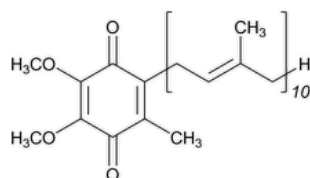


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Ubidecarenone



$C_{59}H_{90}O_4$ 863.34

2,5-Cyclohexadiene-1,4-dione, 2-[(2E,6E,10E,14E,18E,22E,26E,30E,34E)-3,7,11,15,19,23,27,31,35,39-decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl]-5,6-dimethoxy-3-methyl;

2-[(all-E)-3,7,11,15,19,23,27,31,35,39-Decamethyl-2,6,10,14,18,22,26,30,34,38-tetracontadecaenyl]-5,6-dimethoxy-3-methyl-*p*-benzoquinone CAS RN®: 303-98-0.

DEFINITION

Ubidecarenone (Coenzyme Q₁₀) contains NLT 98.0% and NMT 101.0% of ubidecarenone ($C_{59}H_{90}O_4$), calculated on the anhydrous basis.

IDENTIFICATION

Change to read:

• A. [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K ▲](#) (CN 1-MAY-2020)

• B.

Analysis: Dissolve 50 mg of Ubidecarenone in 1 mL of ethyl ether, and add 10 mL of dehydrated alcohol. To 2 mL of this solution add 3 mL of dehydrated alcohol and 2 mL of dimethyl malonate. Add 1 mL of potassium hydroxide solution (1 in 5) dropwise.

Acceptance criteria: A blue color appears.

ASSAY

• PROCEDURE

Mobile phase: Methanol and dehydrated alcohol (65:35)

System suitability solution: 0.5 mg/mL each of [USP Ubidecarenone RS](#) and [USP Ubidecarenone Related Compound A RS](#) in dehydrated alcohol. Heat at 50° for 2 min, if necessary, for complete dissolution.

Standard solution: 1.0 mg/mL of [USP Ubidecarenone RS](#) in dehydrated alcohol. Heat at 50° for 2 min, if necessary, for complete dissolution.

Sample solution: 1.0 mg/mL of Ubidecarenone in dehydrated alcohol. Heat at 50° for 2 min, if necessary, for complete dissolution.

Chromatographic system

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

Mode: LC

Detector: UV 275 nm

Column: 4.6-mm × 15-cm; packing L1

Column temperature: 35°

Flow rate: Adjust to obtain a retention time of about 11 min for ubidecarenone.

Injection size: 5 µL

System suitability

Sample: System suitability solution

[NOTE—The relative retention times for ubidecarenone related compound A and ubidecarenone are about 0.75 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 4 between ubidecarenone related compound A and ubidecarenone

Relative standard deviation: NMT 0.8% for ubidecarenone

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ubidecarenone ($C_{59}H_{90}O_4$) in the portion of Ubidecarenone 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 Ubidecarenone RS](#) in the *Standard solution* (mg/mL)

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

Acceptance criteria: 98.0%–101.0% on the anhydrous basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 0.1%

• **CHROMATOGRAPHIC PURITY**

Procedure 1: Coenzymes Q_7 , Q_8 , Q_9 , Q_{11} , and Related Impurities

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

Analysis

Sample: *Sample solution*

Calculate the percentage of impurities in the portion of Ubidecarenone taken:

$$\text{Result} = (r_{T1}/r_{T2}) \times 100$$

r_{T1} = sum of all peak responses, other than that for ubidecarenone

r_{T2} = sum of all peak responses

Acceptance criteria: NMT 1.0%

Procedure 2: Ubidecarenone (2Z)-Isomer and Related Impurities

Mobile phase: *n*-Hexane and ethyl acetate (97:3)

System suitability solution: 1 mg/mL of [USP Ubidecarenone for System Suitability RS](#) in *n*-hexane

Sample solution: 1 mg/mL of Ubidecarenone in *n*-hexane

Chromatographic system

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

Mode: LC

Detector: UV 275 nm

Column: 4.6-mm × 25-cm; packing L3

Flow rate: 2 mL/min

Injection size: 20 µL

System suitability

Sample: *System suitability solution*

[NOTE—The relative retention times for ubidecarenone (2Z)-isomer and ubidecarenone are about 0.85 and 1.0, respectively.]

Suitability requirements

Resolution: NLT 1.5 between the ubidecarenone (2Z)-isomer and ubidecarenone

Analysis

Sample: *Sample solution*

Calculate the percentage of impurities in the portion of Ubidecarenone taken:

$$\text{Result} = (r_{T1}/r_{T2}) \times 100$$

r_{T1} = sum of all peak responses, other than that for ubidecarenone

r_{T2} = sum of all peak responses

Acceptance criteria: NMT 1.0%

Total impurities: NMT 1.5%, obtained from *Chromatographic Purity Procedures 1 and 2*