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Tetracaine and Menthol Ointment

» Tetracaine and Menthol Ointment contains not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of tetracaine ($C_{15}H_{24}N_2O_2$) and menthol ($C_{10}H_{20}O$) in a suitable ointment base.

Packaging and storage—Preserve in collapsible ointment tubes.

USP REFERENCE STANDARDS (11)—

[USP Menthol RS](#)

[USP Tetracaine Hydrochloride RS](#)

Identification—

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

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 \(741\)](#)) (presence of tetracaine).

C: When chromatographed as directed in the *Assay for menthol*, the *Assay preparation* exhibits a major peak for menthol, the retention time of which corresponds to that exhibited by menthol in the *Standard preparation*.

MINIMUM FILL (755): meets the requirements.

Assay for tetracaine—

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

Assay preparation—Using Ointment, proceed as directed in the [Assay](#) under [Tetracaine Ointment](#).

Procedure—Proceed as directed for *Procedure* in the [Assay](#) under [Tetracaine Ointment](#).

Assay for menthol—

Internal standard solution—Dissolve decanol in *n*-hexane to obtain a solution having a concentration of about 1 mg per mL.

Standard preparation—Dissolve an accurately weighed quantity of [USP Menthol RS](#) in *n*-hexane to obtain a solution having a known concentration of about 1 mg per mL. Transfer 5.0 mL of this solution and 5.0 mL of *Internal standard solution* to a 50-mL volumetric flask, dilute with ether to volume, and mix. Combine 2.0 mL of this solution and 2.0 mL of ether in a suitable container, and mix. This *Standard preparation* has a known concentration of about 0.05 mg per mL.

Assay preparation—Transfer an accurately weighed quantity of Ointment, equivalent to about 5 mg of menthol, to a 50-mL volumetric flask, add 5.0 mL of *Internal standard solution*, dilute with *n*-hexane to volume, mix, and sonicate. Using a suitable syringe attached firmly to a 25- x 12.5-mm chromatographic cartridge containing packing L4, force 2.0 mL of the solution through the cartridge at a rate of 1 mL per 12 seconds. Wash the cartridge at the same rate with two 5-mL portions of *n*-hexane, and discard the washings. Force two 2.0-mL portions of ether through the cartridge, combine the ether eluates in a suitable container, and mix.

Chromatographic system (see [Chromatography \(621\)](#))—The gas chromatograph is equipped with a flame-ionization detector and contains a 2-mm x 1.8-m column packed with 10% phase G16 on support S1AB. The column temperature is maintained isothermally at about 170° , the injection port temperature is maintained at about 260° , and the detector block temperature is maintained at about 240° . Dry helium is used as the carrier gas at a flow rate of about 50 mL per minute.

System suitability—Chromatograph three injections of the *Standard preparation*, and record the peak responses as directed for *Procedure*: the retention time of menthol is about 0.7 relative to decanol; the resolution, R , between the 2 peaks is not less than 2.5; and the relative standard deviation of the ratio of the peak response obtained with menthol to that obtained with decanol is not more than 2%.

Procedure—Separately inject equal volumes (about 2 μ L) of the *Assay preparation* and the *Standard preparation* into the gas chromatograph, and measure the peak responses for menthol and decanol in each chromatogram. Calculate the quantity, in mg, of $C_{10}H_{20}O$ in the portion of Ointment taken by the formula:

$$100C(R_u/R_s)$$

in which C is the concentration, in mg per mL, of [USP Menthol RS](#) in the *Standard preparation*; and R_u and R_s are the peak response ratios of menthol to decanol obtained from 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 AND MENTHOL 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

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