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Valproate Sodium Injection

DEFINITION

Valproate Sodium Injection is a sterile aqueous solution of sodium valproate, formed from the interaction of Valproic Acid and Sodium Hydroxide, in Water for Injection, and one or more suitable buffering or sequestering agents. It contains NLT 90.0% and NMT 110.0% of the labeled amount of valproic acid ($C_8H_{16}O_2$). It contains no antimicrobial agents.

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*.

Add the following:

▲• **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-Dec-2019)

Change to read:

• ▲**C.**▲ (USP 1-Dec-2019) **Identification Tests—General** ⟨191⟩*, Chemical Identification Tests, Sodium*: Meets the requirements

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 water from a suitable volume of Injection

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-Dec-2019)

Column: 4.6-mm × 15.0-cm; 5-µm packing L7

Flow rate: 1 mL/min

Injection volume: 20 µL

▲**Run time:** NLT 1.6 times the retention time of valproic acid▲ (USP 1-Dec-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 Injection 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

• **Bacterial Endotoxins Test** ⟨85⟩**:** NMT 23 USP Endotoxin Units/mL of Injection

• **Sterility Tests** ⟨71⟩, *Test for Sterility of the Product to Be Examined, Membrane Filtration***:** Meets the requirements

• **Particulate Matter in Injections** ⟨788⟩**:** Meets the requirements for small-volume parenterals

• **pH** ⟨791⟩**:** 7.0–9.0

• **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in single-dose containers as described in *Packaging and Storage Requirements* ⟨659⟩, *Injection Packaging*, preferably of Type I glass. Store at controlled room temperature.

• **Labeling:** It states the name and quantity of any buffering or sequestering agent used. It states that it is intended for use by intravenous infusion only.

• **USP Reference Standards** ⟨11⟩

USP Valproic Acid RS

USP Valproic Acid Related Compound B RS

(2*RS*)-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
VALPROATE SODIUM INJECTION	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

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