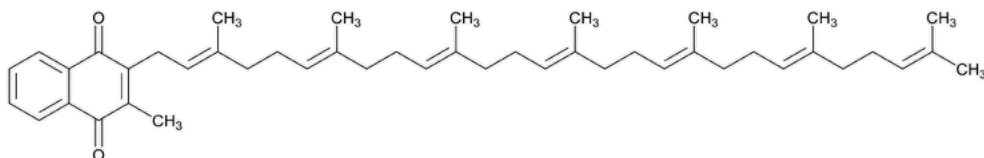


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Menaquinone-7



$C_{46}H_{64}O_2$ 649.00

(*all-E*)-2-(3,7,11,15,19,23,27-Heptamethyl-2,6,10,14,18,22,26-octacosaeptaenyl)-3-methyl-1,4-naphthalenedione CAS RN®: 2124-57-4; UNII: 8427BML8NY.

DEFINITION

Menaquinone-7 contains NLT 96.0% and NMT 101.0% of menaquinone-7 ($C_{46}H_{64}O_2$) and NMT 3% of menaquinone-6 ($C_{41}H_{56}O_2$), calculated on the as-is basis.

IDENTIFICATION

Change to read:

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

Change to read:

- **B.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Ultraviolet-Visible Spectroscopy: 197U](#)▲ (CN 1-MAY-2020)

[NOTE—Use low-actinic glassware.]

Analytical wavelength: 200–450 nm

Sample solution: 40 µg/mL of Menaquinone-7 in [dehydrated alcohol](#)

Acceptance criteria: Meets the requirements

- **C.** 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

[NOTE—Protect the *Standard solution* and *Sample solution* from light, and inject immediately after preparation.]

Mobile phase: [Dehydrated alcohol](#) and [water](#) (97:3)

Standard solution: Transfer 25 mg of [USP Menaquinone-7 RS](#) into a 50-mL volumetric flask, add 1 mL of [tetrahydrofuran](#), and dilute with [dehydrated alcohol](#) to volume. Transfer 5.0 mL of this solution into a 25-mL volumetric flask, and dilute with [dehydrated alcohol](#) to volume.

Sample solution: Transfer 25 mg of Menaquinone-7 into a 50-mL volumetric flask, add 1 mL of [tetrahydrofuran](#), and dilute with [dehydrated alcohol](#) to volume. Transfer 5.0 mL of this solution into a 25-mL volumetric flask, and dilute with [dehydrated alcohol](#) to volume.

Chromatographic system

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

Mode: LC

Detector: UV 268 nm

Column: 4.6-mm × 10-cm; 2.6-µm packing L1

Column temperature: 25°

Flow rate: 0.7 mL/min

Injection volume: 10 µL

Run time: NLT 3 times the retention time of menaquinone-7

System suitability

Sample: *Standard solution*

Suitability requirements

Relative standard deviation: NMT 3.0% from 6 replicate injections

Analysis

Samples: *Standard solution* and *Sample solution*

[NOTE—The relative retention times for menaquinone-6 and menaquinone-7 are 0.81 and 1.00, respectively.]

Calculate the percentage of menaquinone-7 ($C_{46}H_{64}O_2$) in the portion of Menaquinone-7 taken:



$$\text{Result} = (r_{U7}/r_S) \times (C_S/C_U) \times 100$$

r_{U7} = peak response of menaquinone-7 from the *Sample solution*

r_S = peak response of menaquinone-7 from the *Standard solution*

C_S = concentration of [USP Menaquinone-7 RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Menaquinone-7 in the *Sample solution* (mg/mL)

Calculate the percentage of menaquinone-6 ($C_{41}H_{56}O_2$) in the portion of Menaquinone-7 taken:

$$\text{Result} = (r_{U6}/r_S) \times (C_S/C_U) \times 100$$

r_{U6} = peak response of menaquinone-6 from the *Sample solution*

r_S = peak response of menaquinone-7 from the *Standard solution*

C_S = concentration of [USP Menaquinone-7 RS](#) in the *Standard solution* (mg/mL)

C_U = concentration of Menaquinone-7 in the *Sample solution* (mg/mL)

Acceptance criteria

Menaquinone-7: 96.0%–101.0% on the as-is basis

Menaquinone-6: NMT 3% on the as-is basis

IMPURITIES

- [RESIDUE ON IGNITION \(281\)](#): NMT 0.2%
- [ELEMENTAL IMPURITIES—PROCEDURES \(233\)](#)

Acceptance criteria

Arsenic: NMT 2.0 µg/g

Cadmium: NMT 1.0 µg/g

Lead: NMT 3.0 µg/g

Mercury: NMT 0.1 µg/g

• ISOMERIC PURITY

Mobile phase: [Water](#), [dehydrated alcohol](#), [methanol](#), and [tetrahydrofuran](#) (1:15:80:10)

Sample solution: [NOTE—Protect the solution from light and inject immediately after preparation.] Transfer 40 mg of Menaquinone-7 into a 100-mL volumetric flask, add 2 mL of [tetrahydrofuran](#), and shake to dissolve the sample. Dilute with [dehydrated alcohol](#) to volume. Transfer 1.0 mL of this solution into a 10-mL volumetric flask, and dilute with [dehydrated alcohol](#) to volume. Pass the solution through a membrane filter of 0.45-µm pore size.

Chromatographic system

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

Mode: LC

Detector: UV 268 nm

Column: 4.6-mm × 25-cm; 5-µm packing L62

Column temperature: 25°

Flow rate: 0.8 mL/min

Injection volume: 20 µL

Run time: NLT 1.5 times the retention time of *all-trans*-menaquinone-7

System suitability

Sample: *Sample solution*

[NOTE—The relative retention times of *all-trans*-menaquinone-7 and *cis*-menaquinone-7 are 1.0 and 1.1, respectively.]

Suitability requirements

Resolution: NLT 1.5 between *all-trans*-menaquinone-7 and *cis*-menaquinone-7

Analysis

Sample: *Sample solution*

Calculate the percentage of *cis*-menaquinone-7 in the portion of Menaquinone-7 taken:

$$\text{Result} = [r_C/(r_T + r_C)] \times 100$$

r_C = peak response of *cis*-menaquinone-7 from the *Sample solution*

r_T = peak response of *all-trans*-menaquinone-7 from the *Sample solution*

Acceptance criteria: NMT 2% of *cis*-menaquinone-7