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Acyclovir for Injection

DEFINITION
Acyclovir for Injection contains NLT 90.0% and NMT 110.0% of the labeled amount of acyclovir ($C_8H_{11}N_5O_3$).

IDENTIFICATION
• **A.** 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**

Mobile phase: 0.02 M acetic acid

System suitability solution A: 0.1 mg/mL each of USP Acyclovir RS and guanine in 0.1 N sodium hydroxide

System suitability solution B: 2.0 µg/mL of guanine in 0.1 N sodium hydroxide

Standard solution: 0.1 mg/mL of USP Acyclovir RS in 0.1 N sodium hydroxide

Sample solution: Nominally 0.1 mg/mL of acyclovir prepared as follows. Constitute 1 vial of Acyclovir for Injection with water. Transfer an amount, equivalent to 10 mg of acyclovir, to a 100-mL volumetric flask, and dilute with water to volume.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.2-mm × 25-cm; packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution A* and *System suitability solution B*

[Note—The relative retention times for guanine and acyclovir are 0.6 and 1.0, respectively, in *System suitability solution A*.]

Suitability requirements

Resolution: NLT 2.0 between guanine and acyclovir, *System suitability solution A*

Relative standard deviation: NMT 2.0% for the acyclovir peak, *System suitability solution A*

Relative standard deviation: NMT 2.0%, *System suitability solution B*

Analysis

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

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

r_U = peak response of the *Sample solution*

r_S = peak response of the *Standard solution*

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

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

Acceptance criteria: 90.0%–110.0%

IMPURITIES

Change to read:

• **Procedure**

Solution A: 0.17 M acetic acid and methanol (125:8)

Solution B: Methanol

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	100	0
15	100	0
45	65	35
46	100	0
56	100	0

System suitability solution: 0.5 µg/mL each of purine and USP Acyclovir RS in *Solution A*

Acyclovir standard solution: 5 µg/mL of USP Acyclovir RS in *Solution A*

Guanine solution: 0.05 mg/mL of guanine prepared as follows. Dissolve 25 mg of guanine in 50 mL of 0.1 N sodium hydroxide in a 500-mL volumetric flask, and bring the solution to volume with water.

Standard solution A: 0.5 µg/mL of ▲USP Acyclovir RS from▲ (ERR 1-Apr-2022) *Acyclovir standard solution* in *Solution A*

Standard solution B: 5 µg/mL of ▲guanine from▲ (ERR 1-Apr-2022) *Guanine solution* in *Solution A*

Sample solution: Equivalent to 0.5 mg/mL of acyclovir from a mixture of NLT 10 reconstituted vials of Acyclovir for Injection in *Solution A*

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 4.6-mm × 25-cm; packing L1

Flow rate: 1 mL/min

Injection volume: 50 µL

System suitability

Samples: *System suitability solution*, *Standard solution A*, and *Standard solution B*

[NOTE—Typical retention times for guanine and acyclovir of *Standard solution A* and *Standard solution B* are 5.8 and 14 min, respectively.]

Suitability requirements

Resolution: NLT 2.0 between purine and acyclovir, *System suitability solution*

Relative standard deviation: NMT 1% for the acyclovir and the guanine peaks, *Standard solution A* and *Standard solution B*

Analysis 1

Calculate the percentage of guanine in the Acyclovir for Injection taken:

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

r_U = peak response for guanine, if present, in the *Sample solution*

r_S = peak response of guanine in ▲*Standard solution B*▲ (ERR 1-Apr-2022)

C_S = concentration of guanine in ▲*Standard solution B*▲ (ERR 1-Apr-2022) (mg/mL)

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

Acceptance criteria 1: NMT 1.0% guanine

Analysis 2

Calculate the percentage of each other impurity in the portion of Acyclovir for Injection taken:

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

r_U = peak response for each impurity

r_S = peak response of acyclovir in ▲*Standard solution A*▲ (ERR 1-Apr-2022)

C_S = concentration of USP Acyclovir RS in ▲*Standard solution A*▲ (ERR 1-Apr-2022) (mg/mL)

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

Acceptance criteria 2: NMT 0.15% for any peak having a relative retention time of about 0.7 compared to the acyclovir peak; NMT 0.5% for any other individual impurity; and NMT 1.0% for the total of all other impurities

SPECIFIC TESTS

- **pH ⟨791⟩:** 11.0–12.5, 50 mg/mL of acyclovir
- **Water Determination, *Method I* ⟨921⟩:** NMT 5.5%
- **Sterility Tests ⟨71⟩:** Meets the requirements
- **Uniformity of Dosage Units ⟨905⟩:** Meets the requirements
- **Bacterial Endotoxins Test ⟨85⟩:** NMT 0.174 USP Endotoxin Unit/mg of acyclovir
- **Other Requirements:** Meets the requirements for labeling in *Labeling ⟨7⟩, Labels and Labeling for Injectable Products*

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers. Store between 15° and 25°. Protect from light.
- **USP Reference Standards ⟨11⟩**
  USP Acyclovir RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ACYCLOVIR FOR INJECTION	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

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