

Certificate of Analysis

XYS-J-QA-17 (0)

Product Name	D-alpha Tocopheryl Acetate		Product Code	C1360
Specification	1360 IU		Report Date	2020.01.20
Batch No.	C20200101		Mfg. Date	2020.01.18
Test Standard	USP 42		Expiry Date	2022.01.17
Product Standards	Items	Standard requirement	Method	Results
USP 42	Identification	1 Positive	USP	Positive
	1 Color reaction	2 $\geq +24^\circ$	USP<781>	+24.6°
	2 Specific Rotation $[\alpha]_D^{25^\circ}$	3 The retention time of the major peak in the test solution is the same as that of the standard preparation.	USP	Conform
	3 Retention Time			
	Acidity	≤ 1.0 ml	USP	0.03 ml
	Assay	96.0%~102.0% ≥ 1306 IU	USP	97.2% 1322IU
Appearance		The liquid forms are clear, colorless to yellow, viscous oily.	Visual	Conform
*Benzo(a)Pyrene		≤ 2 ppb	GC-MS	<2 ppb
Solvent residue-Hexane		≤ 290 ppm	USP<467>	0.8 ppm
Heavy Metals (As Pb)		≤ 10 mg/kg	USP <231>II	Conform
*Heavy Metals	Lead	≤ 1 mg/kg	AAS	<1 mg/kg
	Arsenic	≤ 1 mg/kg	AFS	<1 mg/kg
	Cadmium	≤ 1 mg/kg	AAS	<1 mg/kg
	Mercury	≤ 0.1 mg/kg	AFS	<0.1 mg/kg
*Microbiology	Total Bacterial Count	≤ 1000 (cfu/g)	USP<61>	Conform
	Yeast and Molds	≤ 100 (cfu/g)	USP<61>	Conform
	Escherichia Coli	≤ 10 (cfu/g)	USP<61>	Conform
	Salmonella	Negative/25g	USP<61>	Negative
	Staphylococcus Aureus	Negative/10g	USP<61>	Negative
Conclusion: Conforms to USP 42.				
Remarks: *Test periodically to ensure requirements are met.				
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