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:

\[
\frac{L}{2D}(8-I)
\]

in which \(L\) is the labeled quantity in Penicillin G Units, in the container, or in the volume of Injectable Suspension taken; \(D\) 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.

**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 Endotoxin RS
USP Penicillin G Pipassium 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, 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 (1) and Uniformity of Dosage Units (905).

**Assay**—


**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 No. 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 No. 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.

**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 (C₂₃H₄₁N₇O₁₂).

**Packaging and storage**—Preserve in well-closed, dispensable 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, 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 No. 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 No. 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 No. 1 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 contained therein. Dilute this solution quantitatively with Buffer No. 1 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.

**Penicillin G Procaine and Dihydrostreptomycin Sulfate Injectable Suspension**

» Penicillin G Procaine and Dihydrostreptomycin Sulfate Injectable Suspension is a sterile suspension of Penicillin G Procaine in a solution of Dihydrostreptomycin Sulfate in Water for Injection, and contains one or more suitable buffers, preservatives, and dispersing or suspending agents. It may contain Procaine Hydrochloride in a concentration not exceeding 2.0 percent, and it 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 amounts of Penicillin G Units and of dihydrostreptomycin (C21H41N7O12).

**Packaging and storage**—Preserve in single-dose or multiple-dose, tight containers.

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

**USP Reference standards** (11)—USP Dihydrostreptomycin Sulfate RS USP Endotoxin RS USP Penicillin G Potassium RS

**Identification**—It responds to Identification tests A and B under Penicillin G Procaine, Dihydrostreptomycin Sulfate, Chlorpheniramine Maleate, and Dexamethasone Suspension.

**Bacterial endotoxins** (85)—It contains not more than 0.01 USP Endotoxin Unit per 100 Penicillin G Units.

**Stability** (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 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 Thiglycollate Medium containing an amount of sterile penicillinase sufficient to inactivate the penicillin G in each vessel.

**pH** (791): between 5.0 and 8.0.

**Assay for penicillin G**—


**Assay preparation**—Dilute an accurately measured volume of Injectable Suspension quantitatively with Buffer No. 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), except in the Blank Determination to add 0.1 mL of 1.2 N hydrochloric acid immediately before the 10.0 mL of 0.01 N iodine VS. Calculate the quantity, in Penicillin G Units, in the portion of Injectable Suspension taken by the formula:

\[
(L / 2D)(f)(8 - l)
\]

in which \(L\) is the labeled quantity, in Penicillin G Units, in the volume of Injectable Suspension taken, and \(D\) is the concentration, in Penicillin G Units per mL, of the Assay preparation, on the basis of the labeled quantity in the portion of Injectable Suspension taken and the extent of dilution, and the other terms are as defined therein.

**Assay for dihydrostreptomycin**—Proceed as directed for the turbidimetric assay for dihydrostreptomycin under Antibiotics—Microbial Assays (81), using an accurately measured volume of Injectable Suspension diluted quantitatively with water to yield a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard.

**Penicillin G Procaine, Dihydrostreptomycin Sulfate, Chlorpheniramine Maleate, and Dexamethasone Injectable Suspension**

» Penicillin G Procaine, Dihydrostreptomycin Sulfate, Chlorpheniramine Maleate, and Dexamethasone Injectable Suspension is a sterile suspension of Penicillin G Procaine and Dexamethasone in a solution of Sterile Dihydrostreptomycin Sulfate and Chlorpheniramine Maleate in Water for Injection. It contains one or more suitable buffers, preservatives, and dispersing or suspending agents. It may contain Procaine Hydrochloride in a concentration not exceeding 2.0 percent, and it 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 amounts of Penicillin G Units and of dihydrostreptomycin (C21H41N7O12), and not less than 90.0 percent and not more than 110.0 percent of the labeled amounts of chlorpheniramine...