

Add the following:

Valine Compounded Oral Solution

DEFINITION

Valine Compounded Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of valine (C₅H₁₁NO₂).
Prepare Valine Compounded Oral Solution 10 mg/mL as follows (see [Pharmaceutical Compounding—Nonsterile Preparations \(795\)](#)).

Valine	1 g
Methylparaben	0.05 g
Propylparaben	0.025 g
Purified Water, a sufficient quantity to make	100 mL

In an appropriately sized container, add *Methylparaben* and *Propylparaben* to about 80 mL of *Purified Water*. Stir until dissolved. [NOTE—May heat up to 50° to facilitate dissolution.] Dissolve the *Valine* in the previously prepared solution of *Methylparaben* and *Propylparaben* and bring to final volume with *Purified Water*.

ASSAY

PROCEDURE

Solution A: 6.8 g/L of potassium phosphate monobasic in water. Filter.
Mobile phase: Acetonitrile and *Solution A* (65:35). Filter.
Diluent: Acetonitrile and *Solution A* (50:50)
Standard solution: 1 mg/mL of [USP L-Valine RS](#) in *Diluent*
Sample solution: Transfer 1 mL of Oral Solution into a 10-mL volumetric flask, dilute with *Diluent* to volume, and mix.
Chromatographic system
(See [Chromatography \(621\), System Suitability](#).)
Mode: LC
Detector: UV 210 nm
Column: 4.6-mm × 25-cm; 5-µm packing [L8](#)
Flow rate: 1.0 mL/min
Injection volume: 10 µL
System suitability
Sample: *Standard solution*
[NOTE—The retention time for valine is about 8.9 min.]
Suitability requirements
Tailing factor: NMT 2.0
Relative standard deviation: NMT 2.0% for replicate injections
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of the labeled amount of valine (C₅H₁₁NO₂) in the portion of Oral Solution taken:

Result = (r_U/r_S) × (C_S/C_U) × 100

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

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

C_s = concentration of [USP L-Valine RS](#) in the *Standard solution* (mg/mL)

C_u = nominal concentration of valine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- [pH \(791\)](#): 5.7–6.7

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Package in tight, light-resistant containers. Store in a refrigerator or at controlled room temperature.
- **BEYOND-USE DATE:** NMT 90 days after the date on which it was compounded when stored in a refrigerator or at controlled room temperature
- **LABELING:** Label it to state the *Beyond-Use Date*.
- **USP REFERENCE STANDARDS (11).**
[USP L-Valine RS](#) ▲ (USP 1-Aug-2023)

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
VALINE COMPOUNDED ORAL SOLUTION	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:

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