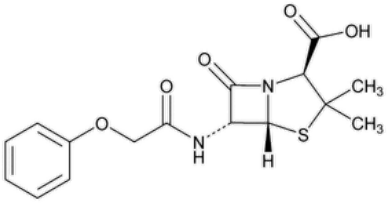
Status: Currently Official on 16-Feb-2025
Official Date: Official as of 01-May-2020
Document Type: USP Monographs
DocId: GUID-E7B52E9A-A968-4FD8-9A0A-CE4A418714F9_2_en-US
DOI: https://doi.org/10.31003/USPNF_M61790_02_01
DOI Ref: zaw1t

Penicillin V



$C_{16}H_{18}N_2O_5S$ 350.39

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

(2*S*,5*R*,6*R*)-3,3-Dimethyl-7-oxo-6-(2-phenoxyacetamido)-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid CAS RN®: 87-08-1; UNII: Z61I075U2W.

DEFINITION

Penicillin V has a potency of NLT 1525 and NMT 1780 Penicillin V Units/mg.

IDENTIFICATION

Change to read:

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

Sample: Do not dry.

Acceptance criteria: Meets the requirements

ASSAY

• **Procedure**

Mobile phase: Acetonitrile, glacial acetic acid, and water (350:5.75:650)

System suitability solution: 2.5 mg/mL each of USP Penicillin G Potassium RS and USP Penicillin V Potassium RS in *Mobile phase*

Standard solution: 2.5 mg/mL of USP Penicillin V Potassium RS in *Mobile phase*

Sample solution: 2.5 mg/mL of Penicillin V in *Mobile phase*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; 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 *p*-hydroxypenicillin V, penicillin G, and penicillin V are about 0.4, 0.8, and 1.0, respectively.]

Suitability requirements

Resolution: NLT 3.0 between penicillin G and penicillin V, *System suitability solution*

Column efficiency: NLT 1800 theoretical plates, *System suitability solution*

Relative standard deviation: NMT 1.0% for penicillin V potassium, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

r_U = sum of the peak responses of *p*-hydroxypenicillin V and penicillin V from the *Sample solution*

r_S = sum of the peak responses of *p*-hydroxypenicillin V and penicillin V from the *Standard solution*

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

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

P = potency of penicillin V in USP Penicillin V Potassium RS (Penicillin V Units/mg)

Acceptance criteria: 1525–1780 Penicillin V Units/mg

IMPURITIES

- **Limit of Phenoxyacetic Acid**

Mobile phase: Acetonitrile, glacial acetic acid, and water (35:1:65)

Diluent: pH 6.6 phosphate buffer (see *Reagents, Indicators, and Solutions—Buffer Solutions*)

Standard solution: 0.1 mg/mL of phenoxyacetic acid in *Diluent*

Sample solution: 20.0 mg/mL of Penicillin V in *Diluent*. Use this solution on the day prepared.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 5-µm packing L1

Flow rate: 1 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 1.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of phenoxyacetic acid in the portion of Penicillin V taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak area of phenoxyacetic acid from the *Sample solution*

r_S = peak area of phenoxyacetic acid from the *Standard solution*

C_S = concentration of phenoxyacetic acid in the *Standard solution* (mg/mL)

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

Acceptance criteria: NMT 0.5%

- **Limit of *p*-Hydroxypenicillin V**

Mobile phase, System suitability solution, Standard solution, Sample solution, Chromatographic system and **System suitability:** Proceed as directed in the *Assay*.

Analysis

Sample: *Sample solution*

Calculate the percentage of *p*-hydroxypenicillin V in the portion of Penicillin V taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response of *p*-hydroxypenicillin V from the *Sample solution*

r_T = sum of the peak responses of *p*-hydroxypenicillin V and penicillin V

Acceptance criteria: NMT 5.0%

SPECIFIC TESTS

- **Crystallinity ⟨695⟩:** Meets the requirements
- **pH ⟨791⟩**

  Sample solution: Prepare a suspension containing 30 mg/mL of Penicillin V in water

  Acceptance criteria: 2.5–4.0
- **Water Determination ⟨921⟩, *Method I*:** NMT 2.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **Labeling:** Label it to indicate that it is to be used in the manufacture of nonparenteral drugs only.
- **USP Reference Standards ⟨11⟩**

  USP Penicillin G Potassium RS

  USP Penicillin V RS

  USP Penicillin V Potassium RS

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

Topic/Question	Contact	Expert Committee
PENICILLIN V	Documentary Standards Support	SM12020 Small Molecules 1
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM12020 Small Molecules 1

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 45(6)

Current DocID: GUID-E7B52E9A-A968-4FD8-9A0A-CE4A418714F9_2_en-US

DOI: https://doi.org/10.31003/USPNF_M61790_02_01

DOI ref: zaw1t