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

• **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
•	100	0
•	1••	•
•	100	0
•	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 *Acyclovir standard solution* in *Solution A*
Standard solution B: 5 µg/mL of *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 the *Standard solution*
C_S = concentration of guanine in the *Standard solution* (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 the *Standard solution*
C_S = concentration of USP Acyclovir RS in the *Standard solution* (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.

Change to read:

• **USP REFERENCE STANDARDS** ⟨11⟩
USP Acyclovir RS
• (CN 1-May-2018)

Acyclovir Ointment

DEFINITION

Acyclovir Ointment contains NLT 90.0% and NMT 110.0% of the labeled amount of acyclovir ($C_8H_{11}N_5O_3$), in a suitable ointment base.

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. Transfer an amount of Ointment, equivalent to 10 mg of acyclovir, to a 100-mL volumetric flask. Dissolve in and dilute with 0.1 N sodium hydroxide to volume.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: LC
Detector: UV 254 nm
Column: 4.6-mm × 25-cm; packing L1
Flow rate: 3 mL/min
Injection volume: 20 µL
System suitability
Samples: *System suitability solution A* and *System suitability solution B*