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Famciclovir Tablets

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DEFINITION

Famciclovir Tablets contain Famciclovir ▲▲ (USP 1-Aug-2022) equivalent to NLT 90.0% and NMT 110.0% of the labeled amount of famciclovir ($C_{14}H_{19}N_5O_4$).

IDENTIFICATION

- **A. SPECTROSCOPIC IDENTIFICATION TESTS (197), Infrared Spectroscopy:** 197K

Sample: Transfer a portion of finely powdered Tablets, equivalent to 1000 mg of famciclovir, to a 250-mL volumetric flask, and add 100 mL of [acetonitrile](#). Sonicate for 5 min and centrifuge for 10 min. Pass a portion through a filter of 0.45-μm or finer pore size into a 250-mL evaporating flask. Evaporate the solution to dryness at low heat (about 70°).

Acceptance criteria: Meet the requirements

- **B.** 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

Buffer A: 13.8 g/L of [monobasic sodium phosphate](#) in [water](#). Adjust with 1 M [sodium hydroxide](#) or [phosphoric acid](#) to a pH of 4.5 ± 0.05 .

Buffer B: 13.8 g/L of [monobasic sodium phosphate](#) in [water](#). Adjust with 1 M [sodium hydroxide](#) to a pH of 7.0 ± 0.05 .

Mobile phase: [Methanol](#) and *Buffer B* (30:70)

Standard solution: 0.1 mg/mL of [USP Famciclovir RS](#) in *Buffer A*

Sample stock solution: Nominally 1 mg/mL of famciclovir prepared as follows. Transfer an amount equivalent to 500 mg of famciclovir, from finely powdered Tablets (NLT 20), to an appropriate volumetric flask. Add about 50% of the flask volume of *Buffer A* and sonicate for about 15 min with intermittent shaking. Dilute with *Buffer A* to volume.

Sample solution: Nominally 0.1 mg/mL of famciclovir from *Sample stock solution* in *Buffer A*. Pass through a suitable filter of 0.45-μm or finer pore size.

Chromatographic system

(See [Chromatography \(621\), System Suitability](#).)

Mode: LC

Detector: UV 222 nm

Column: 4.6-mm × 15-cm; 5-μm packing [L1](#)

Column temperature: 40°

Flow rate: 1.5 mL/min

Injection volume: 20 μL

Run time: NLT 2 times the retention time of famciclovir

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of famciclovir ($C_{14}H_{19}N_5O_4$) in the portion of Tablets taken:

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

r_U = peak response of famciclovir from the *Sample solution*

r_S = peak response of famciclovir from the *Standard solution*

C_S = concentration of [USP Famciclovir RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of famciclovir in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

• [DISSOLUTION \(711\)](#)

Test 1

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Buffer: 6.8 g/L of [monobasic potassium phosphate](#) in water. Adjust with [phosphoric acid](#) to a pH of 3.0. Pass through a suitable filter of 0.45-µm pore size.

Mobile phase: [Methanol](#) and *Buffer* (30:70)

Standard stock solution: 0.55 mg/mL of [USP Famciclovir RS](#) prepared as follows. Transfer 55 mg of [USP Famciclovir RS](#) to a 100-mL volumetric flask, dissolve in about 50 mL of *Medium*, and dilute with *Buffer* to volume.

Standard solution: 0.055 mg/mL of [USP Famciclovir RS](#) in *Buffer* from *Standard stock solution*

Sample solution: Pass a portion of the solution under test through a suitable filter of 0.45-µm pore size, and dilute with *Buffer* to obtain a concentration similar to that of the *Standard solution*.

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 310 nm

Column: 4.6-mm × 15-cm; 5-µm packing [L1](#)

Column temperature: 35°

Flow rate: 1 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of famciclovir ($C_{14}H_{19}N_5O_4$) dissolved:

$$\text{Result} = (r_U/r_S) \times C_S \times V \times D \times (1/L) \times 100$$

r_U = peak response of famciclovir from the *Sample solution*

r_S = peak response of famciclovir from the *Standard solution*

C_S = concentration of [USP Famciclovir RS](#) in the *Standard solution* (mg/mL)

V = volume of *Medium*, 900 mL

D = dilution factor of the *Sample solution*, if applicable

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of famciclovir ($C_{14}H_{19}N_5O_4$) is dissolved.

Test 2: If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N [hydrochloric acid](#); 900 mL

Apparatus 2: 50 rpm

Time: 30 min

Standard solution: 0.55 mg/mL of [USP Famciclovir RS](#) in *Medium*

Sample solution: Pass a portion of the solution under test through a suitable filter and dilute with *Medium*, if necessary.

Instrumental conditions

Mode: UV

Analytical wavelength: 262 nm

Cell: 5 mm

Blank: *Medium*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of famciclovir ($C_{14}H_{19}N_5O_4$) dissolved:

$$\text{Result} = (A_U/A_S) \times C_S \times V \times D \times (1/L) \times 100$$