Neomycin and Polymyxin B Sulfates, Bacitracin, and Hydrocortisone Acetate Ophthalmic Ointment

» Neomycin and Polymyxin B Sulfates, Bacitracin, and Hydrocortisone Acetate Ophthalmic Ointment contains the equivalent of not less than 90.0 percent and not more than 110.0 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 hydrocortisone acetate, in a suitable ointment base.

Packaging and storage—Preserve in collapsible ophthalmic ointment tubes.

USP Reference standards (11)—
USP Bacitracin Zinc RS
USP Hydrocortisone Acetate 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 hydrocortisone acetate to that in the chromatogram of the Standard preparation, as obtained in the Assay for hydrocortisone acetate.

Sterility (71)—It meets the requirements when tested as directed for Membrane Filtration under Test for Sterility of the Product to be Examined.

Minimum fill (755): meets the requirements.

Water, 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.

Metal particles—It meets the requirements of the test for Metal Particles in Ophthalmic Ointments (751).

Assay for neomycin and Assay for polymyxin B—Proceed with Ophthalmic 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 Ophthalmic Ointment as directed in the Assay under Bacitracin Ointment.

Assay for hydrocortisone acetate—Proceed with Ophthalmic Ointment as directed in the Assay under Hydrocortisone Acetate Lotion.

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 (C17H20N2O).

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 hydrocortisone acetate in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay for hydrocortisone acetate.

Minimum fill (755): meets the requirements.

Water, 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

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Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ointment

Neomycin and Polymyxin B Sulfates and Bacitracin Zinc 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. It may contain a suitable local anesthetic.

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

USP Reference standards (11)—
USP Bacitracin Zinc RS
USP Neomycin Sulfate RS
USP Polymyxin B Sulfate RS
Thin-layer chromatographic identification test (201BNP): meets the requirements.
Minimum fill (755): meets the requirements.
Water, 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, Assay for polymyxin B, and Assay for bacitracin—Proceed with Ointment as directed in the Assay for neomycin, in the Assay for polymyxin B, and in the Assay for bacitracin under Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment.

Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment

Neomycin and Polymyxin B Sulfates and Bacitracin Zinc Ophthalmic Ointment contains the equivalent of not less than 90.0 percent and not more than 140.0 percent of the labeled amounts of neomycin, polymyxin B, and bacitracin.

Packaging and storage—Preserve in collapsible ophthalmic ointment tubes.

USP Reference standards (11)—
USP Bacitracin Zinc RS
USP Neomycin Sulfate RS
USP Polymyxin B Sulfate RS
Thin-layer chromatographic identification test (201BNP): meets the requirements.
Sterility (71): meets the requirements.
Minimum fill (755): meets the requirements.
Water, 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.

Metal particles—It meets the requirements of the test for Metal Particles in Ophthalmic Ointments (751).

Assay for neomycin—Proceed as directed under Antibiotics—Microbial Assays (81), using an accurately weighed portion of Ophthalmic Ointment shaken with about 50 mL of ether, and extracted with four 20-mL portions of Buffer No. 3. Combine the aqueous extracts, and dilute with Buffer No. 3 to an appropriate volume to obtain a stock solution. Dilute this stock solution quantitatively and stepwise with Buffer No. 3 to obtain a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard.

Assay for polymyxin B—Proceed as directed under Antibiotics—Microbial Assays (81), using an accurately weighed portion of Ophthalmic Ointment shaken with about 50 mL of ether in a separator, and extracted with four 25-mL portions of Buffer No. 6. Combine the aqueous extracts, and dilute with Buffer No. 6 to an appropriate volume to obtain a stock solution. Dilute this stock solution quantitatively and stepwise with Buffer No. 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 Neomycin Standard, dissolved in Buffer No. 6, to obtain the same concentration of neomycin present in the Test Dilution.

Assay for bacitracin—Proceed as directed under Antibiotics—Microbial Assays (81), using an accurately weighed portion of Ophthalmic Ointment shaken with about 50 mL of ether in a separator, and extracted with four 25-mL portions of 0.01 N hydrochloric acid. Combine the acid extracts, and dilute with 0.01 N hydrochloric acid to an appropriate volume to obtain a stock solution. Dilute this stock solution quantitatively and stepwise with Buffer No. 1 to obtain a Test Dilution having a concentration assumed to be equal to the median dose level of the Standard (1.0 Bacitracin Unit per mL). [NOTE—If the stock solution has a concentration of less than 100 Bacitracin Units per mL, add additional hydrochloric acid to each test dilution of the Standard to obtain the same concentration of hydrochloric acid as the Test Dilution.]

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

Neomycin and Polymyxin B Sulfates, Bacitracin Zinc, and Hydrocortisone 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 hydrocortisone.

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

USP Reference standards (11)—
USP Bacitracin Zinc RS
USP Hydrocortisone 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 hydrocortisone in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay for hydrocortisone.