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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

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

Topic/Question	Contact	Expert Committee
ACYCLOVIR TABLETS	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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