

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:

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](#)

Most Recently Appeared In:

Pharmacopeial Forum: Volume No. PF 41(1)

Current DocID: GUID-C295ECF0-207A-4A96-96F8-1968288928FB_1_en-US

DOI: https://doi.org/10.31003/USPNF_M2161_01_01

DOI ref: [q8an6](#)

OFFICIAL