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Polymyxin B for Injection

» Polymyxin B for Injection contains an amount of Polymyxin B Sulfate equivalent to not less than 90.0 percent and not more than 120.0 percent of the labeled amount of polymyxin B.

Packaging and storage—Preserve as described in *Packaging and Storage Requirements* ⟨659⟩, *Injection Packaging, Packaging for constitution*, protected from light.

Labeling—Label it to indicate that where it is administered intramuscularly and/or intrathecally, it is to be given only to patients hospitalized so as to provide constant supervision by a physician.

USP Reference standards ⟨11⟩—
USP Polymyxin B Sulfate RS

Constituted solution—At the time of use, it meets the requirements for *Injections and Implanted Drug Products* ⟨1⟩, *Specific Tests, Completeness and clarity of solutions*.

Thin-layer chromatographic identification test ⟨201BNP⟩: meets the requirements.

Pyrogen—It meets the requirements of the *Pyrogen Test* ⟨151⟩, the test dose being 1.0 mL per kg of a solution in pyrogen-free saline TS containing 20,000 Polymyxin B Units per mL.

Sterility Tests ⟨71⟩ —It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined*.

Particulate Matter in Injections ⟨788⟩: meets the requirements for small-volume injections.

Residue on ignition ⟨281⟩: not more than 5.0%, the charred residue being moistened with 2 mL of nitric acid and 5 drops of sulfuric acid.

Other requirements—It meets the requirements for *pH* and *Loss on drying* under *Polymyxin B Sulfate*. It also meets the requirements for *Uniformity of Dosage Units* ⟨905⟩ and *Labeling* ⟨7⟩, *Labels and Labeling for Injectable Products*.

Assay—

Assay preparation 1 (where it is represented as being in a single-dose container)—Constitute Polymyxin B for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute quantitatively with *Buffer B.6* to obtain a solution containing a convenient number of Polymyxin B Units per mL.

Assay preparation 2 (where the label states the quantity of polymyxin B in a given volume of constituted solution)—Constitute 1 container of Polymyxin B for Injection in a volume of water, accurately measured, corresponding to the volume of solvent specified in the labeling. Dilute an accurately measured volume of the constituted solution quantitatively with *Buffer B.6* to obtain a solution containing a convenient number of Polymyxin B Units per mL.

Procedure—Proceed as directed under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately measured volume of *Assay preparation* diluted quantitatively with *Buffer B.6* to yield a *Test Dilution* having a concentration assumed to be equal to the median dose level of the Standard.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
POLYMYXIN B FOR INJECTION	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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