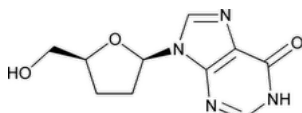


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Didanosine



$C_{10}H_{12}N_4O_3$ 236.23

Inosine, 2',3'-dideoxy-

2',3'-Dideoxyinosine CAS RN®: 69655-05-6; UNII: K3GDH6OH08.

DEFINITION

Didanosine contains NLT 98.0% and NMT 102.0% of $C_{10}H_{12}N_4O_3$, calculated on the anhydrous 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 from the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

Buffer: 0.77 g/L of ammonium acetate in water

Mobile phase: Acetonitrile and *Buffer* (1:21)

Standard solution: 0.1 mg/mL of [USP Didanosine RS](#) in water

Sample solution: 0.1 mg/mL of Didanosine in water

[NOTE—Mix for 1 h to dissolve completely before use.]

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 2 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

[NOTE—The retention time of didanosine is between 7 and 11 min.]

Suitability requirements

Column efficiency: NLT 6000 theoretical plates

Tailing factor: NMT 2.5

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of didanosine ($C_{10}H_{12}N_4O_3$) in the portion of Didanosine 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 the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–102.0% on the anhydrous basis

IMPURITIES

- **RESIDUE ON IGNITION (281):** NMT 0.2%

Change to read:• **RELATED COMPOUNDS**

Buffer: Prepare as directed in the Assay.

Diluent: Adjust the pH of the *Buffer* with sodium hydroxide to 9. Prepare a mixture of acetonitrile and *Buffer* (1:19).

Solution A: Acetonitrile and *Buffer* (1:19)

Solution B: Acetonitrile and *Buffer* (1:3)

System suitability solution: 0.5 mg/mL of ▲ (ERR 1-Jun-2019) [USP Didanosine System Suitability Mixture RS](#) in *Diluent*

Standard stock solution A: 0.05 mg/mL of [USP Didanosine Related Compound A RS](#) in *Diluent*

Standard stock solution B: 0.025 mg/mL of [USP Didanosine RS](#) in *Diluent*

Standard stock solution C: 0.025 mg/mL of [USP Didanosine Related Compound B RS](#) in *Diluent*

Standard solution: 5 µg/mL of [USP Didanosine Related Compound A RS](#), 1.5 µg/mL of [USP Didanosine RS](#), and 1.5 µg/mL of [USP Didanosine Related Compound B RS](#) from a mixture of *Standard stock solution A*, *Standard stock solution B*, and *Standard stock solution C*, respectively, diluted with *Diluent*

Sample solution: 0.5 mg/mL of Didanosine in *Diluent*

Mobile phase: See [Table 1](#).

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
15	100	0
20	0	100
30	0	100
35	100	0
45	100	0

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: 2 mL/min

Injection size: 10 µL

System suitability

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

[NOTE—Didanosine elutes between 6 and 7.5 min; the relative retention times for didanosine, didanosine related compound A, and didanosine related compound B are 1.0, 0.28, and 2.11, respectively.]

Suitability requirements

Resolution: NLT 3.0 between didanosine and dideoxydideohydroinosine, *System suitability solution*

Column efficiency: NLT 6000 theoretical plates for dideoxydideohydroinosine, *System suitability solution*

Relative standard deviation: NMT 2.0% for didanosine related compound A, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of didanosine related compound A in the portion of Didanosine taken:

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

r_U = peak response of didanosine related compound A from the *Sample solution*

r_S = peak response of didanosine related compound A from the *Standard solution*

C_S = concentration of [USP Didanosine Related Compound A RS](#) in the *Standard solution* (mg/mL)

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