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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 ($C_{21}H_{41}N_7O_{12}$).

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 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 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* to which has been added sufficient penicillinase to inactivate the penicillin G and to swirl the vessel until solution is complete before filtering. If it contains carboxymethylcellulose sodium, add also 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 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—

Standard preparation—Using USP Penicillin G Potassium RS, prepare as directed for *Standard preparation* under *Iodometric Assay—Antibiotics* ⟨425⟩.

Assay preparation—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 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:

$$(L/2D)(F)(B - I)$$

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.

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

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Topic/Question	Contact	Expert Committee
PENICILLIN G PROCAINE AND DIHYDROSTREPTOMYCIN SULFATE 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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