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Mepivacaine Hydrochloride Injection

DEFINITION

Mepivacaine Hydrochloride Injection is a sterile solution of Mepivacaine Hydrochloride in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of mepivacaine hydrochloride ($C_{15}H_{22}N_2O \cdot HCl$).

IDENTIFICATION

- **A. Identification—Organic Nitrogenous Bases ⟨181⟩:** Meets the requirements
- **B.**

Analysis: Extract a volume of Injection, equivalent to 200 mg of mepivacaine, with two 10-mL portions of ether, and discard the ether extracts. Render the remaining solution slightly alkaline with sodium carbonate TS, and extract the precipitate with ether. Evaporate the ether extract on a steam bath to dryness, and dry the residue under vacuum at 60° for 1 h.

Acceptance criteria: The mepivacaine obtained melts between 149° and 153°.

ASSAY

- **Procedure**

Buffer: 3.40 g/L of monobasic potassium phosphate and 4.35 g/L of dibasic potassium phosphate in water. Adjust with potassium hydroxide or phosphoric acid to a pH of 6.3.

Mobile phase: Acetonitrile and *Buffer* (35:65)

System suitability solution: 0.05 mg/mL of methylparaben and 1.0 mg/mL of USP Mepivacaine Hydrochloride RS in *Mobile phase*

Standard solution: 1.0 mg/mL of USP Mepivacaine Hydrochloride RS in *Mobile phase*

Sample solution: Nominally 1 mg/mL of mepivacaine hydrochloride from Injection in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 263 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1[1]

Column temperature: 40°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—The relative retention times for mepivacaine and methylparaben are 1.0 and 1.4, respectively.]

Suitability requirements

Resolution: NLT 2.0 between methylparaben and mepivacaine, *System suitability solution*

Capacity factor: NLT 1.0 for the mepivacaine peak, *System suitability solution*

Tailing factor: NMT 2.0 for the mepivacaine peak, *System suitability solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of mepivacaine hydrochloride ($C_{15}H_{22}N_2O \cdot HCl$) in the volume of Injection taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Mepivacaine Hydrochloride RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

- **pH ⟨791⟩:** 4.5–6.8
- **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 0.8 USP Endotoxin Unit/mg of mepivacaine hydrochloride.
- **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass. Injection labeled to contain 2% or less of mepivacaine hydrochloride may be packaged in 50-mL multiple-dose containers.
- **USP Reference Standards ⟨11⟩**
  USP Mepivacaine Hydrochloride RS

[1] A Whatman Partisphere RTF C18 brand of L1 column has been shown to be an appropriate column.

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

Topic/Question	Contact	Expert Committee
MEPIVACAINE 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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