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Valproic Acid Oral Solution

DEFINITION

Valproic Acid Oral Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of valproic acid ($C_8H_{16}O_2$). It is prepared with the aid of Sodium Hydroxide.

IDENTIFICATION

• **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

Change to read:

• **B.** ▲The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.▲ (USP 1-May-2019)

ASSAY

Change to read:

• PROCEDURE

Buffer: 3.5 g/L of [monobasic sodium phosphate](#) in [water](#). Adjust with [phosphoric acid](#) to a pH of 3.5.

Mobile phase: Acetonitrile and *Buffer* (45:55)

Diluent: Acetonitrile and [water](#) (45:55)

System suitability solution: 0.5 mg/mL of [USP Valproic Acid RS](#) and 50 µg/mL of [USP Valproic Acid Related Compound B RS](#) in *Diluent*

Standard solution: 0.5 mg/mL of [USP Valproic Acid RS](#) in *Diluent*

Sample solution: Nominally 0.5 mg/mL of valproic acid in *Diluent* from a suitable volume of Oral Solution

Chromatographic system

(See [Chromatography \(621\)](#), [System Suitability](#).)

Mode: LC

Detector: UV 215 nm. ▲For *Identification B*, use a diode array detector in the range of 200–400 nm.▲ (USP 1-May-2019)

Column: 4.6-mm × 15.0-cm; 5-µm packing [L7](#)

Flow rate: 1 mL/min

Injection volume: 20 µL

▲**Run time:** NLT 2 times the retention of valproic acid▲ (USP 1-May-2019)

System suitability

Samples: *System suitability solution* and *Standard solution*

[NOTE—The relative retention times for valproic acid related compound B and valproic acid are 0.90 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 2.0 between valproic acid related compound B and valproic acid, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of valproic acid ($C_8H_{16}O_2$) in the portion of Oral Solution taken:

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

r_U = peak response from the *Sample solution*

r_S = peak response from the *Standard solution*

C_s = concentration of [USP Valproic Acid RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

- [pH \(791\)](#): 7.0–8.0

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.

- **USP REFERENCE STANDARDS (11).**

[USP Valproic Acid RS](#)

[USP Valproic Acid Related Compound B RS](#)

(2RS)-2-(1-Methylethyl)pentanoic acid.

$C_8H_{16}O_2$ 144.21

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

Topic/Question	Contact	Expert Committee
VALPROIC ACID ORAL SOLUTION	Documentary Standards Support	SM42020 Small Molecules 4
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	SM42020 Small Molecules 4

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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