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Do not distribute

Polymyxin B Sulfate and Bacitracin Zinc Topical Powder

» Polymyxin B Sulfate and Bacitracin Zinc Topical Powder contains not less than 90.0 percent and not more than 130.0 percent of the labeled amounts of polymyxin B and bacitracin.

Packaging and storage—Preserve in well-closed containers.

USP REFERENCE STANDARDS (11).—

[USP Bacitracin Zinc RS](#)

[USP Polymyxin B Sulfate RS](#)

MICROBIAL ENUMERATION TESTS (61) and TESTS FOR SPECIFIED MICROORGANISMS (62).—Collect aseptically in a suitable container about 1 g from not less than 5 containers, dissolve in 500 mL of *Fluid A*, filter through a membrane filter as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined* under [Sterility Tests \(71\)](#), except to place the filter on the surface of Soybean–Casein Digest Agar Medium in a Petri dish, incubate for 7 days at 30° to 35°, and count the number of colonies on the filter. Similarly prepare a second specimen, except to incubate at 20° to 25°. Not more than 20 colonies are observed from the two specimens. It meets also the requirements of the tests for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa* under [Microbial Enumeration Tests \(61\)](#) and [Tests for specified microorganisms \(62\)](#).

WATER DETERMINATION, Method I (921): not more than 7.0%.

Assay for polymyxin B—Proceed as directed for polymyxin B under [Antibiotics—Microbial Assays \(81\)](#), using an accurately weighed portion of Topical Powder, equivalent to about 5000 USP Polymyxin B Units, shaken with 20 mL of water in a suitable volumetric flask. Dilute with *Buffer B.6* to volume, and mix. Dilute an accurately measured volume of the solution so obtained quantitatively with *Buffer B.6* to obtain a *Test Dilution* having a concentration of polymyxin B assumed to be equal to the median dose level of the Standard.

Assay for bacitracin—Proceed as directed for bacitracin under [Antibiotics—Microbial Assays \(81\)](#), using an accurately weighed portion of Topical Powder, equivalent to about 800 USP Bacitracin Units, added to a 100-mL volumetric flask, dilute with 0.01 N hydrochloric acid to volume, and mix. Dilute this solution quantitatively with *Buffer B.1* to obtain a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard. In preparing each test dilution of the Standard, add additional hydrochloric acid to each to obtain the same concentration of hydrochloric acid as in the *Test Dilution*.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

| Topic/Question | Contact | Expert Committee |
|--|---|---|
| POLYMYXIN B SULFATE AND BACITRACIN ZINC TOPICAL POWDER | Ying Han 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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