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# Bleomycin for Injection

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

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

**USP Reference Standards** ⟨11⟩—
USP Bleomycin 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*.

**Identification**—

***Change to read:***

**A:** ▲*Spectroscopic Identification Tests* ⟨197⟩, *Infrared Spectroscopy: 197K*▲ (CN 1-May-2020) ·

**B:** It responds to the tests for *Sulfate* ⟨191⟩.

**Bacterial Endotoxins Test** ⟨85⟩ —It contains not more than 10.0 USP Endotoxin Units per Bleomycin Unit.

**Sterility Tests** ⟨71⟩ —It meets the requirements when tested as directed for *Membrane Filtration* under *Test for Sterility of the Product to be Examined,* the entire contents of each container being used.

**Water Determination,** *Method Ic* ⟨921⟩ **:** not more than 6.0%. Prepare the specimen for test as follows. Use a dry syringe to inject 4 mL of anhydrous methanol through the stoppers of two tared containers, respectively, and shake to dissolve. Using the same syringe, aspirate the contents of the two containers, transfer to the titration vessel, and titrate. Perform a blank determination on 8 mL of the anhydrous methanol. Determine the weights of the empty containers, and calculate the percentage of water.

**Other requirements**—It meets the requirements for *pH, Copper,* and *Content of bleomycins* under *Bleomycin Sulfate*. It meets also the requirements for *Uniformity of Dosage Units* ⟨905⟩ and for *Labeling* ⟨7⟩, *Labels and Labeling for Injectable Products*.

**Assay**—

*Assay preparation*—Constitute Bleomycin for Injection as directed in the labeling. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and quantitatively dilute with *Buffer B.16* to obtain a solution having a convenient concentration.

*Procedure*—Proceed as directed under *Antibiotics—Microbial Assays* ⟨81⟩, using an accurately measured volume of *Assay preparation* diluted quantitatively and stepwise with *Buffer B.16* 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 |
|---|---|---|
| BLEOMYCIN FOR INJECTION | Jennifer Tong Sun<br>Senior Scientist II | BIO42020 Biologics Monographs 4 - Antibiotics |

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