



TECHNICAL DATA SHEET

1910-TDS-ENG-2023

VITAMINA K1 PH.EUR (ALL-RAC-FITOMENADIONA)		
DESCRIPTION DCI: FITOMENADIONA		DESCRIPTION DOE: PHYTOMENADIONE
CAS Nº: 81818-54-4	EC Nº: 279-833-9	AEMPS CODE: ---
MOL. WEIGHT: 450.70	MOL. FORMULA: C31H46O2	ARTICLE CODE: 1910

ATTRIBUTES	SHOULD BE
Appearance	Clear, intense yellow, viscous, oily liquid
Solubility	Practically insoluble in water, sparingly soluble in ethanol (96 %), miscible with fatty oils
Refractive index	About 1.526
Identification A	Complies
Identification B	Complies
Identification C	Complies
Appearance of solution	Clear
Optical rotation	+0.05° / +0.05°
Acid value	=< 2.0
Impurity A	=< 0.2 %
Related substances	
Impurity B	=< 0.2 %
Unspecified impurities	=< 0.15 %
Total impurities	=< 1.0 %
Sulfated ash	=< 0.1 %
Assay	
trans-phytomenadione isomers	=> 85.0 %
um of trans-phytomenadione and cis-phytomenadione isomers	97.0 - 103.0 %

COMPLIES WITH

European Pharmacopoeia 11.0

STORAGE

Reserve in a tightly closed containers. Protect from light, moisture and heat sources.

REMARKS

Phytomenadione (Vitamin K1) is subjected to the requirements of the ICH Q3D "Elemental Impurities" guideline and the requirements of guides EMA/CHMP/ICH/82260/2006.

The product is not of animal origin and no animal product is used in its production, so it is risk-free BSE/TSE.

The product is not derived from GMO. No genetically modified organism is used in its production and no GMO product comes in contact with the product during any stage of production.