100-mL volumetric flask. Dissolve in 10 mL of 0.1 N sodium hydroxide, dilute to volume with water, and filter.

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 about 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: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of acyclovir ($C_8H_{11}N_5O_3$) in the portion of Capsules 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 = nominal concentration of acyclovir in the *Sample solution* (mg/mL)

Acceptance criteria: 93.0%–107.0%

PERFORMANCE TESTS

• **DISSOLUTION** ⟨*711*⟩
Medium: 0.1 N hydrochloric acid; 900 mL
Apparatus 1: 100 rpm
Time: 45 min
Detector: UV 254 nm
Standard solution: USP Acyclovir RS in *Medium*
Sample solutions: Dilute with *Medium* to a concentration that is similar to the *Standard solution*.
Analysis: Determine the amount of acyclovir ($C_8H_{11}N_5O_3$) dissolved from UV absorption at the wavelength of maximum absorption on filtered portions of the solution under test.
Tolerances: NLT 75% (*Q*) of the labeled amount of acyclovir ($C_8H_{11}N_5O_3$) is dissolved.

• **UNIFORMITY OF DOSAGE UNITS** ⟨**905**⟩**:** Meet the requirements for *Content Uniformity*

IMPURITIES

• **PROCEDURE**
Mobile phase, System suitability solution A, System suitability solution B, Sample solution, Chromatographic system, and **System suitability:** Proceed as directed in the *Assay*.
Analysis: *Sample solution*
Calculate the percentage of each impurity in the portion of Capsules taken:

$$\text{Result} = (r_U/r_T) \times 100$$

r_U = peak response for each impurity
r_T = sum of the responses for all of the peaks

Acceptance criteria
Guanine: NMT 2.0%
Any individual impurity: NMT 0.5%

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers. Store between 15° and 25°. Protect from light and moisture.
• **USP REFERENCE STANDARDS** ⟨**11**⟩
USP Acyclovir RS

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*