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Penicillin G Potassium Injection

DEFINITION

Penicillin G Potassium Injection is a sterile isoosmotic solution of Penicillin G Potassium in Water for Injection. It contains one or more suitable buffers and a tonicity-adjusting agent. It contains NLT 90.0% and NMT 115.0% of the labeled number of Penicillin G Units.

IDENTIFICATION

• **A.** The retention time of the penicillin G peak of *Sample solution 1* or *Sample solution 2* corresponds to that of *Standard solution 2*, as obtained in the *Assay*.

ASSAY

• **Procedure**

Buffer A: Dissolve 0.8 g of sodium citrate dihydrate in 150 mL of water. Adjust with 0.1 N hydrochloric acid to a pH of 6.8, and dilute with water to 200 mL.

Buffer B: Dissolve 10 g of monobasic potassium phosphate in 900 mL of water, adjust with phosphoric acid to a pH of 4.15, and dilute with water to 1000 mL.

Mobile phase: Methanol and *Buffer B* (450:550)

Standard stock solution: 2000 Penicillin G Units/mL from USP Penicillin G Potassium RS in *Buffer A*

Standard solution 1: 100 Penicillin G Units/mL from *Standard stock solution* in water

Standard solution 2: 200 Penicillin G Units/mL from *Standard stock solution* in water

Standard solution 3: 300 Penicillin G Units/mL from *Standard stock solution* in water

Sample solution 1 (where it is represented as being in a single-dose container)**:** Allow 1 container of Injection to thaw, and mix. Withdraw all of the withdrawable contents, using a suitable hypodermic needle and syringe, and dilute with water to obtain a solution containing nominally about 200 Penicillin G Units/mL.

Sample solution 2 (where the label states the quantity of penicillin G in a given volume of Injection)**:** Allow 1 container of Injection to thaw, and mix. Dilute a suitable aliquot of the Injection with water to obtain a solution containing nominally about 200 Penicillin G Units/mL.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 225 nm

Column: 4.6-mm × 10-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution 2*

Suitability requirements

Tailing factor: NMT 2

Relative standard deviation: NMT 2%

Analysis

Samples: *Standard solution 1*, *Standard solution 2*, *Standard solution 3*, and *Sample solution 1* or *Sample solution 2*

Plot the peak responses from the *Standard solutions* versus concentration in Penicillin G Units/mL and draw the straight line best fitting the three plotted points.

Calculate the percentage of the labeled number of Penicillin G Units in the portion of Injection taken:

$$\text{Result} = [(N \times D)/L] \times 100$$

N = concentration of *Sample solution 1* or *Sample solution 2* determined from the graph (Penicillin G Units/mL)

D = dilution factor for *Sample solution 1* or *Sample solution 2* (mL/mL)

L = labeled number of Penicillin G Units in Injection (Penicillin G Units/mL)

Acceptance criteria: 90.0%–115.0%

SPECIFIC TESTS

• **Bacterial Endotoxins Test ⟨85⟩:** It contains NMT 0.01 USP Endotoxin Units/100 Penicillin G Units.

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

• **pH ⟨791⟩:** 5.5–8.0

• **Particulate Matter in Injections ⟨788⟩:** Meets the requirements for small-volume injections

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose containers, as described in *Packaging and Storage Requirements ⟨659⟩*. Maintain in the frozen state.

• **Labeling:** It meets the requirements in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*. The label states that it is to be thawed just before use, describes conditions for proper storage of the resultant solution, and directs that the solution is not to be refrozen.

• **USP Reference Standards ⟨11⟩**

USP Penicillin G Potassium RS

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

Topic/Question	Contact	Expert Committee
PENICILLIN G POTASSIUM INJECTION	Ying Han Associate Science & Standards Liaison	BIO42020 Biologics Monographs 4 - Antibiotics
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	BIO42020 Biologics Monographs 4 - Antibiotics

Chromatographic Database Information: Chromatographic Database

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