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Valacyclovir Compounded Oral Suspension

DEFINITION

Valacyclovir Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of valacyclovir ($C_{13}H_{20}N_6O_4$).

Prepare Valacyclovir Compounded Oral Suspension 50 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Valacyclovir tablets[a] equivalent to	5 g of valacyclovir
Vehicle: a 1:1 mixture of Ora-Sweet[b] (regular or sugar-free) and Ora-Plus[b], a sufficient quantity to make	100 mL

[a] Valtrex 500-mg tablets, Glaxo Wellcome Inc., Research Triangle Park, NC.

[b] Paddock Laboratories, Minneapolis, MN.

Calculate the required quantity of each ingredient for the total amount to be prepared. Place the required number of *Valacyclovir tablets* in a suitable mortar, and comminute to a fine powder. Add the *Vehicle* in small portions, and triturate to make a smooth paste. Add increasing volumes of the *Vehicle* to make a valacyclovir liquid that is pourable. Transfer the contents of the mortar, stepwise and quantitatively, to a calibrated bottle. Add enough of the *Vehicle* to bring to final volume, and mix well.

ASSAY

• **Procedure**

Mobile phase: Acetonitrile and 5.0 mM sodium acetate (1:99). Adjust with 6 N hydrochloric acid to a pH of 3.0. Filter and degas.

Diluent: 5.0 mM sodium acetate, adjusted with 6 N hydrochloric acid to a pH of 3.0

Standard solution: Dissolve an appropriately weighed amount of USP Valacyclovir Hydrochloride RS in *Diluent* to be equivalent to 0.2 mg/mL of valacyclovir.

Sample solution: Shake thoroughly by hand each bottle of Oral Suspension. Prepare 0.2 mg/mL of valacyclovir from Oral Suspension and *Diluent*. Pass through a nylon filter of 0.22-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 254 nm

Column: 3.9-mm × 30-cm; 10-µm packing L1

Flow rate: 3.0 mL/min

Injection volume: 10 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for valacyclovir hydrochloride is about 14 min.]

Suitability requirements

Relative standard deviation: NMT 2.0% for replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of valacyclovir ($C_{13}H_{20}N_6O_4$) in the portion of Oral Suspension taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_S = concentration of USP Valacyclovir Hydrochloride RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.2–4.3

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistant glass containers. Store in a refrigerator.

• **Beyond-Use Date:** NMT 14 days after the date on which it was compounded when stored in a refrigerator

• **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 Valacyclovir Hydrochloride RS

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

Topic/Question	Contact	Expert Committee
VALACYCLOVIR COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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