

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

PRODUCT CODE: 1910	CAS Nº: 81818-54-4	ANALYSIS Nº: 181/24
MANUFACTURER BATCH: V240103	CERTIFICATE ID: 42.856	
SUPPLIER BATCH: ----	MANUFACTURING DATE: 20/01/2024	
METAPH BATCH: 0040724	EXPIRY DATE: 19/01/2026	

ATTRIBUTES	SHOULD BE	IS
Appearance	Clear, intense yellow, viscous, oily liquid	Clear, intense yellow, viscous, oily liquid (*)
Solubility	Practically insoluble in water, sparingly soluble in ethanol (96 %), miscible with fatty oils	Complies
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	1.2
Impurity A	=< 0.2 %	Complies
Related substances		
Impurity B	=< 0.2 %	0.01 %
Unspecified impurities	=< 0.15 %	0.14 %
Total impurities	=< 1.0 %	0.60 %
Sulfated ash	=< 0.1 %	0.03 %
Assay		
trans-phytomenadione isomers	=> 85.0 %	86.5 %
um of trans-phytomenadione and cis-phytomenadione isomers	97.0 - 103.0 %	98.3 %

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: 09/08/2024
 Signature: Cristina Borrell Olea (QA/QP)
 Conclusion: Complies

Manufacturer: 40000935