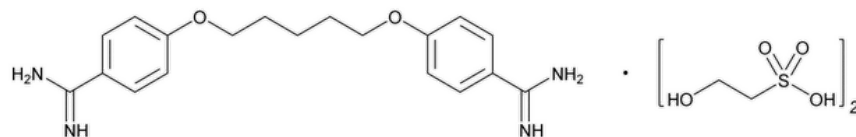


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Pentamidine Isethionate



$C_{19}H_{24}N_4O_2 \cdot (C_2H_6O_4S)_2$ 592.68

Ethanesulfonic acid, 2-hydroxy-, compd. with 4,4'-[1,5-pentanediy]bis[benzenecarboximidamide];

4,4'-[1,5-pentanediy]bis[benzenecarboximidamide] bis(2-hydroxyethanesulfonate) CAS RN®: 140-64-7; UNII: V2P3K60DA2.

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

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)
- **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

- [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%

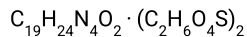
SPECIFIC TESTS

- **pH (791):** 4.5–6.5, in a carbon dioxide-free aqueous solution containing 50 mg/mL of Pentamidine Isethionate
- **Loss on Drying (731):** Dry at 105°: it loses NMT 4.0% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light. Store at controlled room temperature.
- **USP REFERENCE STANDARDS (11).**

[USP Pentamidine Isethionate RS](#)



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

Topic/Question	Contact	Expert Committee
PENTAMIDINE ISETHIONATE	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:

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