

Status: Currently Official on 17-Feb-2025  
Official Date: Official Prior to 2013  
Document Type: USP Monographs  
DocId: GUID-21B01E02-543A-4052-A22E-B9684BEC4190\_1\_en-US  
DOI: [https://doi.org/10.31003/USPNF\\_M6894\\_01\\_01](https://doi.org/10.31003/USPNF_M6894_01_01)  
DOI Ref: tb4gu

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# Bacitracin Methylenedisalicylate Soluble Powder

### DEFINITION

Bacitracin Methylenedisalicylate Soluble Powder contains NLT 90.0% and NMT 120.0% of the labeled amount of bacitracin.

### ASSAY

• [ANTIBIOTICS—MICROBIAL ASSAYS \(81\)](#).

**Diluent:** 20 g/L of sodium bicarbonate

**Sample stock solution:** Transfer a suitable amount of Bacitracin Methylenedisalicylate Soluble Powder to a high-speed glass blender jar, add 99.0 mL of *Diluent* and 1.0 mL of polysorbate 80, and blend for 3 min.

**Test dilution:** To a suitable aliquot of the *Sample stock solution*, add a suitable volume of 0.01 N hydrochloric acid and dilute with *Buffer B.1* to obtain a concentration of bacitracin assumed to be equal to the median dose level of the Standard. [NOTE—The amount of hydrochloric acid in the *Test dilution* should be the same as that in the median dose level of the Standard.]

**Analysis:** Proceed as directed for Bacitracin in [Antibiotics—Microbial Assays \(81\)](#).

**Acceptance criteria:** 90.0%–120.0%

### SPECIFIC TESTS

• [pH \(791\)](#): 8.0–9.5 in a 50 mg/mL solution

• [Loss on Drying \(731\)](#): Dry 100 mg in a capillary-stoppered bottle in a vacuum at a pressure not exceeding 5 mm of mercury at 60° for 3 h: it loses NMT 8.5% of its weight.

### ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.

• **LABELING:** Label it to indicate that it is for veterinary use only. Label it to state the content of bacitracin in terms of grams per pound, each gram of bacitracin being equivalent to 42,000 Bacitracin Units.

• [USP REFERENCE STANDARDS \(11\)](#).

[USP Bacitracin Zinc RS](#)

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

Topic/Question	Contact	Expert Committee
BACITRACIN METHYLENEDISALICYLATE SOLUBLE POWDER	<a href="#">Ying Han</a> Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services <a href="mailto:RSTECH@usp.org">RSTECH@usp.org</a>	BIO42020 Biologics Monographs 4 - Antibiotics

**Chromatographic Database Information:** [Chromatographic Database](#)

### Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 35(5)

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