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Penicillin G Procaine Injectable Suspension

» Penicillin G Procaine Injectable Suspension is a sterile suspension of Penicillin G, Procaine or, where labeled for veterinary use only of sterile penicillin G procaine, in Water for Injection and contains one or more suitable buffers dispersants, or suspending agents, and a suitable preservative. It may contain procaine hydrochloride in a concentration not exceeding 2.0 percent, and may contain one or more suitable stabilizers. 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 mL or per container.

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

Labeling—Where it is intended for veterinary use only, the label so states.

USP Reference standards ⟨11⟩—

USP Penicillin G Potassium RS
USP Procaine Hydrochloride RS

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

Crystallinity ⟨695⟩ (where it is prepared from penicillin G procaine and is labeled for veterinary use only): meets the requirements, the dried residue prepared as directed in the test for *Pencillin G and procaine contents* being used.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 0.01 USP Endotoxin Unit per 100 Penicillin G Units.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined,* except to use a portion of specimen from each container equivalent to 300,000 Penicillin G Units, instead of the minimum volume specified in the *Table 2, Minimum Quantity to be Used for Each Medium*, and to use *Fluid A* to which has been added sufficient sterile penicillinase to inactivate the penicillin G and to swirl the vessel until solution is complete before filtering. If the Injectable Suspension contains lecithin, use *Fluid D.* If it contains carboxymethylcellulose sodium, add sufficient sterile carboxymethylcellulase to *Fluid A* or *Fluid D* to dissolve the carboxymethylcellulose sodium before filtering. If it does not dissolve completely, proceed as directed for *Direct Inoculation of the Culture Medium* under *Test for Sterility of the Product to be Examined*, except to use Fluid Thioglycollate Medium and Soybean–Casein Digest Medium containing an amount of sterile penicillinase sufficient to inactivate the penicillin G in each vessel.

pH ⟨791⟩: between 5.0 and 7.5.

Penicillin G and procaine contents (where it is prepared from penicillin G procaine and is labeled for veterinary use only)—Dilute a portion of it, equivalent to about 300,000 Penicillin G Units, with water to obtain a volume of 10 mL, centrifuge, and remove and discard the supernatant. Resuspend the sediment in 10 mL of water, centrifuge, and remove and discard the supernatant. Dry the sediment in a vacuum desiccator containing silica gel for 18 hours at a temperature not exceeding 25°. The dried material meets the requirements of the test for *Penicillin G and procaine contents* under *Penicillin G Procaine*. [Note—Reserve a portion of the dried material for the test for *Crystallinity.*]

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

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)—Withdraw all of the withdrawable contents of the Injectable Suspension, 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 Injectable Suspension)—Dilute an accurately measured volume of Injectable Suspension quantitatively with *Buffer B.1* to obtain a solution containing about 2000 Penicillin G Units per mL. Pipet 2.0 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 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 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 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 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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