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C.F. e PARTITA IVA 00098610330 CAP. SOC. EURO 2.000.000 I.V. R.I.PC 032-1483 R.D.PC 44507 MECC EXPORT PC002237

#### azienda chimica e farmaceutica

## SPECIFICA TECNICA

# Prodotto VITAMINA A PALM. 1,0 MUI Ph.Eur. c/tocof

NOME INCI Retinyl Palmitate, Helianthus Annuus Seed oil

NOME INCI USA Retinyl Palmitate (and) Helianthus Annuus (Sunflower) Seed o

CAS 79-81-2; 8001-21-6; 10191-41-0 FORMULA Retinyl Palmitate: C36H60O2

PESO MOLECOLARE 524,9 g/mol

SPECIFICA	METODO	Lim. Inf Lim. Sup.	u.m.
Aspetto		Olio giallo o giallo-brunastro	
Identificazione TLC		Conforme	
Titolo		1,00 - 1,10	Mio.I.U/g
Indice di perossidi		<=10,0	meqO2/Kg
Indice di acidità		<=2,0	mgKOH/g
Retinolo		<=1,0	%
Sostanze Correlate			
- Rapporto assorbanze A300 nm / A326 nm		<=0,60	
- Rapporto assorbanze A350 nm / A326 nm		<=0,54	
- Rapporto assorbanze A370 nm / A326 nm		<=0,14	
Metalli pesanti *		<=10	ppm
Nichel *		<=2	ppm
Solventi Residui			
- Metanolo *		<=3.000	ppm
- Eptano, Metile Acetato, Isopropanolo *		<=5.000	ppm
Revisione Capitolato		2	
Data Approvazione		03/01/2017	

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\* test è stato verificato su campioni casuali / test is verified on random samples

The product is stabilized by tocopherol (approx. 10 mg of DL-alpha-Tocopherol per Mio IU).

The product meets the specifications of the following monographs:

- "Vitamin A Concentrate (Oily Form), synthetic" of Ph. Eur.
- "Vitamin A" of USP/NF

### Solubility:

Miscible with hydrocarbons, ethers, fats and oils. The solvent should contain no peroxides. Insoluble in water. It is necessary to use a solubilizer in aqueous alcoholic preparations.

- 1 International unit (IU) can be converted into weight with the following equations:
- 1 IU = 0.55 ug Vitamin A Palmitate

#### Stability and storage:

Vitamin A Esters are sensitive to air, light, moisture and heat. Opened original containers should be flushed with an inert gas and used up quickly. Prior to use, the product must be heated to 40°C in the unopened container and homogenized.

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