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Levocarnitine Tablets

To view the Notice from the Expert Committee that posted in conjunction with this accelerated revision, please click https://www.uspnf.com/rb-levocarnitine-tabs-20240726.

DEFINITION
Levocarnitine Tablets contain 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: Dissolve 1 Tablet in 5 mL of water, filter, and add 5 mL of 1 N hydrochloric acid. Place 2 mL of the filtrate in a test tube, and add a few drops of ammonium reineckate TS.

Acceptance criteria: A red-violet precipitate is produced.

ASSAY
- **Procedure**

Buffer: 0.05 M phosphate buffer, pH 4.5, 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: 1.5 mg/mL of USP Levocarnitine RS and 7 µg/mL of USP Levocarnitine Related Compound A RS in water

Standard solution: 3 mg/mL of USP Levocarnitine RS in water

Sample solution: Transfer 10 Tablets, accurately weighed, to a 500-mL volumetric flask, and add water to volume. Shake until the Tablets have disintegrated completely, and pass through a filter of 0.45-µm pore size. Dilute a portion of the filtrate quantitatively with water to a nominal concentration of about 3 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: 20 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 Tablets 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%

PERFORMANCE TESTS
Change to read:
- **Dissolution ⟨711⟩**

▲**Test 1**▲ (RB 1-Aug-2024)

Medium: Water; 900 mL

Apparatus 2: 75 rpm

Time: 30 min

Standard solution: Known concentration of USP Levocarnitine RS in *Medium*

Sample solution: Filtered portion of the solution under test, suitably diluted with *Medium* if necessary

Analysis

Samples: *Standard solution* and *Sample solution*

Proceed as directed in the *Assay*, making any necessary modifications.

Determine the percentage of the labeled amount of levocarnitine ($C_7H_{15}NO_3$) dissolved:

$$\text{Result} = (r_U/r_S) \times (C_S \times D \times V/L) \times 100$$

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

r_S = peak area of levocarnitine in the *Standard solution*

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

D = dilution factor for the *Sample solution*

V = volume of *Medium*, 900 mL

L = label claim (mg/Tablet)

Tolerances: NLT 75% (Q) of the labeled amount of levocarnitine ($C_7H_{15}NO_3$) is dissolved.

▲**Test 2:** If the product complies with this test, the labeling indicates that it meets USP *Dissolution Test 2*.

Medium: 0.1 N hydrochloric acid; 500 mL

Apparatus 1: 100 rpm

Time: 30 min

Solution A: 300 mL of acetonitrile, 700 mL of water, and 1 mL of phosphoric acid

Solution B: Dilute phosphoric acid with water (1:10).

Mobile phase: Sonicate 2.88 g of sodium lauryl sulfate and 2.3 g of monobasic ammonium phosphate in *Solution A* until dissolved. Adjust with *Solution B* to a pH of 2.4.

Standard solution: 0.66 mg/mL of USP Levocarnitine RS in *Medium*

Sample solution: Pass a portion of the solution under test through a 0.45-µm Nylon filter, discarding the first 4 mL of filtrate.

Chromatographic system

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

Mode: LC

Detector: UV 205 nm

Column: 4.6-mm × 7.5-cm; 3.5-µm packing L7

Column temperature: 35°

Flow rate: 1.5 mL/min

Injection volume: 100 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 3.0% from 6 replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

Determine the percentage of the labeled amount of levocarnitine ($C_7H_{15}NO_3$) dissolved:

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

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

r_S = peak area of levocarnitine in the *Standard solution*

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

V = volume of *Medium*, 500 mL

L = label claim (mg/Tablet)

Tolerances: NLT 80% (*Q*) of the labeled amount of levocarnitine ($C_7H_{15}NO_3$) is dissolved.▲ (RB 1-Aug-2024)

• **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements for *Weight Variation*

ADDITIONAL REQUIREMENTS

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

• **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 TABLETS	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements

Chromatographic Database Information: Chromatographic Database

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