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Colistin and Neomycin Sulfates and Hydrocortisone Acetate Otic Suspension

» Colistin and Neomycin Sulfates and Hydrocortisone Acetate Otic Suspension is a sterile suspension containing the equivalent of not less than 90.0 percent and not more than 135.0 percent of the labeled amount of colistin, not less than 90.0 percent and not more than 125.0 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 acetate ($C_{23}H_{32}O_6$). It contains one or more suitable buffers, detergents, dispersants, and preservatives.

[Note—Where Colistin and Neomycin Sulfates and Hydrocortisone Acetate Otic Suspension is prescribed, without reference to the quantity of colistin, neomycin, or hydrocortisone acetate contained therein, a product containing 3.0 mg of colistin, 3.3 mg of neomycin, and 10 mg of hydrocortisone acetate per mL shall be dispensed.]

Packaging and storage—Preserve in tight containers.

USP Reference standards ⟨11⟩—

USP Colistin Sulfate RS
USP Neomycin Sulfate RS
USP Hydrocortisone Acetate RS

Sterility Tests ⟨71⟩: meets the requirements, 0.25 mL from each container being transferred directly to 90 mL of each medium.

pH ⟨791⟩: between 4.8 and 5.2.

Assay for colistin—Proceed as directed under *Antibiotics—Microbial Assays ⟨81⟩*, using a freshly mixed, accurately measured volume of Otic Suspension 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.

Assay for neomycin—Proceed as directed under *Antibiotics—Microbial Assays ⟨81⟩*, using a freshly mixed, accurately measured volume of Otic Suspension 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.

Assay for hydrocortisone acetate—

Reagent blank—Dilute 200 mL of 22 N sulfuric acid with 100 mL of dehydrated alcohol.

Phenylhydrazine reagent—Dissolve 43.33 mg of phenylhydrazine hydrochloride in 100 mL of *Reagent blank*.

Standard preparation—Dissolve a suitable quantity of USP Hydrocortisone Acetate RS, accurately weighed, in chloroform, and dilute quantitatively and stepwise with chloroform to obtain a solution having a known concentration of about 10 µg per mL.

Assay preparation—Transfer 5.0 mL of freshly mixed Otic Suspension to a 125-mL separator. Extract with three 20-mL portions of chloroform, filtering each chloroform extract through a pledget of cotton previously saturated with chloroform, collect the filtrates in a 100-mL volumetric flask, dilute with chloroform to volume, and mix. Pipet 10 mL of this solution into a 100-mL volumetric flask, dilute with chloroform to volume, and mix. Pipet 20 mL of this solution into a 100-mL volumetric flask, dilute with chloroform to volume, and mix.

Procedure—Pipet 50 mL each of the *Standard* and the *Assay preparation* into separate 125-mL separators, add 2 mL of 0.1 N sodium hydroxide to each separator, shake, and allow the layers to separate. Filter both chloroform layers through glass wool, and collect the filtrates in separate beakers. Pipet two 20-mL portions of each chloroform filtrate into separate 125-mL separators. Add 25.0 mL of *Phenylhydrazine reagent* to one separator each of the filtrates from the *Standard preparation* and the *Assay preparation*, respectively, and add 25.0 mL of *Reagent blank* to the remaining two separators. Shake all four separators well, allow the layers to separate, and discard the chloroform layers. Drain the aqueous layers into separate centrifuge tubes, and centrifuge for 2 minutes. Pipet 10 mL of each solution into separate glass-stoppered test tubes. Place the tubes in a water bath maintained at a temperature of 60° for 30 minutes, then cool the solution to room temperature. Concomitantly determine the absorbances of the solutions at the wavelength of maximum absorbance at about 410 nm, with a suitable spectrophotometer, using water to set the instrument. Calculate the quantity, in mg, of hydrocortisone acetate ($C_{23}H_{32}O_6$) in each mL of the Otic Suspension taken by the formula:

$$C(A_U - A_{UB}/A_S - A_{SB})$$

in which C is the concentration, in µg per mL, of USP Hydrocortisone Acetate RS in the *Standard preparation*; A_U and A_{UB} are the absorbances of

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the solutions from the *Assay preparation* and the *Standard preparation* treated with *Phenylhydrazine reagent*, respectively; and A_{UB} and A_{SB} are the absorbances of the solution from the *Assay preparation* and the *Standard preparation* treated with the *Reagent blank,* respectively.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
COLISTIN AND NEOMYCIN SULFATES AND HYDROCORTISONE ACETATE OTIC SUSPENSION	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

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