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Neomycin Sulfate, Isoflupredone Acetate, and Tetracaine Hydrochloride Topical Powder

» Neomycin Sulfate, Isoflupredone Acetate, and Tetracaine Hydrochloride Topical Powder contains the equivalent of not less than 90.0 percent and not more than 125.0 percent of the labeled amount of neomycin, and not less than 90.0 percent and not more than 120.0 percent of the labeled amounts of isoflupredone acetate ($C_{23}H_{29}FO_6$) and tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$).

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 Isoflupredone Acetate RS
USP Neomycin Sulfate RS
USP Tetracaine Hydrochloride RS

Identification—

A: *Thin-Layer Chromatographic Identification Test* ⟨201⟩—

Test solution—Add 20 mL of chloroform to 1 g of Topical Powder, shake for 5 to 10 minutes, and centrifuge. Evaporate a 10-mL portion of the clear solution to dryness, and dissolve the residue in 1 mL of a mixture of chloroform and alcohol (1:1).

Standard solution: 0.5 mg of USP Isoflupredone Acetate RS per mL, in a mixture of chloroform and alcohol (1:1).

Application volume: 30 µL.

Developing solvent system: a mixture of methylene chloride and methanol (180:16), in a paper-lined chromatographic chamber.

Spray reagent: a solution of sulfuric acid in methanol (70 in 100).

Procedure—Proceed as directed in the chapter, except to use a plate that has been activated by heating in an oven at 105° for 60 minutes. Allow the plate to cool before using. Locate the spots under short- and long-wavelength UV light. Spray the plate with *Spray reagent*, heat at 90° for 30 minutes, and locate the spots under short- and long-wavelength UV light (*presence of isoflupredone acetate*).

B: *Thin-Layer Chromatographic Identification Test* ⟨201⟩—

Test solution—To 1 g of Topical Powder in a centrifuge tube add 5 mL of water, and shake until dissolved. Prepare a suspension of 10 g of cation-exchange resin in 10 mL of water, add 5 mL of a solution of sodium hydroxide (1 in 2), mix, and wash the resin with water until the pH of the wash is about 9. Add 0.3 g of this suspension to the solution of Topical Powder, and shake for 10 seconds. Centrifuge for 1 minute, and discard the supernatant. Wash the resin in the tube with 10 mL of water, centrifuge, and discard the supernatant. Add 2 mL of 1 M ammonium hydroxide, shake for 10 seconds, and filter. Use the filtrate.

Standard solution, *Application volume*, *Developing solvent system*, *Spray reagent*, and *Procedure*— Proceed as directed in *Identification* test *A* under *Neomycin Sulfate, Isoflupredone Acetate, and Tetracaine Hydrochloride Ointment* (*presence of neomycin*).

Minimum fill ⟨755⟩: meets the requirements.

Loss on drying ⟨731⟩—Dry about 2 g in vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 hours: it loses not more than 8.0% of its weight.

Assay for neomycin—Proceed as directed under *Antibiotics—Microbial Assays* ⟨81⟩, the *Test Dilution* being prepared as follows. Use an accurately weighed quantity of Topical Powder diluted quantitatively with *Buffer B.3* to obtain a solution having a suitable concentration of neomycin. Dilute this stock solution quantitatively with *Buffer B.3* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Assay for isoflupredone acetate—

Mobile phase, *Diluent*, *Internal standard solution*, *Standard preparation*, and *Chromatographic system*—Proceed as directed in the *Assay* under *Isoflupredone Acetate.*

Assay preparation—Transfer an accurately weighed portion of Topical Powder, equivalent to about 4 mg of isoflupredone acetate, to a suitable container. Add 8.0 mL of *Internal standard solution*, 32.0 mL of *Diluent*, and about 10 glass beads. Shake for about 15 minutes, centrifuge, and

use the clear chloroform portion.

Procedure—Proceed as directed in the *Assay* under *Isoflupredone Acetate.* Calculate the quantity, in mg, of isoflupredone acetate ($C_{23}H_{29}FO_6$) in the portion of Topical Powder taken by the formula:

$$W_S(R_U/R_S)$$

in which the terms are as defined therein.

Assay for tetracaine hydrochloride—

Standard preparation—Prepare a solution having a known concentration of 5.5 µg of USP Tetracaine Hydrochloride RS per mL.

Assay preparation—Transfer an accurately weighed portion of Topical Powder, equivalent to about 5.5 mg of tetracaine hydrochloride, to a 100-mL volumetric flask, dilute with water to volume, and mix. Pass about 30 mL through a fine, sintered-glass filter. Transfer 10.0 mL of the clear filtrate to a second 100-mL volumetric flask, dilute with water to volume, and mix.

Procedure—Concomitantly determine the absorbances of the *Standard preparation* and the *Assay preparation* at the wavelength of maximum absorbance at about 310 nm, with a suitable spectrophotometer, using water to zero the instrument. Calculate the quantity, in mg, of tetracaine hydrochloride ($C_{15}H_{24}N_2O_2 \cdot HCl$) in the portion of Topical Powder taken by the formula:

$$1000C(A_U/A_S)$$

in which C is the concentration, in mg per mL, of USP Tetracaine Hydrochloride RS in the *Standard preparation;* and A_U and A_S are the absorbances of the *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
NEOMYCIN SULFATE, ISOFLUPREDONE ACETATE, AND TETRACAINE HYDROCHLORIDE TOPICAL POWDER	Julie Zhang 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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