

产品检验报告单

Certificate of Analysis

品名 Product	L-苯丙氨酸 L-Phenylalanine	生产日期 Date of Manufacture	2023-08-04
批号 Batch No.	H4012208011	检验日期 Date of Certificate	2023-08-08
重量 Quantity	300kg	复验期至 Date of Retest	2025-08-03
检验标准 Specification	EP8/USP41/FCC10		
检验项目 Analysis Contents	检验标准 Analysis Standard	检验结果 Analysis Results	
Characters, Appearance	White or almost white, crystalline powder or colourless crystals	white crystalline powder	
Characters, Solubility	Freely soluble in formic acid, sparingly soluble in water, practically insoluble in ethanol	Conform	
鉴别 Identification IR	Infrared absorption	Conform	
含量 Assay (%)	98.5~101.0	99.7	
灼烧残渣 Residue on ignition (%)	≤ 0.1	0.02	
氯化物 Chloride (%)	≤ 0.02	<0.02	
硫酸盐 Sulfate (%)	≤ 0.03	<0.03	
铵盐 Ammonium (%)	≤0.02	<0.02	
铁 Iron (ppm)	≤10	<10	
铅 Lead (ppm)	≤1	<1	
砷 Arsenic (ppm)	≤0.5	<0.5	
镉 Cadmium (ppm)	≤0.5	<0.5	
汞 Mercury (ppm)	≤0.1	<0.1	
重金属 Heavy metals (ppm)	≤10	<10	
纯度 Chromatographic purity	Individual impurities (%) ≤0.5	<0.5	
	Total impurities (%) ≤2.0	<2.0	
比旋光度 Specific rotation $[\alpha]_D^{20}$	-33.2~ -35.2	-33.8	
PH值	5.4 ~6.0	5.7	
干燥失重 Loss on drying (%)	≤0.2	0.13	
菌落总数 Total plate count (cfu/g)	≤ 1000	<1000	
霉菌和酵母菌 Mould & Yeasts (cfu/g)	≤ 100	<100	
Enterobacteriaceae (cfu/10g)	negative	conform	
沙门氏菌 Salmonella (cfu/25g)	negative	conform	
大肠埃希菌 E. coli (cfu/g)	negative	conform	
大肠杆菌 Coliform (cfu/g)	negative	conform	
金黄色葡萄球菌 Staphylococcus aureus (cfu/g)	negative	conform	
Bacillus sp. (cfu/g)	negative	conform	
Clostridium sp.	negative	conform	
结论 Conclusion	符合 EP8/USP41/FCC10 标准 The product complies to EP8/USP41/FCC10		



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