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Bupivacaine Hydrochloride Injection

DEFINITION

Bupivacaine Hydrochloride Injection is a sterile solution of Bupivacaine Hydrochloride in Water for Injection. It contains NLT 93.0% and NMT 107.0% of the labeled amount of bupivacaine hydrochloride ($C_{18}H_{28}N_2O \cdot HCl$).

IDENTIFICATION

- **A.** Identification—Organic Nitrogenous Bases ⟨181⟩

  Sample solution: 2 mg/mL of bupivacaine hydrochloride in 0.01 N hydrochloric acid, from Injection

  Analysis: Proceed as directed in the chapter beginning with "Transfer the liquid to a separator".

  Acceptance criteria: Meets the requirements

- **B.** The retention time of the bupivacaine peak in the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY

Change to read:

- **Procedure**

  Buffer: 1.94 g/L of monobasic potassium phosphate and 2.48 g/L of dibasic potassium phosphate in water. Adjust, if necessary, with 1 N potassium hydroxide or 1 M phosphoric acid to a pH of 6.8.

  Mobile phase: Acetonitrile and *Buffer* (65:35). Adjust, if necessary, with 1 M phosphoric acid to a pH of 7.7 ± 0.2. Filter the solution through a membrane filter of 1-µm or finer pore size, and degas.

  Internal standard solution: 1.3 mg/mL of dibutyl phthalate in methanol

  Standard solution: 0.5 mg/mL of USP Bupivacaine Hydrochloride RS, prepared as follows. In a 100-mL volumetric flask, dissolve 50 mg of USP Bupivacaine Hydrochloride RS in 10.0 mL of water, using sonication if necessary. Add 10 mL of *Internal standard solution*, and dilute with methanol to volume.

  Sample solution: Nominally 0.5 mg/mL of bupivacaine hydrochloride, prepared as follows. In a 100-mL volumetric flask, transfer an amount of Injection equivalent to 50 mg of bupivacaine hydrochloride, add 10.0 mL of *Internal standard solution*, and dilute with methanol to volume.

  Chromatographic system

  (See *Chromatography ⟨621⟩, System Suitability*.)

  Mode: LC

  Detector: UV 263 nm

  Column: ▲3.9-mm▲ (ERR 1-May-2023) × 30-cm; packing L1

  Flow rate: 2 mL/min

  Injection volume: 20 µL

  System suitability

  Sample: *Standard solution*

  [Note—The relative retention times for bupivacaine ▲▲ (ERR 1-May-2023) and dibutyl phthalate are about 1.0 and 1.2, respectively.]

  Suitability requirements

  Resolution: NLT 2.0 between bupivacaine ▲▲ (ERR 1-May-2023) and dibutyl phthalate

  Relative standard deviation: NMT 1.0% for the ▲peak response▲ (ERR 1-May-2023) ratio of bupivacaine to the internal standard from three replicate injections

  Analysis

  Samples: *Standard solution* and *Sample solution*

  Calculate the percentage of the labeled amount of bupivacaine hydrochloride ($C_{18}H_{28}N_2O \cdot HCl$) in the portion of Injection taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

  R_U = peak response ratio of bupivacaine to the internal standard from the *Sample solution*

  R_S = peak response ratio of bupivacaine to the internal standard from the *Standard solution*

  C_S = concentration of USP Bupivacaine Hydrochloride RS, calculated on the anhydrous basis, in the *Standard solution* (mg/mL)

C_U = nominal concentration of bupivacaine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 93.0%–107.0%

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** NMT 2.5 USP Endotoxin Units/mg of bupivacaine hydrochloride
- **pH ⟨791⟩:** 4.0–6.5
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or in multiple-dose containers, preferably of Type I glass. Injection labeled to contain 0.5% or less of bupivacaine hydrochloride may be packaged in 50-mL, multiple-dose containers.
- **USP Reference Standards ⟨11⟩**
  USP Bupivacaine Hydrochloride RS

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

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

Chromatographic Database Information: Chromatographic Database

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