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Add the following:

▲Phytonadione Compounded Oral Suspension

DEFINITION

Phytonadione Compounded Oral Suspension contains NLT 90.0% and NMT 110.0% of the labeled amount of phytonadione ($C_{31}H_{46}O_2$).

Prepare Phytonadione Compounded Oral Suspension 1 mg/mL as follows (see *Pharmaceutical Compounding—Nonsterile Preparations ⟨795⟩*).

Phytonadione Injectable Emulsion[a] equivalent to	30 mg of phytonadione
Simple Syrup,[b] a sufficient quantity to make	30 mL

[a] Phytonadione 10-mg/mL Injectable Emulsion, Hospira, Inc., Lake Forest, IL.

[b] Simple Syrup, Humco, Inc., Texarkana, TX.

Open the ampule(s) of *Phytonadione Injection Emulsion* and withdraw the contents through a 5-µm filter needle. Remove the filter needle and transfer the *Phytonadione Injection Emulsion* into a calibrated container. Add sufficient *Simple Syrup* to bring to final volume. Mix well.

ASSAY

• **Procedure**

Mobile phase: Methanol and water (95:5)

Standard solution: 0.04 mg/mL of USP Phytonadione RS in methanol

Sample solution: Transfer 1.0 mL of Oral Suspension into a 25-mL volumetric flask and add methanol to volume.

Chromatographic system

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

Mode: LC

Detector: UV 270 nm

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

Temperatures

Autosampler: 4°

Column: 35°

Flow rate: 1.2 mL/min

Injection volume: 40 µL

System suitability

Sample: *Standard solution*

[Note—The retention time for phytonadione is about 11.6 min.]

Suitability requirements

Tailing factor: NMT 2.0

Relative standard deviation: NMT 2.0% for replicate injections

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 Oral Suspension taken:

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

r_U = peak response of phytonadione from the *Sample solution*

r_S = peak response of phytonadione 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%

SPECIFIC TESTS

• **pH** ⟨791⟩**:** 3.2–4.2

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Package in tight, light-resistance containers. Store at controlled room temperature or in a refrigerator.

• **Beyond-Use Date:** NMT 60 days after the date on which it was compounded when stored at controlled room temperature or NMT 90 days after the date on which it was compounded when stored in a refrigerator

• **Labeling:** Label it to indicate that it is to be well-shaken before use, and to state the *Beyond-Use Date*.

• **USP Reference Standards** ⟨11⟩

USP Phytonadione RS▲ (USP 1-Aug-2019)

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

Topic/Question	Contact	Expert Committee
PHYTONADIONE COMPOUNDED ORAL SUSPENSION	Brian Serumaga Science Program Manager	CMP2020 Compounding 2020
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	CMP2020 Compounding 2020

Chromatographic Database Information: Chromatographic Database

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