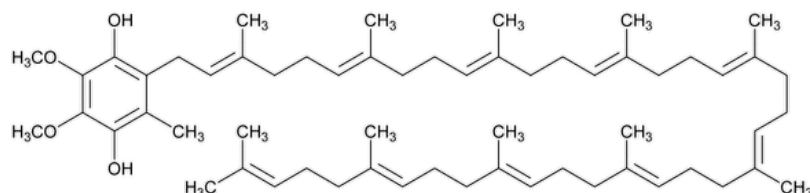


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# Ubiquinol



$C_{59}H_{92}O_4$  865.37

2-[(2E,6E,10E,14E,18E,22E,26E,30E,34E)-3,7,11,15,19,23,27,31,35,39-Decamethyltetraconta-2,6,10,14,18,22,26,30,34,38-decaenyl]-5,6-dimethoxy-3-methylbenzene-1,4-diol CAS RN®: 992-78-9.

## DEFINITION

Ubiquinol contains NLT 96.0% and NMT 102.0% of ubiquinol ( $C_{59}H_{92}O_4$ ), calculated on the anhydrous basis.

## IDENTIFICATION

**Change to read:**

- **A.** ▲ [SPECTROSCOPIC IDENTIFICATION TESTS \(197\)](#), [Infrared Spectroscopy: 197K](#) ▲ (CN 1-MAY-2020)
- **B.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the Assay.

## ASSAY

### PROCEDURE

**Mobile phase:** Acetonitrile and alcohol (50:50)

[NOTE—Protect the following solutions from exposure to air after preparation, because ubiquinol is readily oxidized to ubiquinone when exposed to air.]

**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:** 0.5 mg/mL of Ubiquinol in *Diluent*. Sonicate, if necessary, for complete dissolution.

### Chromatographic system

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

**Mode:** LC

**Detector:** UV 290 nm

**Column:** 4.6-mm × 10-cm; 3-μm packing L1

**Column temperature:** 35°

**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 ubiquinone are about 1.0 and 1.2, respectively.]

### Suitability requirements

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

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

### Analysis

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

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

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

$r_U$  = peak response from the *Sample solution*

$r_S$  = peak response from the *Standard solution*

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

$C_U$  = concentration of Ubiquinol in the *Sample solution* (mg/mL)

**Acceptance criteria:** 96.0%–102.0% on the anhydrous basis

## IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%

### • UBIDECARENONE AND OTHER RELATED COMPOUNDS

**Mobile phase, System suitability solution, Chromatographic system, and System suitability:** Proceed as directed in the Assay.

**Standard solution:** 0.02 mg/mL of [USP Ubidecarenone RS](#) in *Diluent*

**Sample solution:** 1.0 mg/mL of Ubiquinol in *Diluent*

### Analysis

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

[NOTE—Protect the *Sample solution* from exposure to air after preparation, because ubiquinol is readily oxidized to ubidecarenone when exposed to air.]

Calculate the percentage of ubidecarenone in the portion of Ubiquinol taken:

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

$r_U$  = peak response of ubidecarenone from the *Sample solution*

$r_S$  = peak response of ubidecarenone from the *Standard solution*

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

$C_U$  = concentration of Ubiquinol in the *Sample solution* (mg/mL)

Calculate the percentage of other related compounds in the portion of Ubiquinol taken:

$$\text{Result} = (r_U/r_T) \times 100$$

$r_U$  = peak response of individual related compounds from the *Sample solution*

$r_T$  = sum of all the peak responses from the *Sample solution*

### Acceptance criteria

**Ubidecarenone:** NMT 2.0%

**Other individual related compounds:** NMT 0.5%

**Sum of other related compounds:** NMT 1.0%

## SPECIFIC TESTS

- [WATER DETERMINATION, Method Ic \(921\)](#): NMT 0.3%

## ADDITIONAL REQUIREMENTS

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