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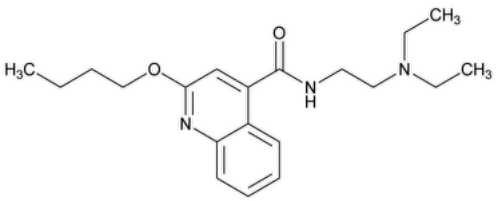
Dibucaine Hydrochloride



• HCl

$C_{20}H_{29}N_3O_2 \cdot HCl$ 379.92

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

2-Butoxy-*N*-[2-(diethylamino)ethyl]cinchoninamide monohydrochloride CAS RN®: 61-12-1.

DEFINITION

Dibucaine Hydrochloride contains NLT 97.0% and NMT 100.5% of dibucaine hydrochloride ($C_{20}H_{29}N_3O_2 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197M

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

Change to read:

• **C. Identification Tests—General ⟨191⟩, *Chemical Identification Tests, Chloride*:** ▲Meets the requirements when tested as specified for amine hydrochlorides▲ (USP 1-May-2021)

ASSAY

Change to read:

• **Procedure**

Mobile phase: Dissolve 1.20 g of sodium dodecyl 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 filter of 0.5-µm or finer pore size.

Diluent: Methanol and water (70:30)

Standard solution: 1 mg/mL of USP Dibucaine Hydrochloride RS in *Diluent*. Pass through a filter of 0.5-µm or finer pore size.

Sample solution: 1 mg/mL of Dibucaine Hydrochloride in *Diluent*. Pass through a filter of 0.5-µm or finer pore size.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; ▲10-µm▲ (USP 1-May-2021) packing L1

Flow rate: 1.5 mL/min

Injection volume: 10 µL

▲**Run time:** NLT 2.5 times the retention time of dibucaine▲ (USP 1-May-2021)

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1500 theoretical plates

Tailing factor: NMT 3.0

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of dibucaine hydrochloride ($C_{20}H_{29}N_3O_2 \cdot HCl$) in the portion of Dibucaine Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of dibucaine from the *Sample solution*

r_S = peak response of dibucaine from the *Standard solution*

C_S = concentration of USP Dibucaine Hydrochloride RS in the *Standard solution* (mg/mL)

C_U = concentration of Dibucaine Hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 97.0%–100.5% on the dried basis

IMPURITIES

• **Residue on Ignition ⟨281⟩:** NMT 0.1%

Change to read:

• **Organic Impurities**

Standard solution: 40 mg/mL of USP Dibucaine Hydrochloride RS in chloroform

Sample solution: ▲40▲ (USP 1-May-2021) mg/mL of Dibucaine Hydrochloride in chloroform

Comparison solution A: 40 µg/mL of USP Dibucaine Hydrochloride RS from the *Standard solution* in chloroform (0.1%)

Comparison solution B: 120 µg/mL of USP Dibucaine Hydrochloride RS from the *Standard solution* in chloroform (0.3%)

Comparison solution C: 200 µg/mL of USP Dibucaine Hydrochloride RS from the *Standard solution* in chloroform (0.5%)

Chromatographic system

(See *Chromatography ⟨621⟩, ▲General Procedures, Thin-Layer Chromatography.*▲ (USP 1-May-2021))

Mode: TLC

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 5 µL

Developing solvent system: Toluene, acetone, methanol, and ammonium hydroxide (50:30:5:1)

Spray reagent: 5 mg/mL of potassium dichromate in ▲7 N sulfuric acid TS▲ (USP 1-May-2021)

Analysis

Samples: *Standard solution*, *Sample solution*, and each *Comparison solution*

Proceed as directed in the general chapter. Develop the chromatogram in the *Developing solvent system* until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the chamber, mark the solvent front, and air-dry. Spray the plate heavily with *Spray reagent*. Place the plate in an oven at 140° for 10 min, and view under short-wavelength UV light.

Acceptance criteria: The principal spot from the *Sample solution* corresponds in R_F value, color, and intensity to that from the *Standard solution*; the sum of the intensities of any secondary spots, if present in the *Sample solution*, is NMT 1.0%, and the intensity of any secondary spot does not exceed 0.5% of that of the principal spot from the *Standard solution* on the basis of comparison with the spots from each *Comparison solution*.

SPECIFIC TESTS

• **Loss on Drying ⟨731⟩**

Analysis: Dry at 80° for 5 h.

Acceptance criteria: NMT 2.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Dibucaine Hydrochloride RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
DIBUCAINE HYDROCHLORIDE	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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