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Bacitracin for Injection

DEFINITION

Bacitracin for Injection has a potency of NLT 50 Bacitracin Units/mg. It contains NLT 90.0% and NMT 115.0% of the labeled amount of bacitracin.

IDENTIFICATION

• **A. Thin-Layer Chromatographic Identification Test ⟨201BNP⟩:** Meets the requirements

ASSAY

• **Procedure**

(See *Antibiotics—Microbial Assays ⟨81⟩*.)

Sample solution 1: Nominally 100 Bacitracin Units/mL, prepared as follows. Constitute one container of Bacitracin for Injection as directed in the labeling. Using a suitable hypodermic needle and syringe, withdraw the contents of the container, and dilute with *Buffer B.1* (see the chapter) to a suitable volume.

Sample solution 2 (where the label states the number of Bacitracin Units in a given volume of constituted solution)**:** Nominally 100 Bacitracin Units/mL, prepared as follows. Constitute one container of Bacitracin for Injection as directed in the labeling. Dilute a suitable aliquot of the constituted solution with *Buffer B.1* (see the chapter) to a suitable final volume.

Analysis

Samples: *Sample solution 1* or *Sample solution 2*

Proceed as directed in the chapter. Add sufficient 0.01 N hydrochloric acid to the *Sample solution* so that the amount of hydrochloric acid in the *Test Dilution* is the same as in the median level of the standard. Dilute with *Buffer B.1* to obtain a *Test Dilution* having a bacitracin concentration that is nominally equivalent to the median level of the standard.

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements

IMPURITIES

• **Residue on Ignition ⟨281⟩**

Analysis: Moisten the charred residue with 2 mL of nitric acid and 5 drops of sulfuric acid.

Acceptance criteria: NMT 3.0%

SPECIFIC TESTS

• **Constituted Solution:** At the time of use, it meets the requirements in *Injections and Implanted Drug Products ⟨1⟩, Specific Tests, Completeness and clarity of solutions*.

• **pH ⟨791⟩**

Sample solution: A solution containing 10,000 Bacitracin Units/mL

Acceptance criteria: 5.5–7.5

• **Loss on Drying ⟨731⟩**

Analysis: Dry 100 mg in a capillary-stoppered bottle under vacuum at a pressure of NMT 5 mm of mercury at 60° for 3 h.

Acceptance criteria: NMT 5.0%

• **Sterility Tests ⟨71⟩:** It meets the requirements when tested as directed in *Test for Sterility of the Product to Be Examined, Membrane Filtration*.

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 0.01 USP Endotoxin Unit/Bacitracin Unit.

• **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products ⟨1⟩*

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve as described in *Packaging and Storage Requirements ⟨659⟩, Injection Packaging, Packaging for constitution*, and store in a cool place.

• **USP Reference Standards ⟨11⟩**

USP Bacitracin Zinc RS

Topic/Question	Contact	Expert Committee
BACITRACIN FOR INJECTION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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