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Phytonadione Tablets

DEFINITION

Phytonadione Tablets contain NLT 90.0% and NMT 110.0% of the labeled amount of phytonadione ($C_{31}H_{46}O_2$).

IDENTIFICATION

• **A. Ultraviolet Absorption**

Standard solution: 0.01 mg/mL of USP Phytonadione RS in dehydrated alcohol

Sample solution: A portion of finely powdered Tablets, equivalent to 0.01 mg/mL of phytonadione in dehydrated alcohol. Shake vigorously, and filter. Use the filtrate.

Acceptance criteria: The UV absorption spectrum of the *Sample solution* exhibits maxima and minima at the same wavelengths as that of the *Standard solution* concomitantly measured.

• **B. HPLC Identification Test**

Analysis: Proceed as directed in the *Assay*.

Acceptance criteria: The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*.

ASSAY

• **Procedure**

[Note—Use low-actinic glassware throughout the *Assay*, and otherwise protect the solutions from light.]

Mobile phase: Dehydrated alcohol and water (95:5)

Standard solution: 0.10 mg/mL of USP Phytonadione RS in dehydrated alcohol

Sample solution: 0.1 mg/mL of phytodione in dehydrated alcohol prepared as follows. Mix a portion of finely powdered Tablets (NLT 20) with dehydrated alcohol to obtain a nominal concentraion of 0.4 mg/mL of phytonadione. Shake by mechanical means for 15 min, dilute with dehydrated alcohol to 0.10 mg/mL, and filter.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 254 nm

Column: 4-mm × 30-cm; packing L1

Flow rate: 1.5 mL/min

Injection size: 10 µL

System suitability

Sample: *Standard solution* (three replicate injections)

Suitability requirements

Column efficiency: NLT 915 theoretical plates, determined from the analyte peak

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0%

[Note—*Z*- and *E*-isomers coelute in this chromatographic system.]

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of phytonadione ($C_{31}H_{46}O_2$) in the portion of Tablets taken:

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

r_U = peak area from the *Sample solution*

r_S = peak area from the *Standard solution*

C_S = concentration of USP Phytonadione RS in the *Standard solution* (mg/mL)

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

Acceptance criteria: 90.0%–110.0%

PERFORMANCE TESTS

- **Disintegration ⟨701⟩**

  Time: 30 min

- **Uniformity of Dosage Units ⟨905⟩:** Meet the requirements

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed, light-resistant containers.
- **USP Reference Standards ⟨11⟩**

  USP Phytonadione RS

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
PHYTONADIONE TABLETS	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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