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Neomycin and Polymyxin B Sulfates and Lidocaine Cream

» Neomycin and Polymyxin B Sulfates and Lidocaine Cream contains 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, and not less than 90.0 percent and not more than 110.0 percent of the labeled amount of lidocaine ($C_{14}H_{22}N_2O$).

Packaging and storage—Preserve in well-closed containers, preferably at controlled room temperature.

USP Reference standards ⟨11⟩—

USP Lidocaine RS
USP Neomycin Sulfate RS
USP Polymyxin B Sulfate RS

Identification—

A: It meets the requirements under *Thin-Layer Chromatographic Identification Test ⟨201BNP⟩*.

B: The retention time of the major peak for lidocaine in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation*, as obtained in the *Assay for lidocaine*.

Minimum fill ⟨755⟩: meets the requirements.

Change to read:

Assay for neomycin—▲Proceed as directed under *Antibiotics—Microbial Assays ⟨81⟩*, using an accurately weighed portion of Cream, equivalent to about 1.75 mg of neomycin, shaken in a separator with about 50 mL of ether, and extracted with four 20-mL portions of *Buffer B.3*. Combine the aqueous extracts, and dilute with *Buffer B.3* to an appropriate volume to obtain a stock solution of convenient concentration. Dilute this stock solution quantitatively and stepwise with *Buffer B.3* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.▲ (ERR 1-Jul-2024)

Change to read:

Assay for polymyxin B—▲Proceed as directed under *Antibiotics—Microbial Assays ⟨81⟩*, using an accurately weighed portion of Cream shaken with about 50 mL of ether in a separator, and extracted with four 25-mL portions of *Buffer B.6*. Combine the aqueous extracts, and dilute with *Buffer B.6* to an appropriate volume to obtain a stock solution. Dilute this stock solution quantitatively and stepwise with *Buffer B.6* to obtain 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 USP Neomycin Sulfate RS, dissolved in *Buffer B.6*, to obtain the same concentration of neomycin present in the *Test Dilution*.▲ (ERR 1-Jul-2024)

Assay for lidocaine—

Mobile phase, *Standard preparation*, and *Chromatographic system*—Proceed as directed in the *Assay for lidocaine* under *Neomycin and Polymyxin B Sulfates, Bacitracin, and Lidocaine Ointment*.

Assay preparation—Using Cream, proceed as directed for the *Assay preparation* in the *Assay for lidocaine* under *Neomycin and Polymyxin B Sulfates, Bacitracin, and Lidocaine Ointment*.

Procedure—Proceed as directed for *Procedure* in the *Assay for lidocaine* under *Neomycin and Polymyxin B Sulfates, Bacitracin, and Lidocaine Ointment*. Calculate the quantity, in mg, of lidocaine ($C_{14}H_{22}N_2O$) in the portion of Cream taken by the formula:

$$100C(r_U/r_S)$$

in which C is the concentration, in mg per mL, of USP Lidocaine RS in the *Standard preparation;* and r_U and r_S are the lidocaine 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 LIDOCAINE CREAM	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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