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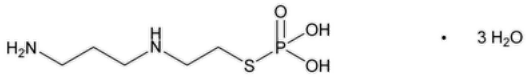
Amifostine



$C_5H_{15}N_2O_3PS \cdot 3H_2O$ 268.27

Ethanethiol, 2-[(3-aminopropyl)amino]-, dihydrogen phosphate (ester), trihydrate;

S-[2-(3-Aminopropyl)amino]ethyl]dihydrogen phosphorothioate, trihydrate CAS RN®: 112901-68-5; UNII: M487QF2F4V.

DEFINITION

Amifostine contains NLT 78.0% and NMT 82.0% of $C_5H_{15}N_2O_3PS$, calculated on the as-is basis.

IDENTIFICATION

Change to read:

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

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

ASSAY

• **Procedure**

Buffer: 0.94 g/L of sodium 1-hexanesulfonate. Adjust with phosphoric acid to a pH of 3.0.

Mobile phase: Methanol and *Buffer* (7:18)

Standard solution: 3 mg/mL of USP Amifostine RS in water. [Note—Inject immediately after preparation.]

Sample solution: 3 mg/mL of Amifostine in water.
[Note—Inject immediately after preparation.]

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 4.6-mm × 25-cm; 5-µm packing L7

Autosampler temperature: 4°

Flow rate: 1.0 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Column efficiency: NLT 1000 theoretical plates

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of $C_5H_{15}N_2O_3PS$ in the portion of Amifostine taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

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

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

Acceptance criteria: 78.0%–82.0% on the as-is basis

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IMPURITIES

Organic Impurities

- **Procedure**

Mobile phase and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 70 µg/mL of USP Amifostine Thiol RS and 16 µg/mL of USP Amifostine RS in water. [Note—Inject immediately after preparation.]

System suitability solution: Use the *Standard solution* as described in the *Assay*. [Note—Inject immediately after preparation.]

Sample solution: 15 mg/mL of Amifostine in water.

[Note—Inject immediately after preparation.]

System suitability

Samples: *Standard solution* and *System suitability solution*

Suitability requirements

Column efficiency: NLT 1000 theoretical plates, *System suitability solution*

Tailing factor: NMT 2.0, *System suitability solution*

Relative standard deviation: NMT 15.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of amifostine thiol in the portion of Amifostine taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (M_{r1}/M_{r2}) \times 100$$

r_U = peak response of amifostine thiol from the *Sample solution*

r_S = peak response of amifostine thiol from the *Standard solution*

C_S = concentration of USP Amifostine Thiol RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of amifostine in the *Sample solution* (mg/mL)

M_{r1} = molecular weight of amifostine thiol, 134.24

M_{r2} = molecular weight of amifostine thiol dihydrochloride, 207.17

Calculate the percentage of any other individual impurity in the portion of Amifostine taken:

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

r_U = peak response of each individual impurity in the *Sample solution*

r_S = peak response of amifostine in the *Standard solution*

C_S = concentration of USP Amifostine RS in the *Standard solution* (µg/mL)

C_U = concentration of the *Sample solution* (µg/mL)

Acceptance criteria

Amifostine thiol: NMT 0.3%

Any individual impurity, excluding amifostine thiol: NMT 0.1%

Total impurities including amifostine thiol: NMT 0.3%

SPECIFIC TESTS

- **pH** ⟨791⟩**:** 6.5–7.5, in a solution (5 in 100)
- **Water Determination,** *Method Ic*⟨921⟩

Sample solution: To 100.0 mg of Amifostine, contained in a stoppered centrifuge tube, add 10.0 mL of the solution of *N*-ethylmaleimide in methanol (4 in 100), and sonicate for 15 min. Shake to disperse, and sonicate for an additional 15 min. Use 1.0 mL of the supernatant.

Acceptance criteria: 19.2%–21.2%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight, light-resistant containers, and store in a refrigerator.
- **USP Reference Standards** ⟨11⟩

USP Amifostine RS

USP Amifostine Thiol RS

Ethanethiol, 2-[(3-aminopropyl)amino]-, dihydrochloride.

$C_5H_{16}N_2SCl_2$ 207.17

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Topic/Question	Contact	Expert Committee
AMIFOSTINE	Documentary Standards Support	SM22020 Small Molecules 2
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM22020 Small Molecules 2

Chromatographic Database Information: Chromatographic Database

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