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Procainamide Hydrochloride Injection

» Procainamide Hydrochloride Injection is a sterile solution of Procainamide Hydrochloride in Water for Injection. It contains not less than 95.0 percent and not more than 105.0 percent of the labeled amount of $C_{13}H_{21}N_3O \cdot HCl$.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass.

Labeling—Label it to indicate that the Injection is not to be used if it is darker than slightly yellow, or is discolored in any other way.

USP Reference standards ⟨11⟩—
USP Procainamide Hydrochloride RS

Identification—It responds to the *Thin-Layer Chromatographic Identification Test ⟨201⟩*, 5 µL of the clear supernatant being used to prepare the *Assay preparation* in the *Assay* and 5 µL of the stock solution being used to prepare the *Standard preparation* in the *Assay* being applied to the plate, and a solvent system consisting of a mixture of ethyl acetate, methanol, and ammonium hydroxide (22:2:1) being used to develop the chromatogram.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.35 USP Endotoxin Unit per mg of procainamide hydrochloride.

pH ⟨791⟩: between 4.0 and 6.0.

Particulate Matter in Injections ⟨788⟩: meets the requirements under Small-volume injections.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

Mobile phase, Standard preparation, Resolution solution, and *Chromatographic system*—Prepare as directed in the *Assay* under *Procainamide Hydrochloride*.

Assay preparation—Transfer an accurately measured volume of Injection, equivalent to about 500 mg of procainamide hydrochloride, to a 500-mL volumetric flask, dilute with methanol to volume, and mix. Transfer 5.0 mL of this stock solution to a 100-mL volumetric flask, reserving the remainder of the stock solution for the *Identification* test. Dilute with *Mobile phase* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Procainamide Hydrochloride*. Calculate the quantity, in mg, of $C_{13}H_{21}N_3O \cdot HCl$ in each mL of the Injection taken by the formula:

$$10{,}000(C/V)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Procainamide Hydrochloride RS in the *Standard preparation*, V is the volume, in mL, of Injection taken, and r_U and r_S are the peak responses obtained from the *Assay preparation* and the *Standard preparation*, respectively.

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

Topic/Question	Contact	Expert Committee
PROCAINAMIDE HYDROCHLORIDE INJECTION	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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