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Levocarnitine Injection

DEFINITION

Levocarnitine Injection is a sterile solution of Levocarnitine in Water for Injection. 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*, as obtained in the *Assay*.
- **B. Color Reaction**

Analysis: Transfer 2 mL of Injection to a test tube, add 5 mL of 1 N hydrochloric acid and a few drops of ammonium reineckate TS.

Acceptance criteria: A red-violet precipitate is produced.

ASSAY

- **Procedure**

Buffer: 0.05 M phosphate buffer, prepared by dissolving 6.805 g of monobasic potassium phosphate in 1 L of water

Mobile phase: Acetonitrile and *Buffer* (65:35). Adjust with phosphoric acid to a pH of 4.7, and mix.

System suitability solution: 5 mg/mL of USP Levocarnitine RS and 0.024 mg/mL of USP Levocarnitine Related Compound A RS in water

Standard solution: 10 mg/mL of USP Levocarnitine RS in water

Sample solution: Pool the contents of 10 containers, and dilute an accurately measured volume of Injection quantitatively with water to obtain a solution having a nominal concentration of about 10 mg/mL of levocarnitine.

Chromatographic system

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

Mode: LC

Detector: UV 205 nm

Column: 3.9-mm × 30-cm; 10-µm packing L8

Flow rate: 1 mL/min

Injection volume: 5 µL

System suitability

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

Suitability requirements

Resolution: NLT 1.0 between levocarnitine related compound A (crotonoylbetaine) and levocarnitine, *System suitability solution*

Relative standard deviation: NMT 2.0% for levocarnitine, *Standard solution*

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 Injection taken:

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

r_U = peak area of levocarnitine from the *Sample solution*

r_S = peak area of levocarnitine 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

- **Bacterial Endotoxins Test ⟨85⟩ :** It contains NMT 0.1 USP Endotoxin Units/mg of levocarnitine.
- **pH ⟨791⟩:** 6.0–6.5
- **Particulate Matter in Injections ⟨788⟩ :** Meets the requirements for small-volume injections
- **Injections and Implanted Drug Products ⟨1⟩:** Meets the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in single-dose containers, preferably of Type I glass. Store below 25°. Do not freeze.
- **USP Reference Standards ⟨11⟩**

USP Levocarnitine RS

USP Levocarnitine Related Compound A RS

2-Propen-1-aminium, 3-carboxy-*N*,*N*,*N*-trimethyl-, chloride.

$C_7H_{14}ClNO_2$ 179.65

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

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

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