

Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-5BC13493-2A79-4BF8-818B-A9F9245AC5D9_2_en-US
DOI: https://doi.org/10.31003/USPNF_M81610_02_01
DOI Ref: r95bk

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Tetracaine Hydrochloride Cream

» Tetracaine Hydrochloride Cream contains Tetracaine Hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$) equivalent to not less than 90.0 percent and not more than 110.0 percent of the labeled amount of tetracaine ($C_{15}H_{24}N_2O_2$) in a suitable water-miscible base.

Packaging and storage—Preserve in collapsible, lined metal tubes.

USP REFERENCE STANDARDS (11)—

[USP Tetracaine Hydrochloride RS](#)

Change to read:

Identification, [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U](#) [▲ \(CN 1-May-2020\)](#) : Assay preparation compared to the Standard preparation from the Assay.

MICROBIAL ENUMERATION TESTS (61) and **TESTS FOR SPECIFIED MICROORGANISMS (62)**—It meets the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

MINIMUM FILL (755): meets the requirements.

pH (791): between 3.2 and 3.8.

Assay—

pH 6 Acetate buffer—Dissolve 250 g of sodium acetate in about 500 mL of water in a 1000-mL volumetric flask, add 5.0 mL of glacial acetic acid, dilute with water to volume, and mix.

Standard preparation—Transfer about 25 mg of [USP Tetracaine Hydrochloride RS](#), accurately weighed, to a 100-mL volumetric flask, dissolve in isopropyl alcohol, add isopropyl alcohol to volume, and mix. Transfer 2.0 mL of this solution to another 100-mL volumetric flask, add 2.0 mL of **pH 6 Acetate buffer**, dilute with isopropyl alcohol to volume, and mix. The concentration of [USP Tetracaine Hydrochloride RS](#) in the **Standard preparation** is about 5 μ g per mL.

Assay preparation—Transfer an accurately weighed portion of Cream, equivalent to about 4.5 mg of tetracaine, to a 50-mL beaker, add 25 mL of isopropyl alcohol, and warm on a steam bath to dissolve the specimen completely. Transfer the solution with the aid of isopropyl alcohol to a 100-mL volumetric flask, dilute with isopropyl alcohol to volume, and mix. Transfer 10.0 mL of this solution to another 100-mL volumetric flask, add 2.0 mL of **pH 6 Acetate buffer**, dilute with isopropyl alcohol to volume, and mix.

Procedure—Concomitantly determine the absorbances of the **Assay preparation** and the **Standard preparation** in 1-cm cells at the wavelength of maximum absorbance at about 310 nm, with a suitable spectrophotometer, using a 1 in 50 solution of **pH 6 Acetate buffer** in isopropyl alcohol as the blank. Calculate the quantity, in mg, of $C_{15}H_{24}N_2O_2$ in the portion of Cream taken by the formula:

$$(264.36/300.82)(C)(A_u/A_s)$$

in which 264.36 and 300.82 are the molecular weights of tetracaine and tetracaine hydrochloride, respectively; C is the concentration, in μ g 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 CREAM	Documentary Standards Support	SM52020 Small Molecules 5
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM52020 Small Molecules 5

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. Information currently unavailable

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