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Tetracaine Hydrochloride Topical Solution

» Tetracaine Hydrochloride Topical Solution is an aqueous solution of Tetracaine Hydrochloride. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_{15}H_{24}N_2O_2 \cdot HCl$. It contains a suitable antimicrobial agent.

Packaging and storage—Preserve in tight, light-resistant containers.

Labeling—Label it to indicate that the Topical Solution is not to be used if it contains crystals, or if it is cloudy or discolored.

USP REFERENCE STANDARDS (11).—
[USP Tetracaine Hydrochloride RS](#)

Identification—

Change to read:

A: ▲[Spectroscopic Identification Tests \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-May-2020) —

Solutions: solutions of the Topical Solution employed for measurement of absorbance in the Assay.

B: It responds to the tests for [Chloride \(191\)](#).

pH (791): between 4.5 and 6.0.

Assay—

Standard preparation—Prepare as directed in the Assay under [Tetracaine Hydrochloride in Dextrose Injection](#).

Assay preparation—Using an accurately measured volume of Topical Solution, prepare as directed in the Assay under *Tetracaine Hydrochloride in Dextrose Injection*.

Procedure—Proceed as directed for *Procedure* in the Assay under *Tetracaine Hydrochloride in Dextrose Injection*. Calculate the quantity, in mg, of $C_{15}H_{24}N_2O_2 \cdot HCl$ in the volume of Topical Solution taken by the formula:

$$C(A_U/A_S)$$

in which *C* is the concentration, in µg per mL, of [USP Tetracaine Hydrochloride RS](#) in the *Standard preparation*, and *A_U* and *A_S* are the absorbances of the *Assay preparation* and the *Standard preparation*, respectively.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
TETRACAINE HYDROCHLORIDE TOPICAL SOLUTION	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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