

R#16855
R50240
4-14-23
XYS-J-QA-17 (1)

Certificate of Analysis

Product Name	D-alpha Tocopheryl Acid Succinate		Product Code	H1210
Specification	1210 IU		Report Date	2022.04.16
Batch No.	H20220305		Mfg. Date	2022.03.30
Test Standard	USP 44		Expiry Date	2025.03.29
Product Standards	Items	Standard requirement	Method	Results
USP 44	Identification 1 Color reaction 2 Specific * Rotation $[\alpha]_D^{25^\circ}$ 3 Retention Time	1 Positive	USP	Positive
		2 $\geq +24^\circ$	USP<781>	+24.5°
		3 The retention time of the major peak in the test solution is the same as that of the standard preparation.	USP	Conform
	Acidity	18.0 ml~19.3 ml	USP	18.8 ml
	Assay	96.0%~102.0% ≥ 1162 IU	USP	98.6% 1193 IU
Appearance	White to off-white granular or powder.		Visual	Conform
Particle Size	Residue on 20 meshes $\leq 1\%$		USP<786>	0.4%
Bulk Density	0.45g/cm ³ ~0.60 g/cm ³		USP<616>	0.50 g/cm ³
*Benzo(a)Pyrene	≤ 2 ppb		GC-MS	<2 ppb
Solvent residue	Hexane	≤ 290 ppm	USP<467>	16 ppm
	Ethanol	≤ 5000 ppm		2 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	Aerobic Plate Count	≤ 1000 (cfu/g)	USP<61>	Conform
	Yeast and Molds	≤ 100 (cfu/g)	USP<61>	Conform
	Escherichia Coli	<10 (cfu/g)	USP<62>	Conform
	Salmonella	Negative/25g	USP<62>	Negative
	Staphylococcus Aureus	Negative/10g	USP<62>	Negative
Conclusion: Conforms to USP 44.				
Remarks: *Test periodically to ensure requirements are met.				
Editor: 林娟	Reviewer: 孔维波	Approver: 		

