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Tetracaine Hydrochloride in Dextrose Injection

DEFINITION

Tetracaine Hydrochloride in Dextrose Injection is a sterile solution of Tetracaine Hydrochloride and Dextrose in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amounts of tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$) and dextrose ($C_6H_{12}O_6$).

IDENTIFICATION

Change to read:

- **A.** ▲**Spectroscopic Identification Tests ⟨197⟩, *Ultraviolet-Visible Spectroscopy*: 197U**▲ (CN 1-May-2020)
- **B.** **Identification Tests—General ⟨191⟩, *Chloride***

  Sample solution: 100 mg in 5 mL of water

  Acceptance criteria: Meets the requirements
- **C.**

  Sample solution: Nominally 50 mg/mL of dextrose from Injection

  Analysis: Add a few drops of the *Sample solution* to 5 mL of hot alkaline cupric tartrate TS.

  Acceptance criteria: A copious red precipitate of cuprous oxide is formed.

ASSAY

- **Tetracaine Hydrochloride**

  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 from Injection prepared as follows. Transfer a volume of Injection, equivalent to 10 mg of tetracaine hydrochloride, to a separator. Dilute with water to about 50 mL, and render alkaline by the addition of 5 mL of sodium carbonate TS. Extract immediately with two 50-mL portions of ether, collecting the extracts in a separator. Wash the ether extracts with 20 mL of water, discarding the wash solution, and extract the ether solution with two 20-mL portions and one 5-mL portion of *Diluent*, collecting the extracts in a 50-mL volumetric flask. Dilute with water to volume.

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

  Instrumental conditions

  Mode: UV

  Analytical wavelength: Maximum absorbance at about 310 nm

  Blank: Water

  Analysis

  Samples: *Standard solution*, *Sample solution*, and *Blank*

  Calculate the percentage of labeled amount of tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$) in the portion of 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: 95.0%–105.0%

• **Dextrose**

Sample: Injection

Analysis: Determine the angular rotation of the Injection in a suitable polarimeter tube (see *Optical Rotation* ⟨781⟩).

Calculate the percentage of the labeled amount of dextrose ($C_6H_{12}O_6$) in the portion of Injection taken:

$$\text{Result} = [(100 \times a)/(l \times \alpha)] \times (1/C_U) \times 100$$

a = observed angular rotation of the Injection (°)

l = length of the polarimeter tube (dm)

α = midpoint of the specific rotation range for anhydrous dextrose, 52.9°

C_U = nominal concentration of dextrose in the *Sample* (g/100 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⟩**:** It contains NMT 1.0 USP Endotoxin Unit/mg of tetracaine hydrochloride.

• **pH** ⟨791⟩**:** 3.5–6.0

• **Other Requirements:** It meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or 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 IN DEXTROSE 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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