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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
TETRACAIN 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](#)

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