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Dibucaine Cream

» Dibucaine Cream 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 cream 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—Dissolve an accurately weighed quantity of USP Dibucaine Hydrochloride RS in an amount of 0.1 N hydrochloric acid equivalent to 20% of the flask's volume, and dilute quantitatively, and stepwise if necessary, with methanol to obtain a solution having a known concentration of about 0.25 mg per mL.

Assay preparation—Weigh accurately a portion of Cream, equivalent to about 22 mg of dibucaine, transfer to a separator containing 25 mL of ether, and mix to dissolve. Extract successively with two 9-mL portions of 0.1 N hydrochloric acid, combining the extracts in a 100-mL volumetric flask. Extract the ether phase in the separator with 2 mL of water, collecting the aqueous extract in the 100-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 20 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 Cream taken by the formula:

$$(343.46/379.93)(100C)(r_U/r_S)$$

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 CREAM	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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