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Dibucaine Ointment

» Dibucaine Ointment contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of dibucaine ($C_{20}H_{29}N_3O_2$) in a suitable ointment base.

Packaging and storage—Preserve in collapsible tubes or in tight, light-resistant containers.

USP REFERENCE STANDARDS (11).—
[USP Dibucaine Hydrochloride RS](#)

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in 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.

Assay—

Mobile phase and Chromatographic system—Proceed as directed in the Assay under [Dibucaine](#).
Standard preparation—Transfer about 55 mg of [USP Dibucaine Hydrochloride RS](#), accurately weighed, to a 50-mL volumetric flask, add 24.0 mL of 0.1 N hydrochloric acid, and swirl to dissolve. Dilute with a mixture of methanol and 1.0 N hydrochloric acid (13:12) to volume, and mix. Transfer 10.0 mL of this solution to a 50-mL volumetric flask, dilute with methanol to volume, and mix. Pass through a suitable filter having a 0.5-μm or finer porosity.
Assay preparation—Weigh accurately a portion of Ointment, equivalent to about 50 mg of dibucaine, transfer to a separator containing 50 mL of ether, and mix to dissolve. Extract successively with 50-mL, 40-mL, and 30-mL portions of 0.1 N hydrochloric acid, combining the extracts in a 250-mL volumetric flask. Dilute with methanol to volume, and mix. Pass through a suitable filter having a 0.5-μm or finer porosity.
Procedure—Separately inject equal volumes (about 10 μL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the area responses for the major peaks. Calculate the quantity, in mg, of dibucaine ($C_{20}H_{29}N_3O_2$) in the portion of Ointment taken by the formula:

$$(343.46/379.93)(250C)(r_U/r_S)$$

in which 343.46 and 379.93 are the molecular weights of dibucaine and dibucaine hydrochloride, respectively; C is the concentration, in mg per mL, of [USP Dibucaine Hydrochloride RS](#) in the *Standard preparation*; and r_U and r_S are the area responses of the dibucaine peaks 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
DIBUCAINE OINTMENT	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: [Chromatographic Database](#)

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