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Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Lidocaine Ointment

» Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Lidocaine Ointment contains the equivalent of not less than 90.0 percent and not more than 130.0 percent of the labeled amounts of neomycin, polymyxin B, and bacitracin, 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 Bacitracin Zinc RS
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.

Water Determination, *Method I* ⟨921⟩: not more than 0.5%, 20 mL of a mixture of toluene and methanol (7:3) being used in place of methanol in the titration vessel.

Assay for neomycin—Proceed with Ointment as directed in the *Assay for neomycin* under *Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment*.

Assay for polymyxin B—Proceed with Ointment as directed in the *Assay for polymyxin B* under *Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment*.

Assay for bacitracin—Proceed with Ointment as directed in the *Assay for bacitracin* under *Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment*.

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 the Ointment, proceed as directed for *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 Ointment 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, BACITRACIN ZINC, AND LIDOCAINE OINTMENT	Julie Zhang Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

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Topic/Question	Contact	Expert Committee
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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