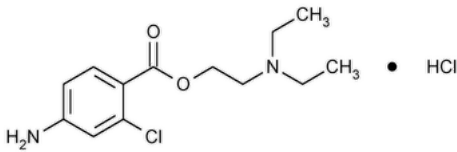


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Chloroprocaine Hydrochloride



$C_{13}H_{19}ClN_2O_2 \cdot HCl$ 307.22
Benzoic acid, 4-amino-2-chloro-, 2-(diethylamino)ethyl ester, monohydrochloride;
2-(Diethylamino)ethyl 4-amino-2-chlorobenzoate monohydrochloride CAS RN®: 3858-89-7; UNII: LT7Z1YW11H.

DEFINITION
Chloroprocaine Hydrochloride contains NLT 98.0% and NMT 102.0% of chloroprocaine hydrochloride ($C_{13}H_{19}ClN_2O_2 \cdot HCl$), calculated on the dried basis.

- IDENTIFICATION**
- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K or 197A
 - **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 (191), Chemical Identification Tests, Chloride:** Meets the requirements

ASSAY

- **PROCEDURE**
Buffer: 1.26 g/L of [ammonium formate](#) in [water](#). Adjust with [formic acid](#) to a pH of 3.5.
Solution A: [Acetonitrile](#) and *Buffer* (10:90)
Solution B: [Acetonitrile](#)
Mobile phase: See [Table 1](#). A re-equilibration time of NLT 20 min to the initial conditions after the gradient is recommended.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
15	30	70
16	100	0
23	100	0

Diluent: [Acetonitrile](#) and [water](#) (10:90)
Standard solution: 0.1 mg/mL of [USP Chloroprocaine Hydrochloride RS](#) in *Diluent*. Sonication may be necessary for complete dissolution.
Sample solution: 0.1 mg/mL of Chloroprocaine Hydrochloride in *Diluent*. Sonication may be necessary for complete dissolution.
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC
Detector: UV 294 nm
Column: 4.6-mm × 25-cm, 5-μm; packing L1
Column temperature: 40°
Flow rate: 1.8 mL/min
Injection volume: 5 μL
System suitability
Sample: *Standard solution*
Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of chloroprocaine hydrochloride ($C_{13}H_{19}ClN_2O_2 \cdot HCl$) in the portion of Chloroprocaine Hydrochloride taken:

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

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

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

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

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

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

IMPURITIES

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

Change to read:

• **ORGANIC IMPURITIES**

Buffer, Solution A, Solution B, Mobile phase, and Diluent: Prepare as directed in the Assay

System suitability solution: 0.03 mg/mL each of [USP Chloroprocaine Hydrochloride RS](#) and [USP Procaine Hydrochloride RS](#) in [methanol](#).

Sonication may be necessary for complete dissolution.

Standard solution: 0.0032 mg/mL of [USP Chloroprocaine Hydrochloride RS](#) in [methanol](#). Sonication may be necessary for complete dissolution.

Sensitivity solution: 0.0016 mg/mL of [USP Chloroprocaine Hydrochloride RS](#) in *Diluent* from *Standard solution*

Sample solution: 3.2 mg/mL of Chloroprocaine Hydrochloride in [methanol](#). Sonication may be necessary for complete dissolution.

Chromatographic system: Proceed as directed in the Assay except for the *Injection volume*.

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

Injection volume: 2 μ L

System suitability

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

[NOTE—See [Table 2](#) for relative retention times.]

Suitability requirements

Resolution: NLT 10 between chloroprocaine and procaine, *System suitability solution*

Relative standard deviation: NMT 5.0%, *Standard solution*

Signal-to-noise ratio: NLT 10, *Sensitivity solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each impurity in the portion of Chloroprocaine Hydrochloride taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 1/F \times 100$$

r_U = peak response of each impurity from the *Sample solution*

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

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

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

F = relative response factor (see [Table 2](#))

Acceptance criteria: See [Table 2](#).

Table 2

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Procaine	0.72	1.39	0.5



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