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Tetracaine Hydrochloride Injection

DEFINITION

Tetracaine Hydrochloride Injection is a sterile solution of Tetracaine Hydrochloride in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$).

IDENTIFICATION

• **A.**

Sample solution: 100 mg in 10 mL of water

Analysis: To the *Sample solution* add 1 mL of potassium thiocyanate solution (1 in 4). A crystalline precipitate is formed. Recrystallize the precipitate from water, and dry at 80° for 2 h.

Acceptance criteria: The crystalline precipitate melts between 130° and 132°.

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

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, methanol, and water (20:20:60) containing 0.06% of sulfuric acid, 0.5% of sodium sulfate, and 0.02% of sodium 1-heptanesulfonate. The pH is about 2.6.

Diluent: Methanol and water (1:1)

Standard solution: 1 mg/mL of USP Tetracaine Hydrochloride RS in *Diluent*

System suitability solution: 4 mg/mL of salicylic acid and 1 mg/mL of tetracaine hydrochloride in *Standard solution*

Sample solution: Nominally 1 mg/mL of tetracaine hydrochloride in *Diluent* from Injection

Chromatographic system

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

Mode: LC

Detector: UV 305 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 2 mL/min

Injection volume: 5 µL

System suitability

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

[Note—The relative retention times for salicylic acid and tetracaine are about 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2 between salicylic acid and tetracaine peaks, *System suitability solution*

Relative standard deviation: NMT 2.0% for replicate injections, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$) in the portion of Injection taken:

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

r_U = peak response of tetracaine from the *Sample solution*

r_S = peak response of tetracaine from the *Standard solution*

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

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

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

- **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.7 USP Endotoxin Units/mg of tetracaine hydrochloride
- **pH ⟨791⟩:** 3.2–6.0
- **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, under refrigeration and protected from light. It may be packaged in 100-mL multiple-dose containers. Injection supplied as a component of spinal anesthesia trays may be stored at room temperature for 12 months.
- **Labeling:** Label it to indicate that the Injection is not to be used if it contains crystals, or if it is cloudy or discolored.
- **USP Reference Standards ⟨11⟩**
  USP Tetracaine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
TETRACAINE 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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