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Neomycin and Polymyxin B Sulfates, Bacitracin, and Lidocaine Ointment

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

Assay for lidocaine—

Mobile phase—Dissolve 4.44 g of docusate sodium in 1000 mL of a mixture of methanol and water (4:1), add 1 mL of 0.1 N sulfuric acid, and mix. Make adjustments if necessary (see *System Suitability* under *Chromatography ⟨621⟩*).

Standard preparation—Dissolve a suitable quantity of USP Lidocaine RS, accurately weighed, in *Mobile phase* to obtain a solution having a known concentration of about 0.4 mg per mL.

Assay preparation—Transfer an accurately weighed quantity of Ointment, equivalent to about 40 mg of lidocaine, to a separator, add 50 mL of *n*-hexane, and shake until the specimen is in solution. Add 30 mL of *Mobile phase*, shake for 1 minute, and allow the layers to separate. Drain the lower layer into a 100-mL volumetric flask, and extract the *n*-hexane layer remaining in the separator with two 30-mL portions of *Mobile phase*, combining the lower layers in the volumetric flask. Dilute the combined extracts in the 100-mL volumetric flask with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 230-nm detector and a 4-mm × 25-cm column that contains packing L1. The flow rate is about 1 mL per minute. Chromatograph the *Standard preparation*, and record the peak response as directed for *Procedure:* the column efficiency determined from the analyte peak is not less than 500 theoretical plates, and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the major peaks. 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 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, BACITRACIN, AND LIDOCAINE OINTMENT	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

Chromatographic Database Information: Chromatographic Database

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