Status: Currently Official on 17-Feb-2025
Official Date: Official as of 01-May-2018
Document Type: USP Monographs
DocId: GUID-EF6827DF-FF44-4599-BE5C-CEDC9123E4CB_3_en-US
DOI: https://doi.org/10.31003/USPNF_M8654_03_01
DOI Ref: g49og

Benzylpenicilloyl Polylysine Injection

» Benzylpenicilloyl Polylysine Injection has a molar concentration of benzylpenicilloyl moiety ($C_{16}N_2H_{19}O_5S$) of not less than 5.4×10^{-5} M and not more than 7.0×10^{-5} *M*. It contains one or more suitable buffers.

Packaging and storage—Preserve in single-dose or in multiple-dose containers, preferably of Type I glass, in a refrigerator.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 5833.0 USP Endotoxin 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*.

pH ⟨791⟩**:** between 6.5 and 8.5.

Assay—

Saline phosphate buffer and *Mercuric chloride solution*—Prepare as directed in the *Assay* under *Benzylpenicilloyl Polylysine Concentrate*.

Assay preparation—Combine the contents of a sufficient number of containers to obtain not less than 3 mL of Injection. Transfer 3.0 mL of Injection to a 10-mL volumetric flask, dilute with *Saline phosphate buffer* to volume, and mix.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Benzylpenicilloyl Polylysine Concentrate*. Calculate the molar concentration of benzylpenicilloyl moiety in the Injection taken by the formula:

$$(10/3)\{[A_m(3 + 0.02n)/3] - A_i\}/22{,}325b$$

in which the terms are as defined therein.

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

Topic/Question	Contact	Expert Committee
BENZYLPENICILLOYL POLYLYSINE INJECTION	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. Information currently unavailable

Current DocID: GUID-EF6827DF-FF44-4599-BE5C-CEDC9123E4CB_3_en-US
Previous DocID: GUID-EF6827DF-FF44-4599-BE5C-CEDC9123E4CB_1_en-US
DOI: https://doi.org/10.31003/USPNF_M8654_03_01
DOI ref: g49og