

Certificate of Analysis

Product Name: Vitamin E powder

Standard:BP/USP/FCC

Origin:China

ITEMS	METHODS	SPECIFICATIONS	RESULTS
Description	Visual	Clear, colourless slightly greenish-yellow, Viscous, oily liquid, EP/USP/FCC	Clear, slightly greenish-yellow, Viscous, oily liquid
Identification			
Optical rotation	Ph.Eur.2.2.7	-0.01°~+0.01°, EP	0.00°
IR	Ph.Eur.2.2.24	To conform, EP/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%, EP	<0.1%
Impurity B	Ph.Eur.2.2.28	≤1.5%, EP	0.49%
Impurity C	Ph.Eur.2.2.28	≤0.5%, EP	<0.1%
Impurities D and E	Ph.Eur.2.2.28	≤1.0%, EP	<0.1%
Any other impurity	Ph.Eur.2.2.28	≤0.25%, EP	<0.1%
Total impurities	Ph.Eur.2.2.28	≤2.5%, EP	0.49%
Acidity	USP/FCC	≤1.0ml, USP/FCC	0.05mL
Residual Solvents			
Isobutyl acetate	Ph.Eur.2.4.24 USP<467>	≤0.5% (in-house)	<0.01%
Heavy metals			
Pb	AA	≤2mg/kg, FCC	<0.05mg/kg (BLD)
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(1)	Ph.Eur.2.2.28	96.5% ~ 102.0%, EP	99.0%
Assay(2)	Ph.Eur.2.2.28	96.0% ~ 102.0%, USP/FCC	99.0%
Microbiological tests			
Total aerobic microbial	USP<61>	≤1000cfu/g, EP/USP	Certified
Total moulds and yeasts	USP<61>	≤100cfu/g, EP/USP	Certified
Escherichia coli	USP<62>	n.d./g, EP/USP	Certified
Pseudomonas aeruginosa	USP<62>	n.d./g, EP/USP	Certified
Staphylococcus aureus	USP<62>	n.d./g, EP/USP	Certified
Enterobacterial	USP<62>	n.d./g, EP/USP	Certified
Salmonella	USP<62>	n.d./1g, EP/USP	Certified

Vitamin E powder COA