



Certificate of Analysis

Product Name	Vitamin E< all-rac- α -Tocopheryl Acetate >		
Batch No.	201202403204	Specification	Raw Material
Sample Source	Plant 201	Package	Drum
Mfg. Date	2024/03/05	Quantity	19000.00kg
Retest Date	2027/03/04	Test Standard	Ph.Eur./USP/FCC

ITEMS	METHODS	SPECIFICATIONS	RESULTS
Description	Visual	Clear, colourless slightly greenish-yellow, Viscous, oily liquid, Ph.Eur./USP/FCC	Clear, slightly greenish-yellow. Viscous, oily liquid
Identification			
Optical rotation	Ph.Eur.2.2.7	-0.01° ~ +0.01°, Ph.Eur.	0.00°
IR	Ph.Eur.2.2.24	To conform, Ph.Eur./USP/FCC	Conform
Color reaction	USP	To conform, USP/FCC	Conform
Retention time	GC	To conform, USP/FCC	Conform
Related Substances			
Impurity A	Ph.Eur.2.2.28	≤0.5%, Ph.Eur.	<0.1%
Impurity B	Ph.Eur.2.2.28	≤1.5%, Ph.Eur.	0.72%
Impurity C	Ph.Eur.2.2.28	≤0.5%, Ph.Eur.	<0.1%
Impurities D and E	Ph.Eur.2.2.28	≤1.0%, Ph.Eur.	<0.1%
Any other impurity	Ph.Eur.2.2.28	≤0.25%, Ph.Eur.	<0.1%
Total impurities	Ph.Eur.2.2.28	≤2.5%, Ph.Eur.	0.72%
Acidity	USP/FCC	≤1.0ml, USP/FCC	0.07mL
Residual Solvents	Ph.Eur.2.4.24 USP<467>	To conform (In-house)	Conform
Heavy metals			
Pb	AA	≤2mg/kg, FCC	<0.5mg/kg
Arsenic	ChP0822	≤1mg/kg(in-house)	<1mg/kg
Copper	ICP-MS	≤25mg/kg(in-house)	<2mg/kg
Zinc	ICP-MS	≤25mg/kg(in-house)	<2mg/kg
Palladium	AA	≤5ppm(in-house)	<1ppm
Assay			
Assay(Ph.Eur.)	Ph.Eur.2.2.28	96.5% ~ 102.0%, Ph.Eur.	98.5%
Assay(Ph.Eur.)	Ph.Eur.2.2.28	434.3mg α -tocopherol/g ~ 459.0mg α -tocopherol/g, Ph.Eur.	443.3mg α -tocopherol/g
Assay(USP/FCC)	Ph.Eur.2.2.28	96.0% ~ 102.0%, USP/FCC	98.5%
Assay(USP/FCC)	Ph.Eur.2.2.28	432.0mg α -tocopherol/g ~ 459.0mg α -tocopherol/g, USP/FCC	443.3mg α -tocopherol/g
Microbial limit¹			
TAMC	USP<61> Ph.Eur.2.6.12	≤1000cfu/g, Ph.Eur./USP	Certified
TYMC			



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ITEMS	METHODS	SPECIFICATIONS	RESULTS
Escherichia coli	USP<61> Ph.Eur.2.6.12	≤ 100 cfu/g, Ph.Eur./USP	Certified
Pseudomonas aeruginosa	USP<62> Ph.Eur.2.6.13	n.d./g, Ph.Eur./USP	Certified
Staphylococcus aureus	USP<62> Ph.Eur.2.6.13	n.d./g, Ph.Eur./USP	Certified
Enterobacterial	USP<62> Ph.Eur.2.6.13	n.d./g, Ph.Eur./USP	Certified
Salmonella	USP<62> Ph.Eur.2.6.13	n.d./10g, Ph.Eur./USP	Certified

Conclusion: Conform to Ph.Eur./USP/FCC

Remark: "1" Conduct every tenth batch.

"Certified" indicates data obtained by statistically designed sampling audits.

Material Code:4100102

Reviewer: 吴艳妮

吴艳妮 2024/03/19 09:57:31

Approver: 王乐乐

王乐乐 2024/03/19 10:32:57