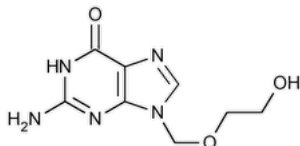


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Acyclovir

Change to read:



$C_8H_{11}N_5O_3$ $\blacktriangle$ 225.21 $\blacktriangle$ (IRA 1-Jun-2024)
 6H-Purin-6-one, 2-amino-1,9-dihydro-9-[(2-hydroxyethoxy)methyl]-;
 9-[(2-Hydroxyethoxy)methyl]guanine CAS RN[®]: 59277-89-3; UNII: X4HES1O11F.

Change to read:

DEFINITION

Acyclovir contains NLT 98.0% and NMT $\blacktriangle$ 102.0% $\blacktriangle$ (IRA 1-Jun-2024) of acyclovir ($C_8H_{11}N_5O_3$), calculated on the anhydrous basis.

IDENTIFICATION

- **A.** [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), *Infrared Spectroscopy*: 197K or 197A
- **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

Change to read:

PROCEDURE

Mobile phase: [Glacial acetic acid](#) in [water](#) (1 in 1000)

Standard stock solution: 0.5 mg/mL of [USP Acyclovir RS](#) prepared as follows. Dissolve about 25 mg of [USP Acyclovir RS](#) in 5 mL of 0.1 N [sodium hydroxide](#) in a 50-mL volumetric flask, and dilute with [water](#) to volume.

Standard solution: 0.1 mg/mL of [USP Acyclovir RS](#) from *Standard stock solution* in 0.01 N [sodium hydroxide](#)

Sample stock solution: 0.5 mg/mL of Acyclovir prepared as follows. Dissolve about 100 mg of Acyclovir in 20 mL of 0.1 N [sodium hydroxide](#) in a 200-mL volumetric flask, and dilute with [water](#) to volume.

Sample solution: 0.1 mg/mL of Acyclovir from *Sample stock solution* in 0.01 N [sodium hydroxide](#)

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; 10-μm packing [L1](#)

Flow rate: 3 mL/min

Injection volume: 20 μL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2

Relative standard deviation: NMT $\blacktriangle$ 0.73% $\blacktriangle$ (IRA 1-Jun-2024)

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of acyclovir ($C_8H_{11}N_5O_3$) in the portion of Acyclovir taken:

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

r_U = peak response of acyclovir from the *Sample solution*

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

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

C_u = concentration of Acyclovir in the *Sample solution* (mg/mL)

Acceptance criteria: 98.0%– $\blacktriangle$ 102.0% $\blacktriangle$ (IRA 1-Jun-2024) on the anhydrous basis

IMPURITIES

Change to read:

• ORGANIC IMPURITIES

Buffer A: 3.48 g/L of $\blacktriangle$ [dibasic potassium phosphate](#) anhydrous $\blacktriangle$ (IRA 1-Jun-2024) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.1.

Buffer B: 3.48 g/L of $\blacktriangle$ [dibasic potassium phosphate](#) anhydrous $\blacktriangle$ (IRA 1-Jun-2024) in [water](#). Adjust with [phosphoric acid](#) to a pH of 2.5.

Solution A: [Acetonitrile](#) and Buffer A (1:99)

Solution B: [Acetonitrile](#) and Buffer B (50:50)

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

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
5	100	0
27	80	20
40	80	20

Diluent: [Dimethyl sulfoxide](#) and [water](#) (20:80 v/v)

System suitability solution: 0.01 mg/mL of [USP Acyclovir RS](#) and 0.5 μ g/mL each of [USP Acyclovir Related Compound A RS](#) and [USP Acyclovir Related Compound F RS](#) prepared as follows. Dissolve a suitable amount of [USP Acyclovir RS](#), [USP Acyclovir Related Compound A RS](#), and [USP Acyclovir Related Compound F RS](#) in 20% of the $\blacktriangle$ (IRA 1-Jun-2024) flask volume of [dimethyl sulfoxide](#) and dilute with [water](#) to volume.

Standard stock solution: 0.1 mg/mL of [USP Acyclovir RS](#) prepared as follows. Dissolve a suitable amount of [USP Acyclovir RS](#) in 20% of the $\blacktriangle$ (IRA 1-Jun-2024) flask volume of [dimethyl sulfoxide](#) and dilute with [water](#) to volume.

Sensitivity solution: 0.3 μ g/mL of [USP Acyclovir RS](#) from *Standard stock solution* in *Diluent*

Standard solution: $\blacktriangle$ 0.001 mg/mL $\blacktriangle$ (IRA 1-Jun-2024) of [USP Acyclovir RS](#) from *Standard stock solution* in *Diluent*

Sample solution: 1 mg/mL of Acyclovir prepared as follows. Dissolve a suitable amount of Acyclovir in 20% of the $\blacktriangle$ (IRA 1-Jun-2024) flask volume of [dimethyl sulfoxide](#) and dilute with [water](#) to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm $\times$ 25-cm; 5- μ m packing [L1](#)

Flow rate: 1 mL/min

Injection volume: 10 μ L

System suitability

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

$\blacktriangle$ [NOTE—The relative retention times in [Table 2](#) are provided as information that could aid in peak assignment.]

Table 2 $\blacktriangle$ (IRA 1-Jun-2024)

Name	Relative Retention Time
Guanine $\blacktriangle$ ^a $\blacktriangle$ (IRA 1-Jun-2024)	0.40
Hydroxyethyl guanine ^b	0.74
N ⁷ -Isomer ^c	