

VITAMINA K1 (ALL-RAC-FITOMENADIONA) (EUR. PH.)

PRODUCT CODE: 1910	CAS Nº: 81818-54-4	ANALYSIS Nº: 091/25
MANUFACTURER BATCH: V250201	CERTIFICATE ID: 45.842	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 21/02/2025	
METAPH BATCH: 0080425	EXPIRY DATE: 20/02/2028	

ATTRIBUTES	SHOULD BE	IS
Appearance	Clear, intense yellow, viscous, oily liquid	Clear, intense yellow, viscous, oily liquid
Refractive index	About 1.526	1.526 (*)
Identification A	Complies	Complies
Identification B	Complies	Complies
Identification C	Complies	Complies
Appearance of solution	Clear	Clear
Optical rotation	+0.05° / +0.05°	+0.0°
Acidity index	=< 2.0	0.3 %
Impurity A	=< 0.2 %	Complies (*)
Related substances		(*)
Impurity B	=< 0.2 %	0.06 %
Unspecified impurities	=< 0.15 %	0.14 %
Total impurities	=< 1.0 %	0.6 %
Sulfated ash	=< 0.1 %	0.01 %
Assay		
trans-phytomenadione isomers	=> 85.0 %	85.2 %
um of trans-phytomenadione and cis-phytomenadione isomers	97.0 - 103.0 %	97.7 %

COMPLIES WITH

European Pharmacopoeia 11.0

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.

(*) Data adapted from the manufacturer's certificate of analysis.

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.

STORAGE

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

 Analysis date: 18/06/2025
 Signature: Albert Sánchez López (QP)
 Conclusion: Complies

Manufacturer: 40000935

