Penicillin V Potassium Tablets

» Penicillin V Potassium Tablets contain not less than 90.0 percent and not more than 120.0 percent of the labeled number of Penicillin V Units.

Packaging and storage—Preserve in tight containers.

Labeling—Label the chewable Tablets to indicate that they are to be chewed before swallowing. The Tablets 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 V Potassium RS

Identification—The retention time of the penicillin V peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Dissolution ⟨711⟩**—**

Medium: pH 6.0 phosphate buffer (see *Buffer Solutions* in the section *Reagents, Indicators, and Solutions*); 900 mL.

Apparatus 2: 50 rpm.

Time: 45 minutes.

Procedure—Determine the amount of Penicillin V Units by a suitable validated spectrophotometric analysis of a filtered portion of the solution under test, suitably diluted with *Dissolution Medium*, if necessary, in comparison with a Standard solution of USP Penicillin V Potassium RS in the same medium having a known concentration of Penicillin V Units.

Tolerances—Not less than 75% *(Q)* of the labeled amount of Penicillin V Units is dissolved in 45 minutes.

Uniformity of dosage units ⟨905⟩: meet the requirements.

Loss on drying ⟨731⟩**—**Dry about 100 mg in a capillary-stoppered bottle in vacuum at 60° for 3 hours: it loses not more than 1.5% of its weight.

Assay—

Mobile phase, Standard preparation, Resolution solution, and *Chromatographic system*—Proceed as directed in the *Assay* under *Penicillin V*.

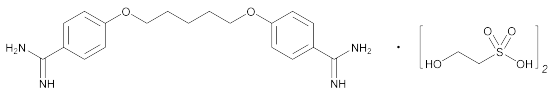
Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 400,000 USP Penicillin V Units, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and shake for about 5 minutes. Filter a portion of this solution through a suitable filter having a 0.5-µm or finer porosity, and use the filtrate as the *Assay preparation*.

Procedure—Proceed as directed for *Procedure* in the *Assay* under *Penicillin V*. Calculate the number of USP Penicillin V Units in the portion of Tablets taken by the formula:

$$100CP(r_U / r_S)$$

in which the terms are as defined therein.

Pentamidine Isethionate



$C_{19}H_{24}N_4O_2 \cdot (C_2H_6O_4S)_2$ 592.70

Ethanesulfonic acid, 2-hydroxy-, compd. with 4,4′-[1,5-pentanediylbis(oxy)]bis [benzenecarboximidamide]; 4,4′-(Pentane-1,5-diylbis(oxy))dibenzimidamide bis(2-hydroxyethanesulfonate) [140-64-7].

DEFINITION

Pentamidine Isethionate contains NLT 98.5% and NMT 101.5% of $C_{19}H_{24}N_4O_2 \cdot (C_2H_6O_4S)_2$, calculated on the dried basis.

IDENTIFICATION

- **A. Infrared Absorption** ⟨197K⟩
- **B. Oxygen-Flask Combustion** ⟨471⟩

Barium chloride solution: 60 mg/mL of barium chloride in water

Analysis: Burn 150 mg, using 10 mL of 3% hydrogen peroxide as the absorbing liquid. When the process is complete, acidify with 1 mL of diluted hydrochloric acid, and add 1 mL of the *Barium chloride solution*.

Acceptance criteria: A white precipitate is formed.

- **C.** The retention time of the pentamidine isethionate peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the test for *Organic Impurities*.

ASSAY

- **Procedure**

Sample solution: 5 mg/mL in dimethylformamide. Add 0.25 mL of thymol blue TS.

Analysis: Titrate under a stream of nitrogen with 0.1 M tetrabutylammonium hydroxide VS, determining the endpoint until the color changes to intense blue. Perform a blank determination, and make any necessary correction (see *Titrimetry* ⟨541⟩). Each mL of 0.1 M tetrabutylammonium hydroxide is equivalent to 29.63 mg of $C_{19}H_{24}N_4O_2 \cdot (C_2H_6O_4S)_2$.

Acceptance criteria: 98.5%–101.5% on the dried basis

IMPURITIES

Inorganic Impurities

- **Heavy Metals,** *Method I* ⟨231⟩**:** NMT 20 ppm
- **Residue on Ignition** ⟨281⟩

Acceptance criteria: NMT 0.1% on a 1-g sample

Organic Impurities

- **Procedure**

Buffer: 30 mg/mL of ammonium acetate in water, adjusted with triethylamine to a pH of 7.5

Mobile phase: Methanol and *Buffer* (65:35)

System suitability solution: Prepare 40.0 mL of a 2.5 mg/mL solution of USP Pentamidine Isethionate RS in water. Adjust with 0.2 M sodium hydroxide to a pH of 10.5, and boil under reflux for 20 min. Cool, and dilute with water to 50.0 mL. Transfer quantitatively 1 mL of this solution to a 50-mL volumetric flask, and dilute with *Mobile phase* to volume.

Standard solution: 2 µg/mL of USP Pentamidine Isethionate RS in *Mobile phase*

Sample solution: 1.0 mg/mL of Pentamidine Isethionate in *Mobile phase*. [NOTE—It must be demonstrated that the final product does not contain a detectable amount of alkyl 2-hydroxyethanesulphonates, a potential in-process impurity.]

Chromatographic system

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

Mode: LC

Detector: UV 265 nm

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

Flow rate: 1 mL/min

Injection size: 10 µL

Run time: 3.5 times the retention time of pentamidine

System suitability

Sample: *System suitability solution*

Suitability requirements

Resolution: NLT 2 between the two major peaks. [NOTE—The chromatogram shows two major peaks.]

Analysis

Samples: *Standard solution* and *Sample solution*

Acceptance criteria

Individual impurities: NMT 0.4%. [NOTE—Exclude any other peak producing a response of less than 0.02%.]

Total impurities: NMT 0.7%