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Penicillin G Procaine Intramammary Infusion

» Penicillin G Procaine Intramammary Infusion is a suspension of Penicillin G Procaine in a suitable vegetable oil vehicle. It may contain one or more buffers, dispersants, preservatives, and thickening agents. It contains not less than 90.0 percent and not more than 115.0 percent of the labeled amount of penicillin G.

Packaging and storage—Preserve in well-closed disposable syringes.

Labeling—Label it to indicate that it is for veterinary use only.

USP Reference standards ⟨11⟩—

USP Penicillin G Potassium RS
USP Penicillin G Procaine RS

Identification—Transfer a portion of it, equivalent to about 100,000 Penicillin G Units, to a test tube, add 25 mL of methanol, and shake. Allow to separate, and use the methanol layer as the test solution. Prepare a Standard solution of USP Penicillin G Procaine RS in methanol containing about 4.5 mg per mL. Apply separately 10 µL of each solution to a thin-layer chromatographic plate (see *Chromatography* ⟨621⟩) coated with a 0.25-mm layer of chromatographic silica gel mixture. Allow the spots to dry, and develop the chromatogram in a solvent system consisting of a mixture of butanol, isopropyl alcohol, acetone, and water (4:4:2:2) until the solvent front has moved about three-fourths of the length of the plate. Remove the plate from the developing chamber, mark the solvent front, and allow the solvent to evaporate. Expose the plate to iodine vapors in a closed chamber for about 15 minutes, and locate the spots: the R_F values and colors of the two principal spots obtained from the test solution correspond to those obtained from the Standard solution.

Water Determination, *Method I* ⟨921⟩**:** not more than 1.4%, 20 mL of a mixture of toluene and methanol (7:3) being used in place of methanol in the titration vessel.

Assay—Proceed as directed under *Antibiotics—Microbial Assays* ⟨81⟩, expelling the contents of 1 syringe of Intramammary Infusion into a high-speed glass blender jar containing 499.0 mL of *Buffer B.1* and 1.0 mL of polysorbate 80, and blending for 3 to 5 minutes. Allow to stand for about 10 minutes, and dilute an accurately measured volume of the aqueous phase quantitatively and stepwise with *Buffer B.1* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

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

Topic/Question	Contact	Expert Committee
PENICILLIN G PROCAINE INTRAMAMMARY INFUSION	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

Chromatographic Database Information: Chromatographic Database

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