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Alpha Lipoic Acid Capsules

DEFINITION

Alpha Lipoic Acid Capsules contain NLT 90.0% and NMT 115.0% of the labeled amount of $C_8H_{14}O_2S_2$.

IDENTIFICATION

The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the test for *Content of Alpha Lipoic Acid*.

STRENGTH

• CONTENT OF ALPHA LIPOIC ACID

Mobile phase: 0.025 M phosphoric acid and acetonitrile (62:38)

Standard solution: 0.05 mg/mL of [USP Alpha Lipoic Acid RS](#) in acetonitrile and water (1:1)

Sample solution A (for hard gelatin Capsules): Empty and mix thoroughly the contents of NLT 20 Capsules. Transfer a portion of the powder, equivalent to 100 mg of alpha lipoic acid, to a suitable container. Add 70 mL of a mixture of acetonitrile and water (1:1), and shake for 45 min by mechanical means. Transfer to a 100-mL volumetric flask, dilute with the mixture of acetonitrile and water (1:1) to volume, and filter a portion of this preparation, discarding the first 5 mL of the filtrate. Transfer 5.0 mL of the remaining filtrate to a 100-mL volumetric flask, and dilute with acetonitrile and water (1:1) to volume.

Sample solution B (for soft gelatin Capsules): Using a suitable cutting instrument, open a number of Capsules equivalent to 500 mg of alpha lipoic acid from a counted number of opened Capsules. Transfer the contents and the shells to a suitable container with stopper, add 500.0 mL of a mixture of acetonitrile and water (1:1), and shake for 45 min by mechanical means. Filter a portion of this preparation, discarding the first 5 mL of the filtrate. Transfer 5.0 mL of the remaining filtrate to a 100-mL volumetric flask, and dilute with acetonitrile and water (1:1) to volume.

Chromatographic system

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

Mode: LC

Detector: UV 220 nm

Column: 3.9-mm × 30-cm; packing L1

Flow rate: 1.5 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitability requirements

Column efficiency: NLT 1300 theoretical plates

Tailing factor: NMT 1.2 for alpha lipoic acid

Relative standard deviation: NMT 1.0%

Analysis

Samples: *Standard solution* and appropriate *Sample solution*

Calculate the percentage of alpha lipoic acid in the portion of Capsules taken:

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

r_U = peak response from *Sample solution A* or *Sample solution B*

r_S = peak response from the *Standard solution*

C_S = concentration of [USP Alpha Lipoic Acid RS](#) in the *Standard solution* (mg/mL)

C_U = nominal concentration of alpha lipoic acid in *Sample solution A* or *Sample solution B* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- [DISINTEGRATION AND DISSOLUTION OF DIETARY SUPPLEMENTS \(2040\)](#): Meet the requirements for *Dissolution*

Medium: Water; 900 mL

Apparatus 1 (for hard gelatin Capsules): 100 rpm

Apparatus 2 (for soft gelatin Capsules): 75 rpm

Time: 60 min

Standard solution: 1 mg/mL of [USP Alpha Lipoic Acid RS](#) in a mixture of acetonitrile and water (1:1). Dilute with water to obtain a concentration of 0.02 mg/mL.

Sample solution: Withdraw a portion of the solution under test, and filter, discarding the first portion of the filtrate. Transfer an aliquot to a volumetric flask, and dilute with water to volume to obtain a solution having an expected concentration of 0.02 mg/mL of alpha lipoic acid.

Mobile phase and Chromatographic system: Proceed as directed in the test for *Content of Alpha Lipoic Acid*.

Injection size: 50 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of alpha lipoic acid ($C_8H_{14}O_2S_2$) dissolved:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

V = volume of dissolution *Medium*, 900 mL

C = concentration of [USP Alpha Lipoic Acid RS](#) in the *Standard solution* (mg/mL)

D = dilution factor of the sample

L = label claim of alpha lipoic acid (mg/Capsule)

Tolerances: NLT 70% of the labeled amount of $C_8H_{14}O_2S_2$ is dissolved.

- [WEIGHT VARIATION OF DIETARY SUPPLEMENTS \(2091\)](#): Meet the requirements

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers.

- [USP REFERENCE STANDARDS \(11\)](#).

[USP Alpha Lipoic Acid RS](#)

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

Topic/Question	Contact	Expert Committee
ALPHA LIPOIC ACID CAPSULES	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](#)

Most Recently Appeared In:

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