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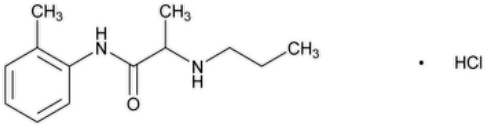
Prilocaine Hydrochloride



$C_{13}H_{20}N_2O \cdot HCl$ 256.77

Propanamide, *N*-(2-methylphenyl)-2-(propylamino)-, monohydrochloride;

2-(Propylamino)-*o*-propionotoluidide monohydrochloride CAS RN®: 1786-81-8; UNII: MJW015BAPH.

DEFINITION

Prilocaine Hydrochloride contains NLT 98.0% and NMT 102.0% of prilocaine hydrochloride ($C_{13}H_{20}N_2O \cdot HCl$), calculated on the dried basis.

IDENTIFICATION

Change to read:

- **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)
- **B.** Identification Tests—General, *Chloride* ⟨191⟩

  Analysis: Dissolve 100 mg in 3 mL of water, render the solution alkaline with 6 N ammonium hydroxide, and filter.

  Acceptance criteria: The filtrate meets the requirements.
- **C.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution,* as obtained in the *Assay.*

ASSAY

- **Procedure**

Buffer: 0.18 g/L of monobasic sodium phosphate and 2.89 g/L of dibasic sodium phosphate dihydrate in water

Mobile phase: Acetonitrile and *Buffer* (26:74)

System suitability solution: 3 µg/mL each of USP Prilocaine Hydrochloride RS and USP Prilocaine Related Compound B RS in *Mobile phase*

Standard solution: 0.3 mg/mL of USP Prilocaine Hydrochloride RS in *Mobile phase*

Sample solution: 0.3 mg/mL of Prilocaine Hydrochloride in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 240 nm

Column: 4.6-mm × 15-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[Note—See *Table 1* for the relative retention times.]

Suitability requirements

Resolution: NLT 3.0 between prilocaine and prilocaine related compound B, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 0.73, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of prilocaine hydrochloride ($C_{13}H_{20}N_2O \cdot HCl$) in the portion of Prilocaine Hydrochloride taken:

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

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

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

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

C_U = concentration of Prilocaine 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%
- **Organic Impurities**

Buffer, Mobile phase, System suitability solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution 1: 3 µg/mL of USP Prilocaine Hydrochloride RS in *Mobile phase*

Standard solution 2: 0.4 µg/mL of USP Prilocaine Related Compound A RS in *Mobile phase*

Sample solution: 3 mg/mL of Prilocaine Hydrochloride in *Mobile phase*

System suitability

Samples: *System suitability solution* and *Standard solution 2*

[Note—See *Table 1* for the relative retention times.]

Suitability requirements

Resolution: NLT 3.0 between prilocaine and prilocaine related compound B, *System suitability solution*

Signal-to-noise ratio: NLT 10 for prilocaine related compound A, *Standard solution 2*

Analysis

Samples: *Standard solution 1*, *Standard solution 2*, and *Sample solution*

Calculate the percentage of prilocaine related compound A in the portion of Prilocaine Hydrochloride taken:

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

r_U = peak response of prilocaine related compound A from the *Sample solution*

r_S = peak response of prilocaine related compound A from *Standard solution 2*

C_S = concentration of USP Prilocaine Related Compound A RS in *Standard solution 2* (mg/mL)

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

Calculate the percentage of any individual unspecified impurity in the portion of Prilocaine Hydrochloride taken:

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

r_U = peak response of any unspecified impurity from the *Sample solution*

r_S = peak response of prilocaine from *Standard solution 1*

C_S = concentration of USP Prilocaine Hydrochloride RS in *Standard solution 1* (mg/mL)

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

Acceptance criteria: See *Table 1*. The reporting level for impurities is 0.05%.

Table 1

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Prilocaine related compound A	0.3	0.01
Prilocaine	1.0	—

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Prilocaine related compound B	1.2	—
Any individual unspecified impurity	—	0.10
Total impurities	—	0.2

SPECIFIC TESTS

• **Loss on Drying** ⟨731⟩

Analysis: Dry a sample at 105° for 4 h.

Acceptance criteria: NMT 0.3%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in well-closed containers. Store at room temperature.

• **USP Reference Standards** ⟨11⟩

USP Prilocaine Hydrochloride RS

USP Prilocaine Related Compound A RS

o-Toluidine hydrochloride.

$C_7H_9N \cdot HCl$ 143.62

USP Prilocaine Related Compound B RS

(*RS*)-*N*-(4-Methylphenyl)-2-(propylamino)propanamide.

$C_{13}H_{20}N_2O$ 220.31

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

Topic/Question	Contact	Expert Committee
PRILOCAINE 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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