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Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension

» Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Suspension is a sterile suspension containing the equivalent of not less than 90.0 percent and not more than 130.0 percent of the labeled amounts of neomycin and of 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 preservatives.

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

Thin-layer chromatographic identification test ⟨201BNP⟩: meets the requirements.

Sterility Tests ⟨71⟩: meets the requirements.

pH ⟨791⟩: between 3.0 and 7.0.

Assay for neomycin and Assay for polymyxin B—Using an accurately measured volume of Otic Suspension, freshly mixed and free from air bubbles, proceed as directed in the *Assay for neomycin* and the *Assay for polymyxin B* under *Neomycin and Polymyxin B Sulfates and Hydrocortisone Otic Solution*.

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 Suspension, freshly mixed and free from air bubbles, 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* 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.

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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 SUSPENSION	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

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