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Penicillin G Procaine, Neomycin and Polymyxin B Sulfates, and Hydrocortisone Acetate Topical Suspension

» Penicillin G Procaine, Neomycin and Polymyxin B Sulfates, and Hydrocortisone Acetate Topical Suspension is a suspension of Penicillin G Procaine, Neomycin Sulfate, Polymyxin B Sulfate and Hydrocortisone Acetate in Peanut Oil or Sesame Oil. It may contain one or more suitable dispersing and suspending agents. It contains not less than 90.0 percent and not more than 140.0 percent of the labeled amounts of Penicillin G Units, of neomycin, and of polymyxin B Units, and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of hydrocortisone acetate ($C_{23}H_{32}O_6$).

Packaging and storage—Preserve in well-closed containers.

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

USP Reference standards ⟨11⟩—

- USP Hydrocortisone Acetate RS
- USP Neomycin Sulfate RS
- USP Penicillin G Potassium RS
- USP Polymyxin B Sulfate 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⟩, using an accurately measured volume of Topical Suspension blended for 2 minutes in a high-speed glass blender jar with 499.0 mL of *Buffer B.1* and 1.0 mL of polysorbate 80. 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 neomycin—Proceed as directed for neomycin under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately measured volume of Topical Suspension shaken in a separator with about 50 mL of ether, and extracted with four 20-mL portions of *Buffer B.3*. Combine the aqueous extracts, and dilute with *Buffer B.3* to an appropriate volume to obtain a stock solution. To an accurately measured volume of this stock solution add an accurately measured volume of penicillinase sufficient to inactivate the penicillin G therein, heat at 37° for 30 minutes, and dilute quantitatively and stepwise with *Buffer B.3* to obtain a *Test Dilution* having a concentration of neomycin assumed to be equal to the median dose level of the Standard.

Assay for polymyxin B—Proceed as directed for polymyxin B under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately measured volume of Topical Suspension blended for 2 minutes in a high-speed glass blender jar containing 499.0 mL of *Buffer B.6* and 1.0 mL of polysorbate 80. Allow to stand for 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 therein. Heat the solution at 37° for 30 minutes, and dilute quantitatively and stepwise with *Buffer B.6* to obtain a *Test Dilution* having a concentration of polymyxin assumed to be equal to the median dose level of the Standard. Add to each test dilution of the Standard a quantity of USP Neomycin Sulfate RS dissolved in *Buffer B.6* to obtain the same concentration of neomycin present in the *Test Dilution*.

Assay for hydrocortisone acetate—Using an accurately measured volume of Topical Suspension, proceed as directed in the *Assay* under *Hydrocortisone Acetate Lotion*.

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

Topic/Question	Contact	Expert Committee
PENICILLIN G PROCAINE, NEOMYCIN AND POLYMYXIN B SULFATES, AND HYDROCORTISONE ACETATE TOPICAL SUSPENSION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

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REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

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