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Tetracaine Hydrochloride for Injection

DEFINITION

Tetracaine Hydrochloride for Injection contains NLT 90.0% and NMT 110.0% of the labeled amount of tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$).

IDENTIFICATION

- **A. Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**

  Sample solution: The *Sample solution* from the *Assay*.

  Acceptance criteria: Meets the requirements

- **B.**

  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°.

ASSAY

- **Procedure**

  Buffer: *Buffer B.6* (see *Antibiotics—Microbial Assays ⟨81⟩, Media and Solutions, Solutions, Buffers*,*Table 12*)

  Diluent: Dilute hydrochloric acid (1 in 200)

  Standard stock solution: 0.2 mg/mL of USP Tetracaine Hydrochloride RS in water

  Standard solution: 0.01 mg/mL of USP Tetracaine Hydrochloride RS prepared as follows. Pipet 5 mL of the *Standard stock solution* into a 100-mL volumetric flask, add 5 mL of *Diluent* and 10 mL of *Buffer*, and dilute with water to volume.

  Sample stock solution: Nominally 0.2 mg/mL of tetracaine hydrochloride in water prepared as follows. Transfer to a tared 20-mL beaker the contents of a sufficient number of containers of Tetracaine Hydrochloride for Injection to yield about 100 mg of tetracaine hydrochloride. Weigh immediately, and transfer with the aid of water to a 500-mL volumetric flask. Dilute with water to volume.

  Sample solution: Nominally 0.01 mg/mL of tetracaine hydrochloride prepared as follows. Transfer 5.0 mL of the *Sample stock solution* to a 100-mL volumetric flask, add 5 mL of *Diluent* and 10 mL of *Buffer*, then dilute with water to volume.

  Instrumental conditions

  Mode: UV

  Analytical wavelength: Maximum absorbance at about 310 nm

  Blank: Water

  Analysis

  Samples: *Standard solution* and *Sample solution*

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

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

  A_U = absorbance of the *Sample solution*

  A_S = absorbance of 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: 90.0%–110.0%

PERFORMANCE TESTS

Change to read:

• **Uniformity of Dosage Units ⟨905⟩:** ▲Meet the requirements▲ (CN 1-Aug-2023)

Procedure for content uniformity

Buffer: *Buffer B.6* (see *Antibiotics—Microbial Assays ⟨81⟩, Media and Solutions, Solutions, Buffers,Table 12*)

Diluent: Dilute hydrochloric acid (1 in 200)

Standard stock solution: 0.2 mg/mL of USP Tetracaine Hydrochloride RS in water

Standard solution: 0.01 mg/mL of USP Tetracaine Hydrochloride RS prepared as follows. Transfer 5 mL of the *Standard stock solution* into a 100-mL volumetric flask, add 5 mL of *Diluent* and 10 mL of *Buffer*, and dilute with water to volume.

Sample stock solution: Transfer the contents of one container, with the aid of water, to a 200-mL volumetric flask, and add water to volume.

Sample solution: Nominally 0.01 mg/mL of tetracaine hydrochloride from the *Sample stock solution* prepared as follows. Pipet a portion of the *Sample stock solution*, equivalent to 1 mg of tetracaine hydrochloride, to a 100-mL volumetric flask, add 5 mL of *Diluent* and 10 mL of *Buffer*, and dilute with water to volume.

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 each container taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

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

▲▲ (CN 1-Aug-2023)

IMPURITIES

• **Residue on Ignition**

Sample: 500 mg

Analysis: Transfer the *Sample* to a beaker, and dissolve in 10 mL of methanol. Filter through paper previously washed with methanol, collecting the filtrate in an ignited and tared crucible, and wash the beaker and the filter paper with 25–30 mL of methanol. Evaporate with the aid of heat and a current of air to dryness, and proceed as directed in *Residue on Ignition ⟨281⟩*, beginning with "Heat gently at a temperature as low as practicable".

Acceptance criteria: NMT 0.1%

• **Organic Impurities**

Standard solution: 0.2 mg/mL of 4-(butylamino) benzoic acid in methanol

Sample solution: 50 mg/mL of Tetracaine Hydrochloride for Injection in water

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Chloroform, methanol, and isopropylamine (98:7:2)

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the chapter. Develop the plate in a suitable chromatographic chamber containing the *Developing solvent system* until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the chamber, and dry in a current of warm air. Examine the plate under short-wavelength UV light.

Acceptance criteria: Any spot from the *Sample solution*, other than the principal spot, is not more intense than the principal spot from the *Standard solution* (0.4%), and the sum of the intensities of any such spots is not greater than 0.8%.

SPECIFIC TESTS

• **pH ⟨791⟩:** 5.0–6.0 in a solution (1 in 100)

- **Water Determination ⟨921⟩, *Method I*:** NMT 2.0%
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.7 USP Endotoxin Units/mg of tetracaine hydrochloride
- **Completeness of Solution ⟨641⟩**

  Sample: Nominally 10 mg of tetracaine hydrochloride

  Acceptance criteria: The *Sample* dissolves in 1 mL of water in NMT 2 s to yield a colorless solution free from undissolved solid.
- **Constituted Solution:** At the time of use, it meets the requirements in *Injections and Implanted Drug Products, ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.
- **Sterility Tests ⟨71⟩:** Meets the requirements
- **Other Requirements:** It meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*, preferably Type I glass.
- **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 FOR 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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

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