

Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-BC556ECF-16CC-4EB1-83A2-9B9D48489D71_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M81658_04_01
 DOI Ref: v0746

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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](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 30(5)

Current DocID: GUID-BC556ECF-16CC-4EB1-83A2-9B9D48489D71_4_en-US

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