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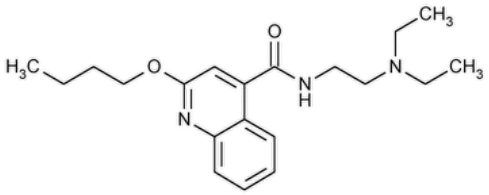
Dibucaine



$C_{20}H_{29}N_3O_2$ 343.46

4-Quinolinecarboxamide, 2-butoxy-*N*-[2-(diethylamino)ethyl]-.

2-Butoxy-*N*-[2-(diethylamino)ethyl]cinchoninamide CAS RN®: 85-79-0; UNII: L6JW2TJG99.

» Dibucaine contains not less than 97.0 percent and not more than 102.5 percent of $C_{20}H_{29}N_3O_2$, calculated on the dried basis.

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

USP Reference standards ⟨11⟩—
USP Dibucaine Hydrochloride RS

Identification—

A: The IR absorption spectrum of a mineral oil dispersion of it, previously dried, exhibits maxima only at the same wavelengths as that of a similar dispersion of the residue prepared by dissolving 30 mg of USP Dibucaine Hydrochloride RS in 5 mL of 0.5 N sodium hydroxide, extracting the resulting solution with 5 mL of ether, evaporating the ether, and drying the residue over phosphorus pentoxide.

B: 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*.

Melting range ⟨741⟩**:** between 62.5° and 66.0°, determined after drying.

Loss on drying ⟨731⟩—Dry it over phosphorus pentoxide for 16 hours: it loses not more than 1.0% of its weight.

Residue on ignition ⟨281⟩**:** not more than 0.2%.

Change to read:

Chromatographic purity—Proceed as directed for ▲*Organic Impurities*▲ (ERR 1-Jan-2025) under *Dibucaine Hydrochloride*, except to use a *Test solution* containing 36.2 mg of Dibucaine per mL: the principal spot obtained from the *Test solution* corresponds in R_F value, color, and intensity to that obtained from the *Standard solution;* the sum of the intensities of any secondary spots, if present in the chromatogram of the *Test solution*, corresponds to not more than 2.0% of that of the principal spot in the chromatogram of the *Standard solution* on the basis of comparison with the spots obtained from the *Comparison solutions.*

Assay—

Mobile phase—Dissolve 1.20 g of sodium lauryl sulfate, 0.20 g of sodium acetate, and 2.0 mL of triethylamine in 300 mL of water. Adjust with glacial acetic acid to a pH of 5.6, add 700 mL of methanol, mix, and pass through a suitable filter having a 0.5-µm or finer porosity. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Solvent mixture—Prepare a mixture of methanol and water (70:30).

Standard preparation—Dissolve an accurately weighed quantity of USP Dibucaine Hydrochloride RS in *Solvent mixture* to obtain a solution having a known concentration of about 1 mg per mL. Pass through a suitable filter having a 0.5-µm or finer porosity.

Assay preparation—Transfer about 90 mg of Dibucaine, accurately weighed, to a 100-mL volumetric flask, add *Solvent mixture* to volume, and mix. Pass through a suitable filter having a 0.5-µm or finer porosity.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a 254-nm detector and a 3.9-mm × 30-cm column that contains packing L1. The flow rate is about 1.5 mL per minute. Chromatograph the *Standard preparation*, and record the peak responses as directed for *Procedure:* the column efficiency, determined from the analyte peak, is not less than 1500 theoretical plates; the tailing factor for the analyte peak is not more than 3.0; and the relative standard deviation for replicate injections is not more than 2%.

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 $C_{20}H_{29}N_3O_2$ in the portion of Dibucaine 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

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per mL, of USP Dibucaine Hydrochloride RS in the *Standard preparation;* and r_U and r_S are the 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	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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