



SPECIFICA TECNICA

Prodotto **VITAMINA E (DL-ALFA TOCOFEROLO) Ph.Eur.**

SPECIFICA	METODO	Lim. Inf. - Lim. Sup.	u.m.
Identificazione IR		conforme alla specifica	
Aspetto		Olio viscoso giallo-marrone	
Identificazione GC		Conforme	
Titolo Tocoferolo (Ph. Eur.)		96,00 - 102,00	g/100 g
Impurezza A		$\leq 0,5$	%
Impurezza B		$\leq 1,50$	%
Impurezza C e D		$\leq 1,00$	%
Ogni altra impurezza		$\leq 0,25$	%
Impurezze totali		$\leq 2,50$	%
Rotazione ottica	EP	-0,01 - 0,01	°
Acidità		Conforme	
Assorbanza specifica (al max. 292 nm in etanolo) (*)		$\geq 72 - \leq 76$	
Indice di rifrazione (*)		$\geq 1,503 - \leq 1,507$	°
Ceneri solforiche (*)		$\leq 0,1$	g/100 g
Metalli pesanti (*)	EP	≤ 10	mg/Kg
Nichel (*)		≤ 2	mg/Kg
Solventi residui (*)	EP	≤ 3000	mg/Kg
Solventi residui (*)	EP	$\leq 0,5$	g/100 g
Revisione Capitolato		0	
Data Approvazione		12/12/2011	



SPECIFICA TECNICA

Prodotto **VITAMINA E (DL-ALFA TOCOFEROLO) Ph.Eur.**

OTHER DATA:

UNIT: 1 mg of DL-alpha-tocopherol=0.74 D-alpha-TE = 1.10 former USP units.

ASSAY Ph.Eur.	96.0 - 101.5	%
ASSAY USP/FCC	96.5 - 101.5	%
OPTICAL ROTATION	-0.01° / +0.01°	
ACIDITY USP/FCC	conforms	
LEAD (FCC, E307)	max. 2	ppm
SPECIFIC ABSORBANCE (E307: at max. 292 nm in ethanol)	72.0 - 76.0	
REFRACTIVE INDEX (E307)	1.503 - 1.507	
SULPHATED ASH (E307)	max. 0.1	%
MERCURY (E307)	max. 1	ppm
ARSENIC (E307)	max. 3	ppm
HEAVY METALS (E307)	max. 10	ppm

Unless otherwise stated, the method of analysis are to be found in the Ph.Eur..

SOLUBILITY: soluble in hydrocarbons, chlorinated hydrocarbons, alcohol fats and oil; insoluble in water.

MONOGRAPHS: The product complies with the current Ph.Eur., USP and FCC monographs and the EC food additives Directive E 307.

STABILIZATION/STABILITY: DL-alpha-tocopherol is sensitive to oxidizing agent. It turns dark when it is exposed to air and light. When it is stored in the unopened containers at room temperature (max. 25 °C) the product is stable for up to 24 months.

APPLICATION:

FOOD PRODUCTS: Tocopherol is used as an antioxidant to increase the stability of fats (oil, margarine, baking and frying fats, fish oil) and fatty products (ready made desserts, that contain cream, soup powders, cocoa products, dietetic foods; deep frozen products, potato crisps, essences and chewing gum) and to protect the Vitamin A and carotene in oils and other food products. The quantities used are usually lie between 200 and 500 mg/Kg of fat, though up to 1000 mg/Kg is used in essences and chewing gum. The shelf life of meat products that are sensitive to oxidation, particularly pork and turkey products can be improved with tocopherol. The acetate is more stable and is therefore preferred for fortifying food products with vitamin E.

COSMETIC: the product is used as an antioxidant and active ingredients in fat-containing cosmetic-preparations, e.g. creams, ointments, emulsion, body & face oil, decorative cosmetics such as lipstick etc..

PHARMACEUTICAL: the product is used mainly as an antioxidant in fat-containing pharmaceutical preparations (ointments, cream & oils).

The acetate is more stable and is therefore preferred as an active ingredients. For parenteral use sterilization of the final product is required. Further information can be found in the book "Functions and applications of Basf Pharmaceutical Excipients"



SPECIFICA TECNICA

Prodotto **VITAMINA E (DL-ALFA TOCOFEROLO) Ph.Eur.**

ALLERGENS:

The product does not contain any fragrance allergen as listed in Annex 3 of the 7th Amendment to the European Cosmetic Directive (2003/15/EC).