

Product Specification

Effective from 20.09.2012

Vitamin E Acetate 98%**PRD-No. 30574840**

® = Registered trademark of BASF group ™ = Trademark of BASF group

120559

Revision 0

NOT FOR REGULATORY PURPOSES

<u>Test parameter</u>	<u>Requirement</u>	<u>Test method</u>
Assay		
Tocopheryl acetate (GC)	98.0 to 102.0 g/100g	Ph. Eur.
Tocopheryl acetate (GC)	98.0 to 102.0 g/100g	PM0827 (USP)
Tocopheryl acetate (GC)	980 to 1020 I.U./g	USP
Characters		
Appearance	Viscous, light yellow oil	Visual
Identification (1)		
Identification	Must comply	Ph. Eur.
Tests		
Impurity A	≤ 0.5 % (area)	Ph. Eur.
Impurity B	≤ 1.5 % (area)	Ph. Eur.
Impurity C	≤ 0.5 % (area)	Ph. Eur.
Sum of impurity D and E	≤ 1.0 % (area)	Ph. Eur.
Any other impurity, each	≤ 0.25 % (area)	Ph. Eur.
Total impurities	≤ 2.5 % (area)	Ph. Eur.
Optical rotation	-0.01 to +0.01 °	Ph. Eur.
Acidity	Must comply	USP
Lead(*)	≤ 2 mg/kg	PM01683
Cadmium(*)	≤ 1 mg/kg	PM01683

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Mercury(*)	≤ 0.1 mg/kg	PM00934
Arsenic(*)	≤ 1 mg/kg	PM01683
Zinc(*)	≤ 10 mg/kg	PM01683
Heavy metals(*)	≤ 10 mg/kg	PM01683
Methanol (residual solvent class 2)(*)	≤ 3000 mg/kg	PM00544
Heptane (residual solvent class 3)(*)	≤ 0.5 g/100g	PM00544

(1) May also be determined by other means/methods (General Notices Ph. Eur./USP)

(*) ensured by quality assurance measures and therefore tested randomly only.

The Product meets the requirements of this specification.

The product meets the specification of current monographs:

"all-rac-alpha-tocopheryl acetate" of Ph. Eur.

"Vitamin E" of USP

"all-rac-alpha-tocopheryl acetate of FCC

"Tocopheryl-Acetate" of IP

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