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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 ($C_5H_{11}NO_2$).

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 ($C_5H_{11}NO_2$) in the portion of Oral Solution taken:

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

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

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