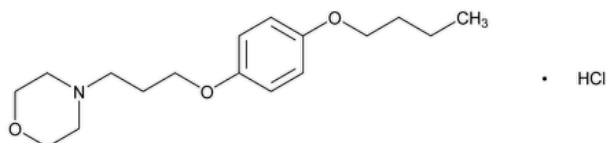


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Pramoxine Hydrochloride



$C_{17}H_{27}NO_3 \cdot HCl$ 329.86
 Morpholine, 4-[3-(4-butoxyphenoxy)propyl]-, hydrochloride;
 4-[3-(*p*-Butoxyphenoxy)propyl]morpholine hydrochloride CAS RN[®]: 637-58-1; UNII: 88AYB867L5.

DEFINITION

Pramoxine Hydrochloride contains NLT 98.0% and NMT 102.0% of pramoxine hydrochloride ($C_{17}H_{27}NO_3 \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.
- **C.** [IDENTIFICATION TESTS—GENERAL, Chloride\(191\)](#): Meets the requirements

ASSAY

• PROCEDURE

Buffer: Dissolve 8.71 g of dibasic potassium phosphate in about 800 mL of water, adjust with dilute phosphoric acid (1 in 10) to a pH of 7.5 ± 0.1 , and add water to make 1000 mL.

Mobile phase: Acetonitrile and *Buffer* (55:45)

Standard solution: 0.5 mg/mL of [USP Pramoxine Hydrochloride RS](#) in *Mobile phase*

Sample solution: 0.5 mg/mL of Pramoxine Hydrochloride in *Mobile phase*

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 224 nm

Column: 4.6-mm $\times$ 25-cm; packing L1

Column temperature: 40°

Flow rate: 2 mL/min

Injection volume: 20 μ L

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1500 theoretical plates

Tailing factor: NMT 1.5

Relative standard deviation: NMT 1.5%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of pramoxine hydrochloride ($C_{17}H_{27}NO_3 \cdot HCl$) in the portion of Pramoxine Hydrochloride taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Pramoxine Hydrochloride RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the dried basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

SPECIFIC TESTS

- [MELTING RANGE OR TEMPERATURE \(741\)](#): 170°–174°
- [Loss on Drying \(731\)](#)

Analysis: Dry at 105° for 1 h.

Acceptance criteria: NMT 1.0%

ADDITIONAL REQUIREMENTS

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

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

Topic/Question	Contact	Expert Committee
PRAMOXINE 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:

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