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Soluble Bacitracin Methylenedisalicylate

DEFINITION

Soluble Bacitracin Methylenedisalicylate is a mixture of Bacitracin Methylenedisalicylate and Sodium Bicarbonate. It has a potency of NLT 8 Bacitracin Units/mg, calculated on the dried basis.

ASSAY

- [ANTIBIOTICS—MICROBIAL ASSAYS \(81\)](#)

Diluent: 20 g/L of sodium bicarbonate

Sample stock solution: Transfer a suitable amount of Soluble Bacitracin Methylenedisalicylate 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: NLT 8 Bacitracin Units/mg on the dried basis

SPECIFIC TESTS

- [pH \(791\)](#): 8.0–9.5, in a 25 mg/mL solution
- [Loss on Drying \(731\)](#): Dry 100 mg in a capillary-stoppered bottle in 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 well-closed containers.
- **LABELING:** Label it to indicate that it is for veterinary use only.
- [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
SOLUBLE BACITRACIN METHYLENEDISALICYLATE	Documentary Standards Support	SM32020 Small Molecules 3
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM32020 Small Molecules 3

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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