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Penicillin G Potassium for Oral Solution

DEFINITION

Penicillin G Potassium for Oral Solution is a dry mixture of Penicillin G Potassium and one or more suitable buffers, colors, diluents, flavors, and preservatives. It contains NLT 90.0% and NMT 130.0% of the labeled number of Penicillin G Units when constituted as directed in the labeling.

IDENTIFICATION

• **A. Thin-Layer Chromatography**

Solution A: Acetone, 0.1 M citric acid, and 0.1 M sodium citrate (2:1:1)

Standard solution: Prepare a solution containing the equivalent of 12,000 Penicillin G Units/mL from USP Penicillin G Potassium RS in *Solution A*

Sample solution: Shake a portion of it, containing nominally 100,000 Penicillin G Units, with 8 mL of *Solution A*

Chromatographic system

(See *Chromatography ⟨621⟩, Thin-Layer Chromatography*.)

Adsorbent: 0.25-mm layer of chromatographic silica gel mixture

Application volume: 20 µL

Developing solvent system: Toluene, dioxane, and glacial acetic acid (90:25:4)

Spray reagent 1: Starch TS

Spray reagent 2: Iodine TS diluted 1 in 10 with water

Analysis

Samples: *Standard solution* and *Sample solution*

Place the plate in a suitable chromatographic chamber. Develop the chromatogram in the *Developing solvent system* until the solvent front has moved three-fourths of the length of the plate. Remove the plate from the chamber, mark the solvent front, and allow to air-dry. Spray the plate with *Spray reagent 1* followed by *Spray reagent 2*. Penicillin G appears as a white spot on a purple background.

Acceptance criteria: The R_F value of the penicillin G spot of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **Procedure**

Standard solution: Prepare as directed in *Iodometric Assay—Antibiotics ⟨425⟩, Standard Preparation*, using USP Penicillin G Potassium RS.

Sample solution: Constitute Penicillin G Potassium for Oral Solution as directed in the labeling using *Buffer B.1* (see *Antibiotics—Microbial Assay ⟨81⟩, Media and Solutions, Solutions*). Dilute a suitable aliquot to obtain a solution containing nominally 2000 Penicillin G Units/mL.

Analysis

Samples: *Standard solution* and *Sample solution*

Pipet 2 mL of the *Sample solution* into each of two glass-stoppered, 125-mL conical flasks. Proceed as directed in *Iodometric Assay—Antibiotics ⟨425⟩, Procedure*, using one of the flasks to perform the *Blank Determination*.

Calculate the percentage of the labeled number of Penicillin G Units in the portion of Penicillin G Potassium for Oral Solution taken:

$$\text{Result} = (B - I) \times F \times [1/(D \times V)] \times 100$$

B = volume of 0.01 N sodium thiosulfate consumed in the *Blank Determination* (mL)

I = volume of 0.01 N sodium thiosulfate consumed in the *Inactivation* and *Titration* (mL)

F = equivalency factor as calculated in the chapter (Penicillin G Unit/mL of 0.01 N sodium thiosulfate consumed by the *Standard solution*)

D = nominal concentration of penicillin G in the *Sample solution* (Penicillin G Units/mL)

V = volume of *Sample solution* used for the *Inactivation* and *Titration* (mL)

Acceptance criteria: 90.0%–130.0%

PERFORMANCE TESTS

• **Uniformity of Dosage Units** ⟨905⟩

For solids packaged in single-unit containers: Meets the requirements

• **Deliverable Volume** ⟨698⟩**:** Meets the requirements

SPECIFIC TESTS

• **pH** ⟨791⟩

Sample solution: Constitute as directed in the labeling.

Acceptance criteria: 5.5–7.5

• **Water Determination** ⟨921⟩, *Method I*: NMT 1.0%

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **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 FOR ORAL SOLUTION	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

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

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