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Phytonadione Injectable Emulsion

» Phytonadione Injectable Emulsion is a sterile, aqueous dispersion of Phytonadione. It contains not less than 90.0 percent and not more than 110.0 percent of the labeled amount of $C_{31}H_{46}O_2$. It contains suitable solubilizing and/or dispersing agents.

Packaging and storage—Preserve in single-dose or multiple-dose containers, preferably of Type I glass, protected from light.

USP Reference standards ⟨11⟩—

USP Phytonadione RS

Identification—The retention time of the major peak in the chromatogram of the *Assay preparation* corresponds to that in the chromatogram of the *Standard preparation,* as obtained in the *Assay*.

Bacterial Endotoxins Test ⟨85⟩ —It contains not more than 14.0 USP Endotoxin Units per mg of phytonadione.

pH ⟨791⟩: between 3.5 and 7.0.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products ⟨1⟩*.

Assay—

[Note—Use low-actinic glassware throughout this assay, and otherwise protect the solutions from exposure to light.]

Mobile phase—Prepare a suitable degassed mixture of dehydrated alcohol and water (95:5).

Standard preparation—Dissolve an accurately weighed quantity of USP Phytonadione RS in *Mobile phase* to obtain a solution having a known concentration of about 1 mg per mL. Pipet 1 mL of this solution into a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix to obtain a *Standard preparation* having a known concentration of about 0.1 mg per mL.

Assay preparation 1 (containing 10 mg or more of phytonadione per mL)—Pipet a volume of Injectable Emulsion, equivalent to 10 mg of phytonadione, into a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Pipet 1 mL of this solution into a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Assay preparation 2 (containing less than 10 mg of phytonadione per mL)—Pipet a volume of Injectable Emulsion, equivalent to 1 mg of phytonadione, into a 10-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

Chromatographic system (see *Chromatography ⟨621⟩*)—The liquid chromatograph is equipped with a 254-nm detector and a 4-mm × 25-cm column that contains packing L1. The flow rate is about 0.7 mL per minute. Chromatograph five replicate injections of the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative standard deviation is not more than 1.5%.

Procedure—Separately inject equal volumes (about 10 µL) of the *Standard preparation* and the appropriate *Assay preparation* into the chromatograph, record the chromatograms, and measure the peak response for the major peak. Calculate the quantity, in mg, of $C_{31}H_{46}O_2$ in each mL of the Injectable Emulsion taken by the formula:

$$D(C/V)(r_U/r_S)$$

in which D is 100 if the Injectable Emulsion contains 10 mg or more of phytonadione per mL, or 10 if the Injectable Emulsion contains less than 10 mg of phytonadione per mL; C is the concentration, in mg per mL, of USP Phytonadione RS in the *Standard preparation; V* is the volume, in mL, of Injectable Emulsion taken; and r_U and r_S are the peak responses of phytonadione obtained from the appropriate *Assay preparation* and the *Standard preparation,* respectively.

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

Topic/Question	Contact	Expert Committee
PHYTONADIONE INJECTABLE EMULSION	Natalia Davydova Scientific Liaison	NBDS2020 Non-botanical Dietary Supplements
REFERENCE STANDARD SUPPORT	RS Technical Services RSTECH@usp.org	NBDS2020 Non-botanical Dietary Supplements

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