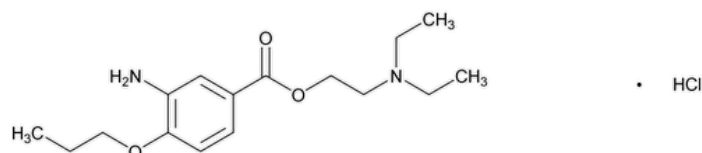


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Proparacaine Hydrochloride



$C_{16}H_{26}N_2O_3 \cdot HCl$ 330.85

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

2-(Diethylamino)ethyl 3-amino-4-propoxybenzoate monohydrochloride CAS RN[®]: 5875-06-9.

DEFINITION

Proparacaine Hydrochloride contains NLT 97.0% and NMT 103.0% of proparacaine hydrochloride ($C_{16}H_{26}N_2O_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

• **A. IDENTIFICATION—ORGANIC NITROGENOUS BASES (181):** Meets the requirements

• **B. ULTRAVIOLET ABSORPTION**

Buffer: Prepare as directed for pH 6.0 phosphate buffer (see [Reagents, Indicators, and Solutions—Solutions, Buffer Solutions](#)). Dilute with [water](#) to prepare a 10% solution.

Analytical wavelength: 310 nm

Sample stock solution: 0.2 mg/mL of Proparacaine Hydrochloride

Sample solution: 0.02 mg/mL of Proparacaine Hydrochloride prepared as follows. To a volume of the *Sample stock solution* equivalent to 10% of the flask volume, add 2% of the flask volume of *Buffer*, and dilute with [water](#) to volume.

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as those of a similarly prepared solution of [USP Proparacaine Hydrochloride RS](#), concomitantly measured, and the respective absorptivities, calculated on the dried basis, do not differ by more than 3.0%.

Change to read:

• **C. IDENTIFICATION TESTS—GENERAL (191), [Chemical Identification Tests, Chloride](#)**

Sample solution: 20 mg/mL of Proparacaine Hydrochloride

Analysis: Proceed as directed in the chapter using the procedure for ▲amine hydrochlorides.▲ (USP 1-May-2021)

Acceptance criteria: Meets the requirements

ASSAY

• **PROCEDURE**

Sample solution: Transfer 250 mg of Proparacaine Hydrochloride to a 250-mL conical flask. Add 80 mL of a 1-in-20 solution of [acetic anhydride](#) in [glacial acetic acid](#), and heat on a steam bath for 10 min. Cool to room temperature, and add 10 mL of [mercuric acetate TS](#).

Titrimetric system

Mode: Direct titration

Titrant: 0.1 N perchloric acid VS

Endpoint detection: Visual

Analysis: Titrate with *Titrant* to a blue-green endpoint using 1 or 2 drops of [crystal violet TS](#) as the indicator. Perform a blank determination, and make any necessary correction. Each milliliter of 0.1 N perchloric acid is equivalent to 33.09 mg of proparacaine hydrochloride ($C_{16}H_{26}N_2O_3 \cdot HCl$).

Acceptance criteria: 97.0%–103.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.15%
- [ORDINARY IMPURITIES \(466\)](#)

Standard solution: [Methanol](#)

Sample solution: [Methanol](#)

Eluant: [Butyl alcohol](#), [glacial acetic acid](#), and [water](#) (5:1:3)

Visualization: 1; 17

Acceptance criteria: Meets the requirements

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE \(741\)](#): 178°–185°, but the range between beginning and end of melting does not exceed 2°
- [LOSS ON DRYING \(731\)](#)

Analysis: Dry at 105° for 3 h.

Acceptance criteria: NMT 0.5%

ADDITIONAL REQUIREMENTS

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

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

Topic/Question	Contact	Expert Committee
PROPARACAINE 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](#)

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