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Penicillin G Procaine for Injectable Suspension

» Penicillin G Procaine for Injectable Suspension is a sterile mixture of Penicillin G Procaine and one or more suitable buffers, dispersants, or suspending agents, and preservatives. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of penicillin G, the labeled amount being not less than 300,000 Penicillin G Units per container or per mL of constituted Suspension.

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

USP Reference standards ⟨11⟩—
USP Penicillin G Potassium RS
USP Procaine Hydrochloride RS

Identification—It responds to the *Identification* test under *Penicillin G Procaine.*

pH ⟨791⟩**:** between 5.0 and 7.5, when constituted as directed in the labeling.

Water Determination, *Method I* ⟨921⟩**:** between 2.8% and 4.2%.

Other requirements—It meets the requirements for *Bacterial endotoxins* and *Sterility* under *Penicillin G Procaine Injectable Suspension.* It meets also the requirements under *Injections and Implanted Drug Products* ⟨1⟩ and *Uniformity of Dosage Units* ⟨905⟩.

Assay—

Standard preparation—Using USP Penicillin G Potassium RS, prepare as directed for *Standard preparation* under *Iodometric Assay—Antibiotics* ⟨425⟩.

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute Penicillin G Procaine for Injectable Suspension as directed in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively with *Buffer B.1* to obtain a solution containing about 2000 Penicillin G Units per mL. Pipet 2 mL of this solution into each of two glass-stoppered, 125-mL conical flasks.

Assay preparation 2 (where the label states the quantity of penicillin G procaine in a given volume of constituted suspension)—Constitute Penicillin G Procaine for Injectable Suspension as directed in the labeling. Dilute an accurately measured volume of the constituted injectable suspension quantitatively with *Buffer B.1* to obtain a solution containing about 2000 Penicillin G Units per mL. Pipet 2 mL of this solution into each of two glass-stoppered, 125-mL conical flasks.

Procedure—Proceed as directed for *Procedure* under *Iodometric Assay—Antibiotics* ⟨425⟩. Calculate the quantity, in Penicillin G Units, in the container, or in the portion of constituted injectable suspension taken by the formula:

$$(L/2D)(F)(B - I)$$

in which L is the labeled quantity, in Penicillin G Units, in the container, or in the volume of constituted injectable suspension taken, and D is the concentration, in Penicillin G Units per mL, of *Assay preparation 1* or of *Assay preparation 2* on the basis of the labeled quantity in the container or in the portion of constituted injectable suspension taken, respectively, and the extent of dilution.

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

Topic/Question	Contact	Expert Committee
PENICILLIN G PROCAINE FOR INJECTABLE SUSPENSION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

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