

Tel: (201) 497-5993
Fax: (201) 497-5994

Certificate of Analysis

Product Name	D-alpha Tocopheryl Acid Succinate	Product Code	H1185	
Specification	1185 IU(HPMC)	Report Date	2023.04.24	
Batch No.	H20230402	Mfg. Date	2023.04.23	
Test Standard	USP-NF 2022	Expiry Date	2025.04.22	
Product Standards	Items	Standard requirement	Method	Results
USP-NF 2022	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	18.0 ml~19.3 ml	USP	18.5 ml
	Assay	96.0%~102.0% ≥ 1162 IU	USP	98.0% 1186 IU
Appearance		White to off-white granular or powder.	Visual	Conform
Particle Size		Residue on 20 meshes $\leq 1\%$	USP<786>	0.2%
Bulk Density		0.45g/cm ³ ~0.60 g/cm ³	USP<616>	0.52 g/cm ³
*Benzo(a)Pyrene		≤ 2 ppb	GC-MS	<2 ppb
Solvent residue	Hexane	≤ 290 ppm	USP<467>	10 ppm
	Ethanol	≤ 5000 ppm		24 ppm
*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	Aerobic Plate Count	≤ 1000 (cfu/g)	USP<61>	<10 (cfu/g)
	Yeast and Molds	≤ 100 (cfu/g)	USP<61>	<10 (cfu/g)
	Escherichia Coli	Negative/g	USP<62>	Negative
	Salmonella	Negative/25g	USP<62>	Negative
	Staphylococcus Aureus	Negative/10g	USP<62>	Negative

Conclusion: Conforms to USP-NF 2022.

Remarks: *Test periodically to ensure requirements are met.