *Test preparation* and *Standard preparations A* and *C* to a portion of the chromatographic plate, and separately apply 1 µL each of the *Test preparation* and *Standard preparation B* to the remaining portion of the plate. Dry the applications in a current of warm air, develop the chromatograms, remove the plate from the developing chamber, and mark the solvent front. Dry the plate in warm circulating air, and examine the plate under short-wavelength UV light: the R_F value of the principal spot obtained from the *Test preparation* corresponds to the spots obtained from the adjacent chromatograms of *Standard preparations A* and *C*. Spray the plate with *Naphthalenediol reagent*, heat at 90° for 5 minutes, and examine the plate: the R_F value of the principal blue-purple spot obtained from the *Test preparation* corresponds to that obtained in the adjacent chromatogram of *Standard preparation B*. Cool the plate, spray it with *Iodoplatinate reagent*, and examine the plate: bupivacaine appears as a blue-purple spot on a salmon-colored background, and the dextrose spots fade slightly: the R_F value of the bupivacaine spot obtained from the *Test preparation* corresponds to those obtained from the adjacent chromatograms of *Standard preparations A* and *C*.

B: It responds to *Identification* test *B* under *Bupivacaine Hydrochloride Injection*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 1.8 USP Endotoxin Units per mg of bupivacaine hydrochloride.

pH ⟨791⟩: between 4.0 and 6.5.

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

Assay for bupivacaine hydrochloride—

pH 6.8 Phosphate buffer, Mobile phase, Internal standard solution, Standard preparation, Chromatographic system, and *Procedure*—Proceed as directed in the *Assay* under *Bupivacaine Hydrochloride Injection*.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 50 mg of bupivacaine hydrochloride, to a 100-mL volumetric flask, add 10.0 mL of *Internal standard solution*, dilute with methanol to volume, and mix.

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 ($C_6H_{12}O_6$) in the portion of Injection taken by the formula:

$$(100/52.9)AR$$

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. PF 41(3)

Current DocID: GUID-034DB8B8-0C5D-4999-8910-9DF7E6532133_3_en-US
Previous DocID: GUID-034DB8B8-0C5D-4999-8910-9DF7E6532133_1_en-US
DOI: https://doi.org/10.31003/USPNF_M10502_03_01
DOI ref: k870t