

Vitamine -E-acetate (DL-alpha-Tocopheryl Acetate)  
 /USP/EP/FCC

TEST PARAMETER	REQUIREMENTS	METHOD
Characters		
Appearance	Light yellow, viscous oil	Visual
Identification		
Identification	Must comply	Ph.Eur. <sup>1)</sup>
Tests		
Optical rotation (2.50 g/25 ml ethanol)	Min. -0.01 Max. +0.01	Ph.Eur.
Acidity	Must comply	USP/FCC
Lead <sup>2)</sup>	Must comply	PM0160
Related substances		Ph.Eur.
Impurity A	Max. 0.5 area %	
Impurity B	Max. 1.5 area %	
Impurity C	Max. 0.5 area %	
Impurities D + E in sum	Max. 1.0 area %	
Any other impurity	Max. 0.25 area % each	
Impurities in total	Max. 2.5 area %	

<sup>1)</sup> May also be guaranteed by other means / methods (General Monographs Ph.Eur./USP)

<sup>2)</sup> Tested every 100 g.

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TEST PARAMETER	REQUIREMENTS	METHOD
Assay		
Tocopheryl acetate vs. USP standard	Min. 96.0 % Max. 102.0 %	PM0827
Tocopheryl acetate (EP)	Min. 96.5 % Max. 102.0 %	Ph. Eur.
Tocopheryl acetate (USP/FCC)	Min. 960 I.U./g Max. 1020 I.U./g	USP/FCC

Residual solvents, class 1 (PhEur/USP) are not present due to synthesis.

Only class 2 solvent methanol and class 3 solvent heptane are likely to be present.

Residual class 2 solvents are below the limits given in PhEur/USP and class 3 solvents are below 0.5%.

Vitamin-E-Acetate meets the requirements of the current monographs of:

Ph.Eur. "all-rac-alpha-Tocopheryl Acetate"

USP/NF "Vitamin E"

FCC "all-rac-alpha-Tocopheryl Acetate"

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom.