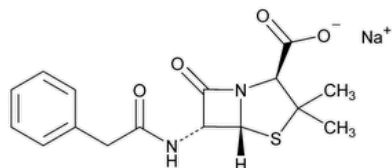


Status: Currently Official on 16-Feb-2025
 Official Date: Official as of 01-May-2020
 Document Type: USP Monographs
 DocId: GUID-F7B6A3A8-33F9-46CD-9A7D-2042C06669F5_4_en-US
 DOI: https://doi.org/10.31003/USPNF_M61728_04_01
 DOI Ref: ye83j

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Penicillin G Sodium



$C_{16}H_{17}N_2NaO_4S$ 356.37

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

Monosodium (2S,5R,6R)-3,3-dimethyl-7-oxo-6-(2-phenylacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylate CAS RN®: 69-57-8; UNII: YS5LY7JF4N.

DEFINITION

Penicillin G Sodium has a potency of NLT 1500 and NMT 1750 Penicillin G Units/mg.

IDENTIFICATION

Change to read:

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **B.** [IDENTIFICATION TESTS—GENERAL \(191\)](#), [Sodium](#): Meets the requirements

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. Shake as needed to dissolve. This solution contains about 160 Penicillin G Units/mL.

Sample solution: 0.1 mg/mL of Penicillin G Sodium in water

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 220 nm

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

Flow rate: 1 mL/min

Injection volume: 10 μ L

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*

Column efficiency: NLT 1000 theoretical plates, *Standard 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 sodium, in Penicillin G Units/mg, in the portion of Penicillin G Sodium 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 Sodium in the *Sample solution* (mg/mL)

P = potency of penicillin G in [USP Penicillin G Potassium RS](#) (Penicillin G Units/mg)

Acceptance criteria: 1500–1750 Penicillin G Units/mg

SPECIFIC TESTS

• [CRYSTALLINITY \(695\)](#): Meets the requirements

• [pH \(791\)](#)

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

Acceptance criteria: 5.0–7.5

• [LOSS ON DRYING \(731\)](#)

Sample: 100 mg of Penicillin G Sodium

Analysis: Dry the *Sample* in a capillary-stoppered bottle under a vacuum at a pressure NMT 5 mm of mercury at 60° for 3 h.

Acceptance criteria: NMT 1.5%

• [STERILITY TESTS \(71\)](#): Where the label states that Penicillin G Sodium is sterile, it meets the requirements when tested as directed in [Test for Sterility of the Product to Be Examined, Membrane Filtration](#).

• [BACTERIAL ENDOTOXINS TEST \(85\)](#): Where the label states that Penicillin G Sodium is sterile or it must be subjected to further processing during the preparation of injectable dosage forms, it contains NMT 0.01 USP Endotoxin Units/100 Penicillin G Units.

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](#)

[USP Penicillin G Sodium RS](#)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
PENICILLIN G SODIUM	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 27(1)

Current DocID: GUID-F7B6A3A8-33F9-46CD-9A7D-2042C06669F5_4_en-US

DOI: https://doi.org/10.31003/USPNF_M61728_04_01

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