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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 µg 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 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 CREAM	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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