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Neomycin Sulfate and Flurandrenolide Ointment

» Neomycin Sulfate and Flurandrenolide Ointment contains the equivalent of not less than 90.0 percent and not more than 135.0 percent of the labeled amount of neomycin, and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of flurandrenolide ($C_{24}H_{33}FO_6$).

Packaging and storage—Preserve in collapsible tubes or in tight containers, protected from light.

USP Reference standards ⟨11⟩—
USP Flurandrenolide RS
USP Neomycin Sulfate RS

Identification—

A: It meets the requirements for neomycin under *Thin-Layer Chromatographic Identification Test ⟨201BNP⟩*.

B: It meets the requirements for the *Identification* test under *Flurandrenolide Cream*.

Minimum fill ⟨755⟩: meets the requirements.

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 neomycin—Proceed with Ointment as directed in the *Assay* under *Neomycin Sulfate Ointment*.

Assay for flurandrenolide—Proceed with Ointment as directed in the *Assay* under *Flurandrenolide Cream*. Calculate the quantity, in mg, of $C_{24}H_{33}FO_6$ in the portion of Ointment taken by the formula:

$$10C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Flurandrenolide RS in the *Standard preparation;* and r_U and r_S are the peak responses obtained from 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 AND FLURANDRENOLIDE OINTMENT	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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