[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 Ointment 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

• **MINIMUM FILL ⟨755⟩:** Meets the requirements

IMPURITIES

• **LIMIT OF GUANINE**

Mobile phase, Sample solution, and Chromatographic system: Proceed as directed in the *Assay*.

Standard solution: 2.0 µg/mL of guanine in 0.1 M sodium hydroxide

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of guanine in the portion of Ointment taken:

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

r_U = peak response of guanine from the *Sample solution*
r_S = peak response of 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⟩:** It meets the requirements of the tests for the absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*.

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight containers. Store between 15° and 25° in a dry place.

• **USP REFERENCE STANDARDS ⟨11⟩**

USP Acyclovir RS

Acyclovir Oral Suspension

DEFINITION

Acyclovir Oral Suspension 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 stock solution: Nominally 1 mg/mL of acyclovir prepared as follows. Transfer an amount of well-shaken Oral Suspension equivalent to 200 mg of acyclovir to a 200-mL volumetric flask. Add 100 mL of 0.1 N sodium hydroxide, shake by mechanical means for 15 min, and sonicate, if necessary, to dissolve the Oral Suspension completely. Dilute with 0.1 N sodium hydroxide to volume.

Sample solution: Transfer 10.0 mL of the *Sample stock solution* 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: 4.6-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*

[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 replicate injections for the acyclovir peak, *System suitability solution A*

Relative standard deviation: NMT 2.0% for replicate injections, *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 Oral Suspension 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%

IMPURITIES

• **LIMIT OF GUANINE**

Mobile phase, System suitability solution A, System suitability solution B, Sample solution, Chromatographic system, and System suitability: Proceed as directed in the *Assay*.

Standard solution: 2.0 µg/mL of guanine in 0.1 M sodium hydroxide

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of guanine in the portion of Oral Suspension taken:

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

r_U = peak response for guanine from the *Sample solution*