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Penicillin G Procaine and Dihydrostreptomycin Sulfate Intramammary Infusion

» Penicillin G Procaine and Dihydrostreptomycin Sulfate Intramammary Infusion is a suspension of Penicillin G Procaine and Dihydrostreptomycin Sulfate in a suitable vegetable oil vehicle. It may contain suitable gelling and thickening agents. It contains not less than 90.0 percent and not more than 120.0 percent of the labeled amounts of Penicillin G Units and of dihydrostreptomycin ($C_{21}H_{41}N_7O_{12}$).

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

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

USP Reference standards ⟨11⟩—

USP Dihydrostreptomycin Sulfate RS
USP Penicillin G Potassium RS
USP Penicillin G Procaine RS

Identification—

A: It responds to the *Identification* test under *Penicillin G Procaine Intramammary Infusion*.

B: Place a portion of it, equivalent to about 100 mg of dihydrostreptomycin, in a separator, add 20 mL of chloroform and 20 mL of water, and shake by mechanical means for 15 minutes. Allow to separate, and discard the lower chloroform layer. Repeat the extraction with a 20-mL portion of chloroform, discarding the chloroform layer. Use the aqueous layer as the test solution. Prepare a Standard solution of USP Dihydrostreptomycin Sulfate RS in water containing 6.5 mg per mL. Apply separately 30 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 *n*-propyl alcohol, water, pyridine, and glacial acetic acid (15:12:10:2) 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. Spray the plate with a reagent prepared by dissolving 2 g of ninhydrin in 100 mL of alcohol and adding 20 mL of glacial acetic acid, heat the plate at 110° for 10 minutes, and examine the chromatograms: the R_F value and color of the principal spot 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 the titration vessel in place of methanol.

Assay for penicillin G—Proceed as directed for penicillin G 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 of penicillin G assumed to be equal to the median dose level of the Standard.

Assay for dihydrostreptomycin—Proceed as directed for the cylinder-plate assay for dihydrostreptomycin 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.3* and 1.0 mL of polysorbate 80, and blending for 3 to 5 minutes. Allow to stand for about 10 minutes, and to an accurately measured volume of the aqueous phase add an accurately measured volume of penicillinase sufficient to inactivate the penicillin G contained therein. Dilute this solution quantitatively with *Buffer B.3* to obtain a *Test Dilution* having a concentration of dihydrostreptomycin assumed to be equal to the median dose level of the Standard, and store at 37° for 30 minutes before filling the cylinders.

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

Topic/Question	Contact	Expert Committee
PENICILLIN G PROCAINE AND DIHYDROSTREPTOMYCIN SULFATE INTRAMAMMARY INFUSION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Documents
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Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

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