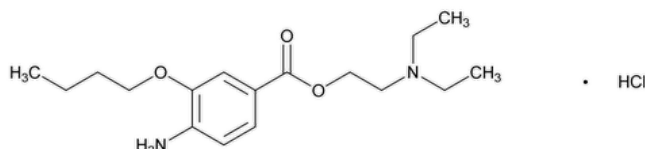


Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-B4C90430-ED27-49F2-B492-04FF36F612EA_2_en-US
DOI: https://doi.org/10.31003/USPNF_M7600_02_01
DOI Ref: v8lss

© 2025 USPC
Do not distribute

Benoxinate Hydrochloride



$C_{17}H_{28}N_2O_3 \cdot HCl$ 344.88

Benzoic acid, 4-amino-3-butoxy-, 2-(diethylamino)ethyl ester, monohydrochloride;

2-(Diethylamino)ethyl 4-amino-3-butoxybenzoate monohydrochloride CAS RN[®]: 5987-82-6; UNII: 0VE4U49K15.

DEFINITION

Benoxinate Hydrochloride contains NLT 98.5% and NMT 101.5% of benoxinate hydrochloride ($C_{17}H_{28}N_2O_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)

Sample: Previously dried

Acceptance criteria: Meets the requirements

Change to read:

- **B.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Ultraviolet-Visible Spectroscopy: 197U](#) ▲ (CN 1-MAY-2020)

Sample solution: 15 µg/mL in water

Acceptance criteria: Meets the requirements

- **C.** [IDENTIFICATION TESTS—GENERAL, Chloride \(191\)](#)

Sample solution: 10 mg/mL

Acceptance criteria: Meets the requirements

ASSAY

PROCEDURE

Sample solution: Dissolve 250 mg of Benoxinate Hydrochloride in a mixture of 20 mL of glacial acetic acid and 20 mL of acetic anhydride.

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Potentiometric

Analysis: Titrate, perform a blank determination, and make any necessary correction. Each mL of 0.1 N perchloric acid is equivalent to 34.49 mg of benoxinate hydrochloride ($C_{17}H_{28}N_2O_3 \cdot HCl$).

Acceptance criteria: 98.5%–101.5% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

- [ORDINARY IMPURITIES \(466\)](#)

Standard solution: Methanol

Sample solution: Methanol

Eluant: A mixture of chloroform, cyclohexane, and diethylamine (5:4:1)

Visualization: 12

SPECIFIC TESTS

- [pH \(791\)](#)

Sample solution: 10 mg/mL

Acceptance criteria: 5.0–6.0

- [LOSS ON DRYING \(731\)](#)

Analysis: Dry a sample at 105° for 3 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.
- **USP REFERENCE STANDARDS (11).**
[USP Benoxinate Hydrochloride RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
BENOXINATE HYDROCHLORIDE	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

Current DocID: GUID-B4C90430-ED27-49F2-B492-04FF36F612EA_2_en-US

DOI: https://doi.org/10.31003/USPNF_M7600_02_01

DOI ref: [v8lss](#)

OFFICIAL