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Chloroprocaine Hydrochloride Injection

DEFINITION

Chloroprocaine Hydrochloride Injection is a sterile solution of Chloroprocaine Hydrochloride in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of chloroprocaine hydrochloride ($C_{13}H_{19}ClN_2O_2 \cdot HCl$).

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

• **B.** The UV absorption spectra of the major peak of the *Sample solution* and that of the *Standard solution* exhibit maxima and minima at the same wavelengths, as obtained in the *Assay*.

ASSAY

Change to read:

• **Procedure**

Mobile phase: Dissolve 800 mg of sodium 1-heptanesulfonate in 740 mL of water. Add 200 mL of acetonitrile, 50 mL of methanol, and 10 mL of glacial acetic acid.

Solution A: 0.2 mg/mL of recrystallized 4-amino-2-chlorobenzoic acid in methanol

Standard solution: 1 mg/mL of USP Chloroprocaine Hydrochloride RS and 0.02 mg/mL of 4-amino-2-chlorobenzoic acid prepared as follows. Transfer about 50 mg of USP Chloroprocaine Hydrochloride RS to a 50-mL volumetric flask containing 5.0 mL of *Solution A*, add 15 mL of methanol, and dilute with water to volume.

System suitability solution: *Solution A* and *Standard solution* (50:50)

Sample solution: Nominally 1 mg/mL of chloroprocaine hydrochloride prepared as follows. Transfer ▲a volume of Injection, equivalent to about 100 mg of chloroprocaine hydrochloride▲ (ERR 1-Feb-2023) to a 100-mL volumetric flask, ▲add▲ (ERR 1-Feb-2023) 40 mL of methanol, and dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 278 nm. For *Identification B*, use a diode array detector in the range of 200–400 nm.

Column: 3.9-mm × 30-cm; 10-µm packing L1

Flow rate: 2 mL/min

Injection volume: 5 µL

System suitability

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

[Note—The relative retention times for 4-amino-2-chlorobenzoic acid and chloroprocaine are about 0.35 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 5.0 between 4-amino-2-chlorobenzoic acid and chloroprocaine, *System suitability solution*

Relative standard deviation: NMT 1.0% from chloroprocaine, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of chloroprocaine hydrochloride ($C_{13}H_{19}ClN_2O_2 \cdot HCl$) in the portion of Injection 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 = nominal concentration of chloroprocaine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: 95.0%–105.0%

IMPURITIES

• **Limit of 4-amino-2-chlorobenzoic acid**

Mobile phase, Solution A, Standard solution, System suitability solution, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 4-amino-2-chlorobenzoic acid ($C_7H_6ClNO_2$) in the portion of Injection taken:

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

r_U = peak response of 4-amino-2-chlorobenzoic acid from the *Sample solution*

r_S = peak response of 4-amino-2-chlorobenzoic acid from the *Standard solution*

C_S = concentration of 4-amino-2-chlorobenzoic acid in the *Standard solution* (mg/mL)

C_U = nominal concentration of chloroprocaine hydrochloride in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 3.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 2.7–4.0

• **Injections and Implanted Drug Products** ⟨1⟩**:** Meets the requirements

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose or multiple-dose containers, preferably of Type I glass. Protect from light and store at controlled room temperature.

• **USP Reference Standards** ⟨11⟩

USP Chloroprocaine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
CHLOROPROCAINE HYDROCHLORIDE INJECTION	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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