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Ubidecarenone Capsules

DEFINITION

Ubidecarenone Capsules contain NLT 90.0% and NMT 115.0% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$).

IDENTIFICATION

• **A.** The retention time of the major peak of either *Sample solution 1* or *Sample solution 2* corresponds to that of the *Standard solution*, as obtained in the *Procedure for Strength*.

STRENGTH

• PROCEDURE

[NOTE—Conduct this test promptly with minimum exposure to actinic light.]

Solvent: *n*-Hexane and dehydrated alcohol (5:2)

Mobile phase: Acetonitrile, tetrahydrofuran, and water (55:40:5)

Standard stock solution: 1.0 mg/mL of [USP Ubidecarenone RS](#) in *Solvent*

Standard solution: 40 µg/mL in dehydrated alcohol, from the *Standard stock solution*

System suitability stock solution: 1.0 mg/mL of [USP Ubidecarenone Related Compound A RS](#) in *Solvent*. Dilute a portion of this solution with dehydrated alcohol to obtain a concentration of 40 µg/mL.

System suitability solution: *Standard solution* and *System suitability stock solution* (1:1)

Sample solution 1 (for soft gelatin Capsules): Open a number of Capsules equivalent to 200 mg of ubidecarenone, quantitatively transfer the shells and contents to a container, add 100 mL of *Solvent*, and shake by mechanical means for 30 min. Using small portions of *Solvent*, quantitatively transfer this mixture to a 200-mL volumetric flask, and dilute with *Solvent* to volume. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.

Sample solution 2 (for hard gelatin Capsules): Empty and thoroughly mix the contents of NLT 20 Capsules. Transfer a portion of the powder, equivalent to 100 mg of ubidecarenone, to a 100-mL volumetric flask, add 60 mL of *Solvent*, and shake by mechanical means for 30 min. Dilute with *Solvent* to volume. Centrifuge a portion of this solution, transfer 1.0 mL of the supernatant to a 25-mL volumetric flask, add 2.5 mL of a 0.1% solution of anhydrous ferric chloride in alcohol, and dilute with alcohol to volume.

Chromatographic system

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

Mode: LC

Detector: UV 280 nm

Column: 8-mm × 10-cm; packing L1

Flow rate: 2.5 mL/min

Injection size: 15 µL

System suitability

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

Suitability requirements

Resolution: NLT 2.5 between ubidecarenone and ubidecarenone related compound A, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

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

Analysis

Samples: *Sample solution 1* or *Sample solution 2*, and *Standard solution*

Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) in the portion of Capsules taken:

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

r_U = peak area of ubidecarenone from *Sample solution 1* or *Sample solution 2*

r_S = peak area of ubidecarenone from the *Standard solution*

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

C_U = nominal concentration of ubidecarenone in *Sample solution 1* or *Sample solution 2* (mg/mL)

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

• **DISINTEGRATION AND DISSOLUTION (2040):** Meet the requirements of the test for *Disintegration*, except where the product is labeled to contain a water-soluble form of ubidecarenone. Capsules labeled to contain a water-soluble form of ubidecarenone meet the requirements for the test for *Dissolution*, as follows.

Medium: Water; 500 mL

Apparatus 2: 75 rpm

Time: 60 min

Standard solution: Dissolve 25 mg of [USP Ubidecarenone RS](#) in 1 mL of ethyl ether, and dilute with alcohol to obtain a concentration of 2.5 µg/mL. [NOTE—Use a freshly prepared solution only.]

Sample solution: Dilute with alcohol a volume of the solution under test, previously passed through a suitable filter of 0.45-µm pore size, to obtain a concentration of 2.5 µg/mL of ubidecarenone.

Mobile phase and Chromatographic system: Proceed as directed in the *Procedure for Strength*, except for *Injection size*.

Injection size: 100 µL

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) dissolved:

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

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

r_S = peak area of ubidecarenone from the *Standard solution*

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

V = volume of *Medium*, 500 mL

D = dilution factor for the *Sample solution*

L = label claim (mg/Capsule)

Tolerances: NLT 75% of the labeled amount of ubidecarenone ($C_{59}H_{90}O_4$) is dissolved.

SPECIFIC TESTS

• **WEIGHT VARIATION OF DIETARY SUPPLEMENTS (2091):** Meet the requirements

ADDITIONAL REQUIREMENTS

• **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

• **LABELING:** Where the product contains a water-soluble form of ubidecarenone, this is so stated on the label.

• **USP REFERENCE STANDARDS (11).**

[USP Ubidecarenone RS](#)

[USP Ubidecarenone Related Compound A RS](#)

Coenzyme Q₉.

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

Topic/Question	Contact	Expert Committee
UBIDECARENONE CAPSULES	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements