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Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution

» Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution is a sterile solution containing the equivalent of not less than 90.0 percent and not more than 130.0 percent of the labeled amounts of neomycin and polymyxin B. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of hydrocortisone. It may contain one or more suitable buffers, dispersants, and solvents.

Packaging and storage—Preserve in tight, light-resistant containers. The containers or individual cartons are sealed and tamper-proof so that sterility is assured at time of first use.

USP REFERENCE STANDARDS (11)—

[USP Hydrocortisone RS](#)
[USP Neomycin Sulfate RS](#)
[USP Polymyxin B Sulfate RS](#)

STERILITY TESTS (71): meets the requirements.

pH (791): between 2.0 and 4.5.

Assay for neomycin—Proceed as directed under [Antibiotics—Microbial Assays \(81\)](#), using an accurately measured volume of Otic Solution diluted quantitatively and stepwise with *Buffer B.3* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard (1.0 µg of neomycin per mL).

Assay for polymyxin B—Proceed as directed under [Antibiotics—Microbial Assays \(81\)](#), using an accurately measured volume of Otic Solution diluted quantitatively and stepwise with *Buffer B.6* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard (10 Polymyxin B Units per mL). Add to each test dilution of the Standard a quantity of Neomycin Standard, dissolved in *Buffer B.6*, to obtain the same concentration of neomycin present in the *Test Dilution*.

Assay for hydrocortisone—

Mobile phase, Standard preparation, and Chromatographic system—Prepare as directed in the Assay for hydrocortisone under [Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment](#).

Assay preparation—Transfer 3.0 mL of Otic Solution to a 200-mL volumetric flask, dilute with a mixture of methanol and water (1:1) to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the Assay for hydrocortisone under [Neomycin and Polymyxin B Sulfates, Bacitracin Zinc and Hydrocortisone Ophthalmic Ointment](#). Calculate the quantity, in mg, of C₂₁H₃₀O₅ in each mL of the Otic Solution taken by the formula:

$$(66.67C)(r_U/r_S)$$

in which C is the concentration, in mg per mL, of [USP Hydrocortisone 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 AND POLYMYXIN B SULFATES AND HYDROCORTISONE OTIC SOLUTION	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](#)

Most Recently Appeared In:

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