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Neomycin Sulfate and Hydrocortisone Otic Suspension

» Neomycin Sulfate and Hydrocortisone Otic Suspension is a sterile suspension containing not less than 90.0 percent and not more than 130.0 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 hydrocortisone. It contains Acetic Acid, and may contain one or more suitable buffers, dispersants, and preservatives.

[NOTE—Where Neomycin Sulfate and Hydrocortisone Otic Suspension is prescribed, without reference to the quantity of neomycin or hydrocortisone contained therein, a product containing 3.5 mg of neomycin and 10 mg of hydrocortisone per mL shall be dispensed.]

Packaging and storage—Preserve in tight, light-resistant containers.

USP REFERENCE STANDARDS (11)—
[USP Hydrocortisone RS](#)
[USP Neomycin Sulfate RS](#)

STERILITY TESTS (71): meets the requirements.

pH (791): between 4.5 and 6.0.

Assay for neomycin—Using an accurately measured volume of Otic Suspension, freshly mixed and free from entrapped air, proceed as directed in the Assay for neomycin under [Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution](#).

Assay for hydrocortisone—

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

Assay preparation—Transfer 3.0 mL of Otic Suspension, freshly mixed and free from entrapped air, to a 200-mL volumetric flask, dilute with a mixture of methanol and water (1:1) to volume, and mix. Filter the solution, rejecting the first 10 mL of the filtrate.

Procedure—Proceed as directed for Procedure in the Assay for hydrocortisone content under [Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Hydrocortisone Ophthalmic Ointment](#). Calculate the quantity, in mg, of $C_{21}H_{30}O_5$ in each mL of the Otic Suspension 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 SULFATE AND HYDROCORTISONE OTIC SUSPENSION	Rebecca C. Potts Associate Scientific 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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