r_S = peak response for guanine from 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: NMT 2.0%

SPECIFIC TESTS

- **MICROBIAL ENUMERATION TESTS ⟨61⟩ and TESTS FOR SPECIFIED MICROORGANISMS ⟨62⟩:** Its total count does not exceed 10^1 cfu/mL, and it meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*.
- **PH ⟨791⟩:** 4.5–7.0

PERFORMANCE TESTS

- **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meets the requirements for Oral Suspension packaged in single-unit containers
- **DELIVERABLE VOLUME ⟨698⟩:** Meets the requirements for Oral Suspension packaged in multiple-unit containers

ADDITIONAL REQUIREMENTS

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

Acyclovir Tablets

DEFINITION

Acyclovir Tablets contain 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. Dissolve in 0.1 N sodium hydroxide, and dilute with water.

System suitability solution B: 2.0 µg/mL of guanine. Dissolve in 0.1 N sodium hydroxide, and dilute with water.

Standard solution: 0.1 mg/mL of USP Acyclovir RS. Dissolve in 0.1 N sodium hydroxide, and dilute with water.

Sample solution: Nominally 0.1 mg/mL of acyclovir prepared as follows. Transfer an amount of finely powdered Tablets equivalent to 10 mg of acyclovir (NLT 10 Tablets) to a 100-mL volumetric flask. Dissolve in 10 mL of 0.1 N sodium hydroxide, dilute with water to volume, and filter.

Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)
Mode: LC
Detector: UV 254 nm
Column: 4.6-mm × 25-cm; packing L1
Column temperature: 40°
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*; NMT 2.0%, *System suitability solution B*

Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of acyclovir ($C_8H_{11}N_5O_3$) in the portion of Tablets 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 Acyclovir RS in the *Standard solution* (mg/mL)
C_U = nominal concentration of acyclovir in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **DISSOLUTION ⟨711⟩**

Medium: 0.1 N hydrochloric acid; 900 mL
Apparatus 2: 50 rpm
Time: 45 min
Instrumental conditions
Mode: UV
Wavelength: 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 absorbance on filtered portions of the solution under test.
Tolerances: NLT 80% (*Q*) of the labeled amount of acyclovir ($C_8H_{11}N_5O_3$) is dissolved.

- **UNIFORMITY OF DOSAGE UNITS ⟨905⟩:** Meet the requirements for *Weight Variation*

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: *Sample solution*
Calculate the percentage of each impurity in the portion of Tablets 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 other 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