



Report Date: 2022/01/07



IG21120169001

Certificate of Analysis

Product Name	Vitamin E< all-rac- $\alpha$ -Tocopheryl Acetate		
Batch No.	201202112214	Specification	Raw Material
Sample Source	Plant 201	Package	Drum
Mfg. Date	2021/12/24	Quantity	16000.00kg
Retest Date	2024/12/23	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
<b>Identification</b>			
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	QC	To conform, USP/FCC	Conform
<b>Related Substances</b>			
Impurity A	Ph.Eur.2.2.28	≤0.5%, Ph.Eur.	<0.1%
Impurity B	Ph.Eur.2.2.28	≤1.5%, Ph.Eur.	0.83%
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.	0.83%
Acidity	USP/FCC	≤1.0ml, USP/FCC	0.08mL
Residual Solvents	Ph.Eur.2.4.24 USP<467>	To conform (In-house)	Conform
<b>Heavy metals</b>			
Pb	AA	≤2mg/kg, FCC	<0.5mg/kg
Arsenic	ChPQ822	≤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
<b>Assay</b>			
Assay(Ph.Eur.)	Ph.Eur.2.2.28	96.5% ~ 102.0%, Ph.Eur.	99.1%
Assay(Ph.Eur.)	Ph.Eur.2.2.28	434.3mg $\alpha$ -tocopherol/g ~ 459.0mg $\alpha$ -tocopherol/g, Ph.Eur.	446.0mg $\alpha$ -tocopherol/g
Assay(USP/FCC)	Ph.Eur.2.2.28	96.0% ~ 102.0%, USP/FCC	99.1%
Assay(USP/FCC)	Ph.Eur.2.2.28	432.0mg $\alpha$ -tocopherol/g ~ 459.0mg $\alpha$ -tocopherol/g, USP/FCC	446.0mg $\alpha$ -tocopherol/g
<b>Microbial limit<sup>1</sup></b>			
TAMC	USP<61> Ph.Eur.2.6.12	≤1000cfu/g, Ph.Eur./USP	Certified

Mfg.:Zhejiang Medicine Co.,Ltd. Xinchang Pharmaceutical Factory  
 Add.:98 East Xinchang Dadao Road,Xinchang,Zhejiang 312500 P.R.China

Tel./Fax:+86-575-86021395/86024675  
 Email: QC@xcpharma.com



**Certificate of Analysis**



Product Name	Vitamin E<sup>α</sup>-all-rac-α-Tocopheryl Acetate		
Batch No.	201202112214	Specification	Raw Material
Sample Source	Plant 201	Package	Drum
Mfg. Date	2021/12/24	Quantity	16000.00kg
Retest Date	2024/12/23	Test Standard	Ph.Eur./USP/FCC

ITEMS	METHODS	SPECIFICATIONS	RESULTS
TYMC	USP<61> Ph.Eur.2.6.12	≤100cfu/g, Ph.Eur./USP	Certified
Escherichia coli	USP<62> Ph.Eur.2.6.13	n.d./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 2022/01/07 16:01:42

Approver: 王乐乐  
 王乐乐 2022/01/07 16:04:51