



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

PRODUCT CODE: 1910	CAS Nº: 81818-54-4	ANALYSIS Nº: 004/25
MANUFACTURER BATCH: V241101	CERTIFICATE ID: 44.648	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 28/11/2024	
METAPH BATCH: 0040125	EXPIRY DATE: 27/11/2026	

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	Complies
Optical rotation	+0.05° / +0.05°	+0° (*)
Acidity index	=< 2.0	1.2
Impurity A	=< 0.2 %	Complies
Related substances		
Impurity B	=< 0.2 %	0.05 %
Unspecified impurities	=< 0.15 %	0.14 %
Total impurities	=< 1.0 %	0.6 %
Sulfated ash	=< 0.1 %	0.02 %
Assay		(*)
trans-phytomenadione isomers	=> 85.0 %	89.3 %
um of trans-phytomenadione and cis-phytomenadione isomers	97.0 - 103.0 %	98.7 %

### 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 controlled by Metapharmaceutical Industrial SL.

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: 12/02/2025

Signature: Albert Sanchez Lopez (QP)

Conclusion: Complies

Manufacturer: 40000935