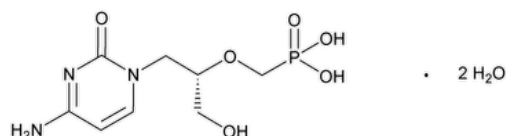


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Cidofovir

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$C_8H_{14}N_3O_6P \cdot 2H_2O$ 315.22

Phosphonic acid, [[2-(4-amino-2-oxo-1(2H)-pyrimidyl)-1-(hydroxymethyl)ethoxy]methyl]-, dihydrate, (S)-;
 1-[(S)-3-Hydroxy-2-(phosphonylmethoxy)propyl]cytosine dihydrate CAS RN®: 149394-66-1.

Anhydrous

$C_8H_{14}N_3O_6P$ 279.19 CAS RN®: 113852-37-2.

DEFINITION

Cidofovir contains NLT 98.0% and NMT 102.0% of cidofovir ($C_8H_{14}N_3O_6P$), 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 *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

ASSAY

PROCEDURE

[NOTE—Solutions containing cidofovir are stable at room temperature for 8 h.]

Solution A: Acetonitrile and water (40:60)

Buffer: Dissolve 1.2 g of [dibasic ammonium phosphate](#) and 2.0 g of [tetrabutylammonium phosphate](#) in 1 L of water. Adjust with [ammonium hydroxide](#) to a pH of 9.2.

Mobile phase: *Solution A* and *Buffer* (22:78)

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

Sample solution: 0.1 mg/mL of Cidofovir in water

Chromatographic system

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

Mode: LC

Detector: UV 274 nm

Column: 4.6-mm × 25-cm; 5-μm packing [L1](#)

Column temperature: 30°

Flow rate: 1 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: 0.8–1.5

Relative standard deviation: NMT 0.73%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of cidofovir ($C_8H_{14}N_3O_6P$) in the portion of Cidofovir 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 Cidofovir RS](#) in the *Standard solution* (mg/mL)

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

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

IMPURITIES

Delete the following:

▲ [RESIDUE ON IGNITION \(281\)](#)

Analysis: Perform the ignition at $850 \pm 50^\circ$; silica crucibles are suitable.

Acceptance criteria: NMT 0.5%▲ (RB 1-Jun-2019)

• ORGANIC IMPURITIES

[NOTE—Solutions containing cidofovir are stable at room temperature for 8 h.]

Mobile phase and Chromatographic system: Proceed as directed in the Assay with a run time four times the retention time of cidofovir.

System suitability solution: 1.5 µg/mL each of [USP Cidofovir Related Compound A RS](#) and [USP Cidofovir Related Compound B RS](#) in water

Standard solution: 0.001 mg/mL of [USP Cidofovir RS](#) in water

Sample solution: 1 mg/mL of Cidofovir in water

System suitability

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

[NOTE—See [Table 1](#) for relative retention times.]

Suitability requirements

Resolution: NLT 1.5 between cidofovir related compound A and cidofovir related compound B, *System suitability solution*

Relative standard deviation: NMT 5%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each individual impurity in the portion of Cidofovir taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times (1/F) \times 100$$

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

r_S = peak response of cidofovir from the *Standard solution*

C_S = concentration of [USP Cidofovir RS](#) in the *Standard solution* (mg/mL)

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

F = relative response factor (see [Table 1](#))

Acceptance criteria

Individual impurities: See [Table 1](#). Disregard any impurity peaks less than 0.02%.

Table 1

Name	Relative Retention Time	Relative Response Factor	Acceptance Criteria, NMT (%)
Cidofovir diol analog ^a	0.30	1.3	0.15
Cidofovir related compound A	0.54	0.74	0.15

