Status: Currently Official on 17-Feb-2025
Official Date: Official Prior to 2013
Document Type: USP Monographs
DocId: GUID-537FBCF3-F004-48C3-B813-792E252FE639_1_en-US
DOI: https://doi.org/10.31003/USPNF_M895_01_01
DOI Ref: 0x1lx

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*

[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

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

Topic/Question	Contact	Expert Committee
ACYCLOVIR OINTMENT	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

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 50(6)

Current DocID: GUID-537FBCF3-F004-48C3-B813-792E252FE639_1_en-US

DOI: https://doi.org/10.31003/USPNF_M895_01_01

DOI ref: 0x1lx