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Neomycin Sulfate and Fluorometholone Ointment

» Neomycin Sulfate and Fluorometholone 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 fluorometholone ($C_{22}H_{29}FO_4$).

Packaging and storage—Preserve in collapsible tubes or in well-closed containers.

USP REFERENCE STANDARDS (11)—

[USP Fluorometholone RS](#)
[USP Neomycin Sulfate RS](#)

Identification—

A: It meets the requirements for neomycin under [Thin-Layer Chromatographic Identification Test \(201BNP\)](#).

B: The ratios of the retention time of the main peak to that of the internal standard peak obtained from the *Standard preparation* and the *Assay preparation* as directed in the *Assay for fluorometholone* do not differ by more than 2.0%.

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 fluorometholone—

Internal standard solution, Mobile solvent, and Standard preparation—Prepare as directed in the Assay under [Fluorometholone Cream](#).

Assay preparation—Transfer an accurately weighed quantity of Ointment, equivalent to about 1 mg of fluorometholone, to a suitable container, add 20.0 mL of *Internal standard solution*, and mix.

Procedure—Treat 20.0 mL each of the *Standard preparation* and the *Assay preparation* in the following manner. To each add 10.0 mL of hexane, shake for about 15 minutes, then allow the layers to separate, and centrifuge, if necessary. Using the lower (acetonitrile) layer, proceed as directed for *Procedure* in the *Assay* under [Fluorometholone Cream](#), beginning with “Using a suitable microsyringe.” Calculate the quantity, in mg, of $C_{22}H_{29}FO_4$ in the portion of Ointment taken by the formula:

$$20C(R_u/R_s)$$

in which the terms are as defined therein.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
NEOMYCIN SULFATE AND FLUOROMETHOLONE OINTMENT	Kishan Chandra Senior Scientist I, Documentary Standards	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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