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Famciclovir Compounded Oral Suspension

DEFINITION

Famciclovir Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of famciclovir ($C_{14}H_{19}N_5O_4$).

Prepare Famciclovir Compounded Oral Suspension 100 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

Famciclovir tablets[a] equivalent to	10 g of famciclovir
Vehicle: a 1:1 mixture of Ora-Plus[b] and Ora-Sweet SF,[b] a sufficient quantity to make	100 mL

[a] Famvir 500-mg tablets, Novartis Pharmaceuticals Corporation, East Hanover, NJ.

[b] Perrigo Laboratories, Allegan, MI.

Place the *Famciclovir tablets* in a suitable container and comminute to a fine powder. Wet the powder with a small amount of *Vehicle* and triturate to make a smooth paste. Add the *Vehicle* to make the contents pourable. Transfer contents stepwise and quantitatively to a calibrated container using the *Vehicle*. Add sufficient *Vehicle* to bring to final volume. Shake to mix well.

ASSAY

• **Procedure**

Solution A: 5 mM monobasic potassium phosphate. Adjust with phosphoric acid to a pH of 3.0. Pass through a nylon filter of 0.45-µm pore size, and degas.

Mobile phase: Methanol and *Solution A* (30:70)

Diluent: Water. Adjust with phosphoric acid to a pH of 3.0.

Standard stock solution: 10 mg/mL of USP Famciclovir RS in *Diluent*. Sonicate to mix well. Store at 2°–8°.

Standard solution: Transfer 1.0 mL of the *Standard stock solution* to a 250-mL volumetric flask, dilute with *Diluent* to volume, and mix well. Transfer an aliquot to a centrifuge tube, and centrifuge at 2°–8° for 5 min at 14,000 rpm. Transfer the supernatant to an amber vial and store at 2°–8°.

Sample solution: Transfer 1.0 mL of Oral Suspension to a 10-mL volumetric flask, dilute with *Diluent* to volume, and sonicate to mix well. Transfer 1.0 mL of the resultant solution to a 250-mL volumetric flask, dilute with *Diluent* to volume, and mix well. Transfer an aliquot to a centrifuge tube, and centrifuge at 2°–8° for 5 min at 14,000 rpm. Transfer the supernatant to an amber vial and store at 2°–8°.

Chromatographic system

(See *Chromatography* ⟨621⟩, *System Suitability*.)

Mode: LC

Detector: UV-Vis 310 nm

Column: 4.6-mm × 15-cm; 5-µm packing L7

Temperatures

Column: 30°

Autosampler: 5°

Flow rate: 1.0 mL/min

Injection volume: 20 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for famciclovir is about 4.5 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

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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 Oral Suspension 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%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.3–6.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant, plastic containers. Store in a refrigerator (2°–8°) or at controlled room temperature.

• **Beyond-Use Date:** NMT 90 days after the date on which it was compounded when stored in a refrigerator (2°–8°) or at controlled room temperature.

• **Labeling:** Label it to indicate that it is to be well shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Famciclovir RS

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

Topic/Question	Contact	Expert Committee
FAMCICLOVIR COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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