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Procaine Hydrochloride Injection

(*This monograph has been updated to the current USP style. No revisions or changes to tests have been made.*)

DEFINITION

Procaine Hydrochloride Injection is a sterile solution of Procaine Hydrochloride in Water for Injection. It contains NLT 95.0% and NMT 105.0% of the labeled amount of procaine hydrochloride ($C_{13}H_{20}N_2O_2 \cdot HCl$).

IDENTIFICATION

• **A. Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*:** 197K

Sample: Evaporate a portion of Injection, equivalent to 20 mg of procaine hydrochloride, on a steam bath just to dryness, and dry over silica gel for 18 h. Use the residue for the test.

• **B.**

Solution A: 100 mg/mL of sodium hydroxide in water

Solution B: 20 mg/mL of 2-naphthol in *Solution A*

Analysis: Dissolve 10 mg of the residue obtained in *Identification A* in 1 mL of water, add 1 drop each of hydrochloric acid and 100 mg/mL of sodium nitrite in water, then add 1 mL of *Solution B*, and shake.

Acceptance criteria: A scarlet-red precipitate is formed.

ASSAY

Procedure

Standard solution: Transfer to a 125-mL separator about 50 mg, accurately weighed, of USP Procaine Hydrochloride RS and dissolve in 20 mL of water.

Sample solution: Transfer to a 125-mL separator an accurately measured volume of Injection, equivalent to about 50 mg of procaine hydrochloride, and dilute with water to 20 mL.

Instrumental conditions

Mode: UV

Analytical wavelength: 280 nm

Blank: Chloroform

Analysis

Samples: *Standard solution* and *Sample solution*

Add 5 mL of ammonium hydroxide, 6 N, to both the *Standard solution* and *Sample solution*, then treat each as follows. Extract with five 25-mL portions of chloroform, and filter the combined extracts through 1 g of sodium sulfate, anhydrous supported on a pledget of glass wool. Receive the filtrate in a 200-mL volumetric flask, and add chloroform to volume. Transfer 3.0 mL of this solution to a 100-mL volumetric flask, and add chloroform to volume. Concomitantly determine the absorbances of both solutions.

Calculate the percentage of the labeled amount of procaine hydrochloride ($C_{13}H_{20}N_2O_2 \cdot HCl$) in the portion of Injection taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

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

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

Acceptance criteria: 95.0%–105.0%

SPECIFIC TESTS

- **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 0.6 USP Endotoxin Units/mg of procaine hydrochloride.
- **pH ⟨791⟩:** 3.0–5.5
- **Particulate Matter in Injections ⟨788⟩:** It meets the requirements under small-volume injections.
- **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose or in multiple-dose containers, preferably of Type I or Type II glass. The Injection may be packaged in 100-mL multiple-dose containers.
- **USP Reference Standards ⟨11⟩**
  USP Procaine Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
PROCAINE 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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