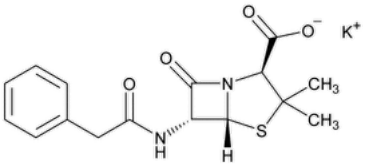
Status: Currently Official on 18-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-CFB4110E-97BA-4B31-BC88-D9D938CA0922_4_en-US
DOI: https://doi.org/10.31003/USPNF_M61540_04_01
DOI Ref: yp3tf

Penicillin G Potassium



$C_{16}H_{17}KN_2O_4S$ 372.48

4-Thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid, 3,3-dimethyl-7-oxo-6-[(phenylacetyl)amino]-, monopotassium salt, [2*S*-(2α,5α,6β)]-;

Monopotassium (2*S*,5*R*,6*R*)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate CAS RN®: 113-98-4; UNII: VL775ZTH4C.

DEFINITION

Penicillin G Potassium has a potency of NLT 1440 and NMT 1680 Penicillin G Units/mg.

IDENTIFICATION

Change to read:

• **A.** ▲Spectroscopic Identification Tests ⟨197⟩, *Infrared Spectroscopy*: **197K**▲ (CN 1-May-2020)

• **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

• **C.**

Diluent: Glycerin and water (25:14)

Solution A: 106 mg/mL of sodium carbonate in water

Solution B: 120 mg/mL of sodium sulfide in *Diluent*, prepared as follows. Dissolve sodium sulfide in *Diluent*, using about 45% of the final volume and heat. Allow to cool, and dilute with *Diluent* to the final volume.

Solution C: 150 mg/mL of tartaric acid in water

Sample solution: 0.1 g of Penicillin G Potassium in 2 mL of water

Analysis

Part 1: Add 1 mL of *Solution A* to the *Sample solution* and heat.

Part 2: To the hot solution from *Part 1* add 0.05 mL of *Solution B*.

Part 3: Cool the mixture from *Part 2* in iced water and add 2 mL of *Solution C*. Allow to stand.

Acceptance criteria: Meets the requirements for *Parts 1*, *2*, and *3*

Part 1: No precipitate is formed.

Part 2: No precipitate is formed.

Part 3: A white precipitate is formed.

ASSAY

• **Procedure**

Solution A: 0.01 M monobasic potassium phosphate

Mobile phase: Methanol and *Solution A* (40:60)

System suitability solution: 0.1 mg/mL each of USP Penicillin G Potassium RS and 2-phenylacetamide in water

Standard solution: 0.1 mg/mL of USP Penicillin G Potassium RS in water. This solution contains about 160 Penicillin G Units/mL. Shake as needed to dissolve.

Sample solution: 0.1 mg/mL of Penicillin G Potassium in water. Shake as needed to dissolve.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

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

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for 2-phenylacetamide and penicillin G are about 0.8 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between 2-phenylacetamide and penicillin G, *System suitability solution*

Tailing factor: NMT 2.0, *Standard solution*

Relative standard deviation: NMT 2.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the potency of penicillin G potassium, in Penicillin G Units/mg, in the portion of Penicillin G Potassium taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times P$$

r_U = peak response of penicillin G from the *Sample solution*

r_S = peak response of penicillin G from the *Standard solution*

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

C_U = concentration of Penicillin G Potassium in the *Sample solution* (mg/mL)

P = potency of USP Penicillin G Potassium RS (Penicillin G Units/mg)

Acceptance criteria: 1440–1680 Penicillin G Units/mg

SPECIFIC TESTS

• **CRYSTALLINITY ⟨695⟩:** Meets the requirements

• **pH ⟨791⟩**

Sample solution: 60 mg/mL of Penicillin G Potassium in water

Acceptance criteria: 5.0–7.5

• **LOSS ON DRYING ⟨731⟩**

Sample: 100 mg of Penicillin G Potassium

Analysis: Dry the *Sample* in a capillary-stoppered bottle under vacuum at 60° for 3 h.

Acceptance criteria: NMT 1.5%

• **BACTERIAL ENDOTOXINS TEST ⟨85⟩:** Where the label states that Penicillin G Potassium is sterile or it must be subjected to further processing during the preparation of injectable dosage forms, it has NMT 0.01 USP Endotoxin Units/100 Penicillin G Units.

• **STERILITY TESTS ⟨71⟩:** Where the label states that Penicillin G Potassium is sterile, it meets the requirements.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers.

• **LABELING:** Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

• **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	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. PF 41(3)

Current DocID: GUID-CFB4110E-97BA-4B31-BC88-D9D938CA0922_4_en-US

DOI: https://doi.org/10.31003/USPNF_M61540_04_01

DOI ref: yp3tf