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Levocarnitine Oral Solution

DEFINITION

Levocarnitine Oral Solution is a solution of levocarnitine in water, and it contains suitable antimicrobial agents. It may contain a suitable flavor. It contains NLT 90.0% and NMT 110.0% of the labeled amount of levocarnitine ($C_7H_{15}NO_3$).

IDENTIFICATION

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

ASSAY

• **Procedure**

Buffer: 0.05 M phosphate buffer, pH 2.4, prepared by mixing 11.5 mL of phosphoric acid, 1900 mL of water, and about 100 mL of 1 N sodium hydroxide

Mobile phase: Dissolve 555 mg of sodium 1-heptanesulfonate in 980 mL of *Buffer* with stirring. Add 20 mL of methanol, and mix.

Internal standard solution: 0.02 mg/mL of *p*-aminobenzoic acid in water

Standard solution: Transfer about 10 mg of USP Levocarnitine RS to a 5-mL volumetric flask, add 1.0 mL of the *Internal standard solution,* and dilute with water to volume.

Sample stock solution: Equivalent to 10 mg/mL of levocarnitine in water from an accurately measured volume of Oral Solution

Sample solution: Wash a 10-mm × 4-cm disposable column containing 500 mg of packing L1, in order, with two column volumes of methylene chloride, two column volumes of methanol, and three column volumes of water. Pipet 5.0 mL of the *Sample stock solution* into the washed disposable column, and rinse the column twice with 6.0-mL portions of water. Collect the filtrate and washings in a 25-mL volumetric flask, add 5.0 mL of the *Internal standard solution,* and dilute with water to volume.

Chromatographic system

(See *Chromatography (621), System Suitability.)*

Mode: LC

Detector: UV 225 nm

Column: 3.9-mm × 30-cm; 10-µm packing L1

Flow rate: 1.5 mL/min

Injection size: 40 µL

System suitability

Sample: *Standard solution*

[Note—The relative retention times for levocarnitine and *p*-aminobenzoic acid are 0.56 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between the levocarnitine and internal standard peaks

Relative standard deviation: NMT 2.0% for levocarnitine

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of levocarnitine ($C_7H_{15}NO_3$) in the portion of Oral Solution taken:

$$\text{Result} = (R_U/R_S) \times (C_S/C_U) \times 100$$

R_U = peak area ratio of levocarnitine to *p*-aminobenzoic acid from the *Sample solution*

R_S = peak area ratio of levocarnitine to *p*-aminobenzoic acid from the *Standard solution*

C_S = concentration of USP Levocarnitine RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of levocarnitine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 4.0–6.0

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers.

• **USP Reference Standards** ⟨11⟩

USP Levocarnitine RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
LEVOCARNITINE ORAL SOLUTION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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