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.[1)]
Tests		
Optical rotation (2.50 g/25 ml ethanol)	Min. –0.01 Max. +0.01	Ph.Eur.
Acidity	Must comply	USP/FCC
Lead[2)]	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 %	

[1)] May also be guaranteed by other means / methods (General Monographs Ph.Eur./USP)
[2)] Tested every 100th batch.

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

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”