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Penicillin V Potassium for Oral Solution

DEFINITION

Penicillin V Potassium for Oral Solution is a dry mixture of Penicillin V Potassium with or without one or more suitable buffers, colors, flavors, preservatives, and suspending agents. It contains NLT 90.0% and NMT 135.0% of the labeled number of Penicillin V Units when constituted as directed.

IDENTIFICATION

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

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: Constitute Penicillin V Potassium for Oral Solution as directed in the labeling. Transfer a suitable aliquot containing nominally 400,000 Penicillin V Units to a suitable volumetric flask. Dilute with *Mobile phase* to volume, and mix to obtain a solution containing nominally 4000 Penicillin V Units/mL. Pass a portion of this solution through a suitable filter of 0.5-µm or finer pore size.

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%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

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

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

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

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

Acceptance criteria: 90.0%–135.0%

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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: 5.0–7.5

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

ADDITIONAL REQUIREMENTS

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

• **Labeling:** It may be labeled in terms of the weight of penicillin V contained therein, in addition to or instead of Units, on the basis that 1600 Penicillin V Units are equivalent to 1 mg of penicillin V.

• **USP Reference Standards** ⟨11⟩

USP Penicillin G Potassium 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 POTASSIUM FOR ORAL SOLUTION	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

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