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Penicillin G Procaine and Novobiocin Sodium Intramammary Infusion

» Penicillin G Procaine and Novobiocin Sodium Intramammary Infusion is a suspension of Penicillin G Procaine and Novobiocin Sodium in a suitable vegetable oil vehicle. It contains a suitable preservative and suspending agent. It contains not less than 90.0 percent and not more than 125.0 percent of the labeled amounts of Penicillin G Units and novobiocin ($C_{31}H_{36}N_2O_{11}$).

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

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

USP Reference standards ⟨11⟩—

USP Novobiocin RS
USP Penicillin G Potassium RS

Water Determination, *Method I* ⟨921⟩**:** not more than 1.0%, 20 mL of a mixture of toluene and methanol (7:3) being used in place of methanol in the titration vessel.

Assay for penicillin G—Proceed as directed for penicillin G under *Antibiotics—Microbial Assays* ⟨81⟩, except to use *Staphylococcus aureus* ATCC No. 12692 as the test organism. Prepare the inoculum by growing the organism at 32° to 35° for 24 hours on Medium 1 to which has been added a solution of novobiocin sodium, containing the equivalent of 2.5 mg of novobiocin per mL that has been filtered through a membrane filter having a 0.2-µm porosity, so that the medium contains the equivalent of 10 µg of novobiocin per mL. Use an inoculum composition of about 5 mL of stock suspension in each 100 mL of Medium 1. Expel the contents of a syringe of Intramammary Infusion into a high-speed glass blender jar containing 1.0 mL of polysorbate 80 and 499.0 mL of *Buffer B.1*, and blend for 3 to 5 minutes. Allow to stand for 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 of penicillin G assumed to be equal to the median dose level of the Standard.

Assay for novobiocin—Proceed as directed for novobiocin under *Antibiotics—Microbial Assays* ⟨81⟩, expelling the contents of a syringe of Intramammary Infusion into a high-speed blender jar containing 1.0 mL of polysorbate 80 and 499.0 mL of *Buffer B.3*, and blend for 3 to 5 minutes. Allow to stand for 10 minutes. To an accurately measured volume of the aqueous phase add sufficient penicillinase to inactivate the penicillin G therein, and dilute quantitatively and stepwise with *Buffer B.6* to obtain a *Test Dilution* having a concentration of novobiocin assumed to be equal to the median dose level of the Standard. [Note—Store this *Test Dilution* at 37° for 30 minutes and allow to cool before using it to fill the cylinders on the plates.]

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

Topic/Question	Contact	Expert Committee
PENICILLIN G PROCAINE AND NOVOBIOCIN SODIUM 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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