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Penicillin G Potassium Tablets

DEFINITION
Penicillin G Potassium Tablets contain NLT 90.0% and NMT 120.0% of the labeled number of Penicillin G Units.

IDENTIFICATION

• **A. Thin-Layer Chromatography**

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

Standard solution: 12,000 Penicillin G Units/mL from USP Penicillin G Potassium RS in *Diluent*

Sample solution: Nominally 12,500 Penicillin G Units/mL from Tablets in *Diluent*. Pass through a suitable filter.

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*

Apply the *Sample solution* and the *Standard solution* to the plate, place in a suitable chromatographic chamber, and develop the chromatogram, using 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 from the *Sample solution* corresponds to that from 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: Nominally 2000 Penicillin G Units/mL, prepared as follows. Place NLT 5 Tablets in a high-speed glass blender jar containing a measured volume of *Buffer B.1*, and blend for 4 ± 1 min. Dilute a suitable aliquot with *Buffer B.1*.

Analysis: Proceed as directed in *Iodometric Assay—Antibiotics ⟨425⟩, Procedure*, using glass-stoppered, 125-mL conical flasks.

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

$$\text{Result} = (B - I) \times (F/2) \times (1/C_U) \times 100$$

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

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

F = factor as calculated in *Iodometric Assay—Antibiotics ⟨425⟩, Calculations*

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

Acceptance criteria: 90.0%–120.0%

PERFORMANCE TESTS

• **Dissolution ⟨711⟩**

Medium: pH 6.0 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*); 900 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: 400 Penicillin G Units/mL from USP Penicillin G Potassium RS in *Medium*

Sample solution: Use a filtered portion of the solution under test.

Solution A: A 1-in-1000 solution of polyoxyethylene (23) lauryl ether in water

Solution B: Dissolve 20 g of hydroxylamine hydrochloride in 5 mL of *Solution A*, and add water to make 1000 mL.

Buffer: 26 mg/mL of sodium hydroxide and 3.1 mg/mL of sodium acetate in water

Ferric nitrate solution: Suspend 233 g of ferric nitrate in about 600 mL of water, add 2.8 mL of sulfuric acid, stir until the ferric nitrate is dissolved, add 1 mL of polyoxyethylene (23) lauryl ether, dilute with water to 1000 mL, and mix.

Apparatus: Automatic analyzer (*Figure 1*) consisting of (1) a liquid sampler, (2) a proportioning pump, (3) suitable spectrophotometers equipped with matched flow cells and analysis capability at 480 nm, (4) a means of recording spectrophotometric readings and/or a computer for data retrieval and calculation, and (5) a manifold consisting of the components illustrated in the figure.

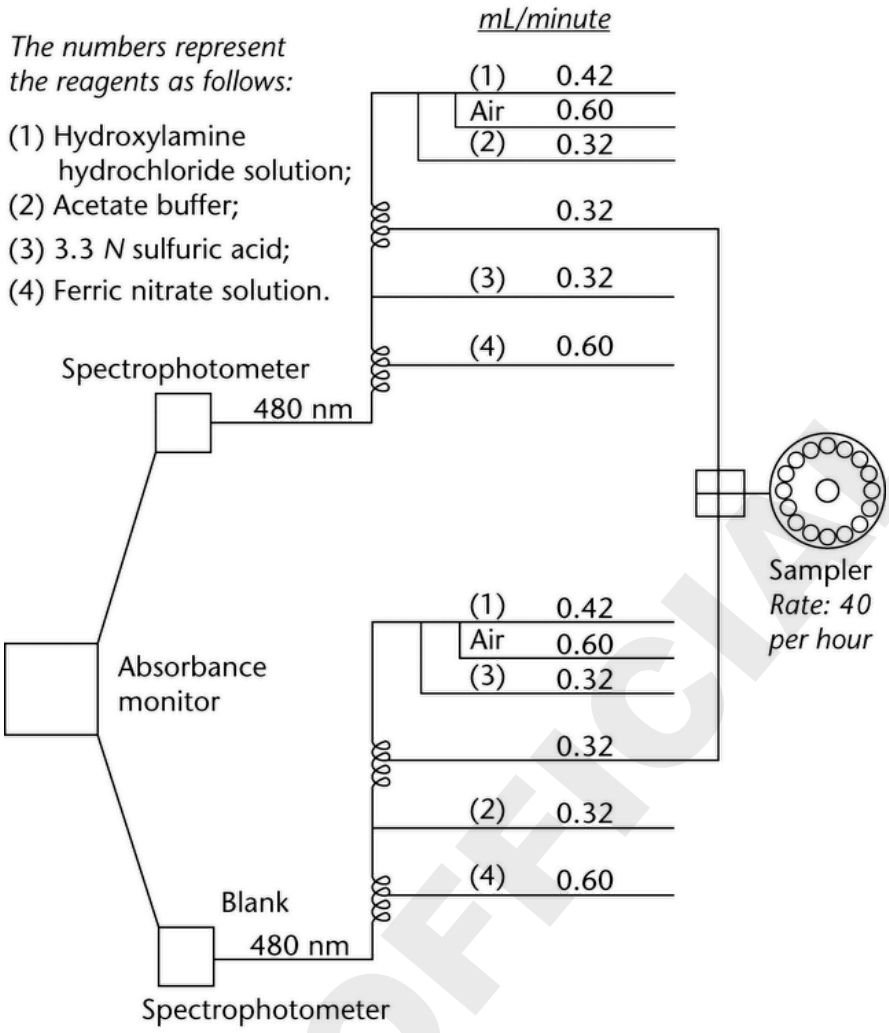

Figure 1

Analysis: With the sample line pumping water, the other lines pumping their respective reagents, and the spectrophotometer set at 480 nm, standardize the system until a steady absorbance baseline has been established. Transfer portions of the *Standard solution* and the *Sample solution* to sampler cups, and place in the sampler. Start the sampler, and conduct determinations of the *Standard solution* and the *Sample solution*, typically at the rate of 40 per h, using a ratio of about 2:1 for sample and wash time.

Calculate the percentage of the labeled amount of Penicillin G Units dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times (1/L) \times 100$$

A_U = absorbance of the *Sample solution*

A_S = absorbance of the *Standard solution*

C_S = concentration of USP Penicillin G Potassium RS in the *Standard solution* (Penicillin G Units/mL)

V = volume of *Medium*, 900 mL

L = label claim (Penicillin G Units/Tablet)

Tolerances: NLT 70% (Q) of the labeled amount of Penicillin G Units is dissolved.

- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

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 TABLETS	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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