Status: Currently Official on 16-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-C1548345-A3D7-4CFE-A0D2-ECC672149E54_1_en-US
DOI: https://doi.org/10.31003/USPNF_M81560_01_01
DOI Ref: y3k65

Tetracaine Ointment

» Tetracaine Ointment contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{15}H_{24}N_2O_2$ in a suitable ointment base.

Packaging and storage—Preserve in collapsible ointment tubes.

USP Reference standards ⟨11⟩—
USP Tetracaine Hydrochloride RS

Identification—

A: The solution employed for measurement of absorbance in the *Assay* exhibits a maximum at 310 ± 2 nm.

B: Dissolve 5 g in 50 mL of ether, extract the ether solution with 5 mL of 3 N hydrochloric acid, and filter the acid extract. Add 2 mL of potassium thiocyanate solution (1 in 2) to the filtrate: a crystalline precipitate is formed, and when recrystallized from water and dried at 80° for 2 hours, it melts between 130° and 132° (see *Melting Range or Temperature ⟨741⟩*).

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.

Assay—

Standard preparation—Transfer about 20 mg of USP Tetracaine Hydrochloride RS, accurately weighed, to a 100-mL volumetric flask, dissolve in water, add water to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, add 5 mL of dilute hydrochloric acid (1 in 240) and 10 mL of *Buffer B.6* (see *Antibiotics—Microbial Assays ⟨81⟩, Media and Solutions, Solutions, Buffers*) dilute with water to volume, and mix. The concentration of USP Tetracaine Hydrochloride RS in the *Standard preparation* is about 10 µg per mL.

Assay preparation—Transfer an accurately weighed portion of Ointment, equivalent to about 9 mg of tetracaine, to a separator, and dissolve in 15 mL of ether. Extract with one 20-mL portion and two 10-mL portions of dilute hydrochloric acid (1 in 240), collecting the acid extracts in a second separator. Render the aqueous solution alkaline by the addition of 5 mL of sodium carbonate TS, and extract immediately with two 50-mL portions of ether, collecting the ether extracts in another separator. Wash the ether solution with 20 mL of water, discard the washing, and extract the ether solution with two 20-mL portions and one 5-mL portion of dilute hydrochloric acid (1 in 240), collecting the acid extracts in a 50-mL volumetric flask. Dilute with water to volume, and mix. Transfer 5.0 mL of this solution to a 100-mL volumetric flask, add 10 mL of *Buffer B.6* (see *Antibiotics—Microbial Assays ⟨81⟩, Media and Solutions, Solutions, Buffers*) dilute with water 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 water as the blank. Calculate the quantity, in mg, of $C_{15}H_{24}N_2O_2$ in the portion of Ointment 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 OINTMENT	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

Current DocID: GUID-C1548345-A3D7-4CFE-A0D2-ECC672149E54_1_en-US

DOI: https://doi.org/10.31003/USPNF_M81560_01_01

DOI ref: y3k65