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Ubiquinol Capsules

DEFINITION

Ubiquinol Capsules contain NLT 90.0% and NMT 115.0% of the labeled amount of ubiquinol ($C_{59}H_{92}O_4$).

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 minimal exposure to air. Ubiquinol is readily oxidized to ubidecarenone when exposed to air.]

Mobile phase: Acetonitrile and alcohol (50:50)

Diluent: Methanol and *n*-hexane (85:15)

System suitability solution: 0.5 mg/mL each of [USP Ubiquinol RS](#) and [USP Ubidecarenone RS](#) in *Diluent*. Sonicate, if necessary, for complete dissolution.

Standard solution: 0.5 mg/mL of [USP Ubiquinol RS](#) in *Diluent*. Sonicate, if necessary, for complete dissolution.

Sample solution 1 (for soft gelatin Capsules): Weigh NLT 20 Capsules in a tared weighing bottle. Open the Capsules, without the loss of shell material, and transfer the contents to a 100-mL beaker. Remove any contents adhering to the empty shells by washing, if necessary, with several portions of ether. Discard the washings, and dry the Capsule shells with the aid of a current of dry air until the odor of ether is no longer perceptible. Weigh the empty Capsule shells in the tared weighing bottle, and calculate the average net weight per Capsule. Transfer a portion of the Capsule contents, equivalent to 250 mg of ubiquinol into a 50-mL volumetric flask. Add 40 mL of *Diluent* and shake by mechanical means for 10 min. Sonicate additionally for about 15 min, cool to room temperature, dilute with *Diluent* to volume, and mix well. Dilute a portion of the resultant solution with *Diluent* to obtain a concentration of 0.5 mg/mL of ubiquinol. Mix well and pass through a membrane filter of 0.45-μm pore size.

Sample solution 2 (for hard gelatin Capsules): Empty and thoroughly mix the contents of NLT 20 Capsules. Transfer a portion of the contents, equivalent to 250 mg of ubiquinol into a 50-mL volumetric flask. Add 40 mL of *Diluent* and shake by mechanical means for 20 min. Sonicate additionally for about 15 min, cool to room temperature, dilute with *Diluent* to volume, and mix well. Dilute a portion of the resultant solution with *Diluent* to obtain a concentration of 0.5 mg/mL of ubiquinol. Mix well and pass through a membrane filter of 0.45-μm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 290 nm

Column: 4.6-mm × 10-cm; 3.5-μm packing L1

Flow rate: 1.5 mL/min

Injection volume: 20 μL

System suitability

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

[NOTE—The relative retention times for ubiquinol and ubidecarenone are about 1.0 and 1.2, respectively.]

Suitability requirements

Resolution: NLT 2.0 between ubiquinol and ubidecarenone, *System suitability solution*

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

Analysis

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

Calculate the percentage of ubiquinol ($C_{59}H_{92}O_4$) in the portion of Capsules taken:

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

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

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

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

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

Acceptance criteria: 90.0%–115.0%

PERFORMANCE TESTS

- [DISINTEGRATION AND DISSOLUTION \(2040\)](#): Meet the requirements for *Disintegration*
- [WEIGHT VARIATION OF DIETARY SUPPLEMENTS \(2091\)](#): Meet the requirements

CONTAMINANTS

- [MICROBIAL ENUMERATION TESTS \(2021\)](#): The total aerobic microbial count does not exceed 3×10^3 cfu/g, and the total combined molds and yeasts count does not exceed 3×10^2 cfu/g.
- [ABSENCE OF SPECIFIED MICROORGANISMS \(2022\)](#): Meet the requirements of the tests for absence of *Salmonella* species and *Escherichia coli*

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- [USP REFERENCE STANDARDS \(11\)](#):
[USP Ubidecarenone RS](#)
[USP Ubiquinol RS](#)

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

Topic/Question	Contact	Expert Committee
UBIQUINOL 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](#)

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