

Certificate of Analysis

报告编号: CPVBL052NLGJ02

产品名称		工工的与工品	
Product Name	L-酪氨酸 L-Tyrosine		
CAS 号 CAS No.	60-18-4	产品编号 Product Code	VBL-NP-052
产品批号 Batch Number	VBL052NLGJ02	检验依据 According to	企业标准
生产日期 Manufacture Date	2024-09-23	有效期至 Expiry Date	2027-09-22
分析项目 Items of Analysis		标准 ication	实测结果 Results
外观 Appearance		晶性粉末 alline powder	白色结晶性粉末 White crystalline powder
鉴别(IR) Identification	应符合 Com	う规定 plies	符合规定 Complies
含量 Assay	98.5~	101.5%	100.2%
比旋度 Specific rotation [a]D ²⁵	-9.8∼-11.2°		-10.9°
干燥失重 Loss on drying	≤0.3% Not more than 0.5%		0.13%
炽灼残渣 Residue on ignition	不高于 0.4% Not more than 0.4%		<0.4%
氯化物 Chloride(Cl)	不高于 0.04% Not more than 0.04%		<0.04%
硫酸盐 Sulfate(SO ₄)	不高于 0.04% Not more than 0.04%		<0.04%
色谱纯度	单杂 Any individual impurities	不高于 0.5% Not more than 0.5%	符合规定 Complies
Chromatographic purity	总杂 Total impurities	不高于 2.0% Not more than 2.0%	符合规定 Complies
重金属 Heavy metals(Pb)	不高于 15ppm Not more than 15ppm		符合规定 Complies
铁 Iron(Fe)	不高于 30ppm Not more than 30ppm		符合规定 Complies
铅 Lead	不高于 3ppm Not more than 3ppm		符合规定 Complies
镉 Cadmium	不高于 1ppm Not more than 1ppm		符合规定 Complies
汞 Mercury(Hg)	不高于 0.1ppm Not more than 0.1ppm		符合规定 Complies

本批次产品已经完成检测分析并释放,生产及管控记录由公司质量管理部门完成审核。根据所采用检测标准进行测试,确认该批次产品符 合上述质量标准规格。This lot has been analyzed and released. The production and control records have been completed and audited by the company's quality management department. Testing was performed according to the testing standards used and it was confirmed that the lot meets the above quality standard specifications. 总部-杭州唯铂莱生物科技有限公司 地址 - 浙江省杭州市西湖区振中路 202 号 2 幢

Headquarter - Hangzhou Viablife Biotech Co., Ltd.

MFG Base - Jiangxi Viablife Biopharmaceutical Co., Ltd.

生产基地 - 江西唯铂莱生物制药有限公司

地址 - 江西省赣江新区直管区仲景路 388 号

ADD - Building 2, 202 Zhenzhong Road. Xihu District, Hangzhou, Zhejiang





		Viablife Biotech
砷 Arsenic	不高于 1.5ppm Not more than 1.5ppm	符合规定 Complies
菌落总数 Total number of colonies	≤1000 CFU/g	符合规定 Complies
霉菌和酵母菌 Yeast and Mould	≤100 CFU/g	符合规定 Complies
大肠杆菌 Escherichia coli	阴性 Negative	符合规定 Complies
金黄色葡萄球菌 Staphylococcus aureus	阴性 Negative	符合规定 Complies
沙门氏菌 Salmonella	阴性 Negative	符合规定 Complies
判定 Decide	本品符合企业标准之规定 This product complies with Enterpris	43
大がり サイナンコ ケート	- 01	V V

检验员:葡萄 Analyst

复核员: 岩埃 Review

2024-09-30

本批次产品已经完成检测分析并释放,生产及管控记录由公司质量管理部门完成审核。根据所采用检测标准进行测试,确认该批次产品符 合上述质量标准规格。This lot has been analyzed and released. The production and control records have been completed and audited by the company's quality management department. Testing was performed according to the testing standards used and it was confirmed that the lot meets the above quality standard specifications.

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Certificate of Analysis

报告编号: CPVBL052NLGK01

产品名称 Product Name			
CAS 号 CAS No.	60-18-4	产品编号 Product Code	VBL-NP-052
产品批号 Batch Number	VBL052NLGK01	检验依据 According to	企业标准
生产日期 Manufacture Date	2024-10-08	有效期至 Expiry Date	2027-10-07
分析项目	质量		实测结果
Items of Analysis	Specifi		Results
外观	白色结晶		白色结晶性粉末
Appearance	White crysta		White crystalline powder
鉴别(IR)	应符台		符合规定
Identification	Comj		Complies
含量 Assay	98.5~101.5%		100.2%
比旋度 Specific rotation [a]D ²⁵	-9.8~-11.2°		-11.0°
干燥失重 Loss on drying	≤0.3% Not more than 0.5%		0.1%
炽灼残渣 Residue on ignition	不高于 0.4% Not more than 0.4%		<0.4%
氯化物 Chloride(Cl)	不高于 0.04% Not more than 0.04%		<0.04%
硫酸盐 Sulfate(SO ₄)	不高于 0.04% Not more than 0.04%		<0.04%
色谱纯度	单杂	不高于 0.5%	符合规定
	Any individual impurities	Not more than 0.5%	Complies
Chromatographic purity	总杂	不高于 2.0%	符合规定
	Total impurities	Not more than 2.0%	Complies
重金属	不高于 15ppm		符合规定
Heavy metals(Pb)	Not more than 15ppm		Complies
铁	不高于 30ppm		符合规定
Iron(Fe)	Not more than 30ppm		Complies
铅	不高于 3ppm		符合规定
Lead	Not more than 3ppm		Complies
镉	不高于 1ppm		符合规定
Cadmium	Not more than 1ppm		Complies
汞	不高于 0.1ppm		符合规定
Mercury(Hg)	Not more than 0.1ppm		Complies

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地址-江西省赣江新区直管区仲景路 388号





Viablife Biotech 砷 不高于 1.5ppm 符合规定 Arsenic Not more than 1.5ppm Complies 菌落总数 符合规定 ≤1000 CFU/g Total number of colonies Complies 霉菌和酵母菌 符合规定 Yeast and Mould ≤100 CFU/g Complies 大肠杆菌 阴性 符合规定 Escherichia coli Negative Complies 金黄色葡萄球菌 阴性 符合规定 Staphylococcus aureus Negative Complies 沙门氏菌 阴性 符合规定 Salmonella Negative Complies 本品符合企业标准之规定 判定 Decide This product complies with Enterprise standards 检验员: 居华 复核员: 黃旗超 2024-10-14

Analyst

Review

本批次产品已经完成检测分析并释放,生产及管控记录由公司质量管理部门完成审核。根据所采用检测标准进行测试,确认该批次产品符 合上述质量标准规格。This lot has been analyzed and released. The production and control records have been completed and audited by the company's quality management department. Testing was performed according to the testing standards used and it was confirmed that the lot meets the above quality standard specifications.

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Certificate of Analysis

报告编号: CPVBL052NLGK02

			IX 百编写: CPVBLU52NLGKU2
产品名称	L-酪氨酸		
Product Name	L-Tyrosine		
CAS 号 CAS No.	60-18-4	产品编号 Product Code	VBL-NP-052
产品批号 Batch Number	VBL052NLGK02	检验依据 According to	企业标准
生产日期 Manufacture Date	2024-10-10	有效期至 Expiry Date	2027-10-09
分析项目		t标准	实测结果
Items of Analysis		fication	Results
外观		晶性粉末	白色结晶性粉末
Appearance		alline powder	White crystalline powder
鉴别(IR)		合规定	符合规定
Identification		nplies	Complies
含量 Assay	98.5~	101.5%	100.5%
比旋度 Specific rotation [a]D ²⁵	-9.8∼-11.2°		-11.0°
干燥失重 Loss on drying	≤0.3% Not more than 0.5%		0.1%
炽灼残渣 Residue on ignition	不高于 0.4% Not more than 0.4%		<0.4%
氯化物 Chloride(Cl)	不高于 0.04% Not more than 0.04%		<0.04%
硫酸盐 Sulfate(SO ₄)		不高于 0.04% Not more than 0.04%	
色谱纯度	单杂	不高于 0.5%	符合规定
	Any individual impurities	Not more than 0.5%	Complies
Chromatographic purity	总杂	不高于 2.0%	符合规定
	Total impurities	Not more than 2.0%	Complies
重金属	不高于 15ppm		符合规定
Heavy metals(Pb)	Not more than 15ppm		Complies
铁	不高于 30ppm		符合规定
Iron(Fe)	Not more than 30ppm		Complies
铅	不高于 3ppm		符合规定
Lead	Not more than 3ppm		Complies
镉	不高于 1ppm		符合规定
Cadmium	Not more than 1ppm		Complies
汞	不高于 0.1ppm		符合规定
Mercury(Hg)	Not more than 0.1ppm		Complies

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Viablife®

Viablife Biotech 砷 不高于 1.5ppm 符合规定 Arsenic Not more than 1.5ppm Complies 菌落总数 符合规定 ≤1000 CFU/g Total number of colonies Complies 霉菌和酵母菌 符合规定 ≤100 CFU/g Yeast and Mould Complies 大肠杆菌 阴性 符合规定 Escherichia coli Negative Complies 金黄色葡萄球菌 阴性 符合规定 Staphylococcus aureus Negative Complies 沙门氏菌 阴性 符合规定 Salmonella Negative Complies 本品符合企业标准之规定 判定 Decide This product complies with Enterprise standards

检验员: 尾尖 Analyst 复核员: 机构铅 Review

审核员:

报告日期: 2024-10-16

Report Date

本批次产品已经完成检测分析并释放,生产及管控记录由公司质量管理部门完成审核。根据所采用检测标准进行测试,确认该批次产品符合上述质量标准规格。This lot has been analyzed and released. The production and control records have been completed and audited by the company's quality management department. Testing was performed according to the testing standards used and it was confirmed that the lot 总部,结构即绝迹性物理技术即以

总部 - 杭州唯铂莱生物科技有限公司 Headquarter - Hangzhou Viablife Biotech Co., Ltd. 生产基地 - 江西唯铂莱生物制药有限公司 MFG Base - Jiangxi Viablife Biopharmaceutical Co., Ltd.

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Certificate of Analysis

报告编号: CPVBL052NLGK03

产品名称	L-酪氨酸		
Product Name	L-Tyrosine		
CAS 号 CAS No.	60-18-4	产品编号 Product Code	VBL-NP-052
产品批号 Batch Number	VBL052NLGK03	检验依据 According to	企业标准
生产日期 Manufacture Date	2024-10-12	有效期至 Expiry Date	2027-10-11
分析项目		标准	实测结果
Items of Analysis		ication	Results
外观		晶性粉末	白色结晶性粉末
Appearance		illine powder	White crystalline powde
鉴别(IR)	应符合		符合规定
Identification	Com		Complies
含量 Assay	98.5~101.5%		99.9%
比旋度 Specific rotation [a]D ²⁵	-9.8∼-11.2°		-10.8°
干燥失重 Loss on drying	≤0.3% Not more than 0.5%		0.09%
炽灼残渣 Residue on ignition	不高于 0.4% Not more than 0.4%		<0.4%
氯化物 Chloride(Cl)	不高于 0.04% Not more than 0.04%		<0.04%
硫酸盐 Sulfate(SO ₄)	不高于 0.04% Not more than 0.04%		<0.04%
色谱纯度	单杂	不高于 0.5%	符合规定
	Any individual impurities	Not more than 0.5%	Complies
Chromatographic purity	总杂	不高于 2.0%	符合规定
	Total impurities	Not more than 2.0%	Complies
重金属	不高于 15ppm		符合规定
Heavy metals(Pb)	Not more than 15ppm		Complies
铁	不高于 30ppm		符合规定
Iron(Fe)	Not more than 30ppm		Complies
铅	不高于 3ppm		符合规定
Lead	Not more than 3ppm		Complies
镉	不高于 1ppm		符合规定
Cadmium	Not more than 1ppm		Complies
汞	不高于 0.1ppm		符合规定
Mercury(Hg)	Not more than 0.1ppm		Complies

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7.1.		Viablife Biotech
砷 Arsenic	不高于 1.5ppm Not more than 1.5ppm	符合规定 Complies
菌落总数 Total number of colonies	≤1000 CFU/g	符合规定 Complies
霉菌和酵母菌 Yeast and Mould	≤100 CFU/g	符合规定 Complies
大肠杆菌 Escherichia coli	阴性 Negative	符合规定 Complies
金黄色葡萄球菌 Staphylococcus aureus	阴性 Negative	符合规定 Complies
沙门氏菌 Salmonella	阴性 Negative	符合规定 Complies
判定	本品符合企业标准之类	
Decide	This product complies with Enter	

检验员: 周奖 Analyst

复核员:新施 Review

Checke

1 报告日期: 2024-10-18

Report Date

本批次产品已经完成检测分析并释放,生产及管控记录由公司质量管理部门完成审核。根据所采用检测标准进行测试,确认该批次产品符合上述质量标准规格。This lot has been analyzed and released. The production and control records have been completed and audited by the company's quality management department. Testing was performed according to the testing standards used and it was confirmed that the lot

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Certificate of Analysis

报告编号: CPVBL052NLGK04

产品名称 Product Name			
CAS 号 CAS No.	产品编号 Product Code		VBL-NP-052
产品批号 Batch Number	VBL052NLGK04	检验依据 According to	企业标准
生产日期 Manufacture Date	2024-10-14	有效期至 Expiry Date	2027-10-13
分析项目	质量		实测结果
Items of Analysis	Specifi		Results
外观	白色结晶		白色结晶性粉末
Appearance	White crysta		White crystalline powder
鉴别(IR)	应符台		符合规定
Identification	Com		Complies
含量 Assay	98.5~101.5%		100.0%
比旋度 Specific rotation [a]D ²⁵	-9.8∼-11.2°		-10.9°
干燥失重 Loss on drying	≤0.3% Not more than 0.5%		0.1%
炽灼残渣 Residue on ignition	不高于 0.4% Not more than 0.4%		<0.4%
氯化物 Chloride(Cl)	不高于 0.04% Not more than 0.04%		<0.04%
硫酸盐 Sulfate(SO ₄)	不高于 0.04% Not more than 0.04%		<0.04%
色谱纯度	单杂	不高于 0.5%	符合规定
	Any individual impurities	Not more than 0.5%	Complies
Chromatographic purity	总杂	不高于 2.0%	符合规定
	Total impurities	Not more than 2.0%	Complies
重金属	不高于 15ppm		符合规定
Heavy metals(Pb)	Not more than 15ppm		Complies
铁	不高于 30ppm		符合规定
Iron(Fe)	Not more than 30ppm		Complies
铅	不高于 3ppm		符合规定
Lead	Not more than 3ppm		Complies
镉	不高于 1ppm		符合规定
Cadmium	Not more than 1ppm		Complies
汞	不高于 0.1ppm		符合规定
Mercury(Hg)	Not more than 0.1ppm		Complies

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		Viablife Biotech
砷 Arsenic	不高于 1.5ppm Not more than 1.5ppm	符合规定 Complies
菌落总数 Total number of colonies	≤1000 CFU/g	符合规定 Complies
霉菌和酵母菌 Yeast and Mould	≤100 CFU/g	符合规定 Complies
大肠杆菌 Escherichia coli	阴性 Negative	符合规定 Complies
金黄色葡萄球菌 Staphylococcus aureus	阴性 Negative	符合规定 Complies
沙门氏菌 Salmonella	阴性 Negative	符合规定 Complies
判定	本品符合企业标准之规	
Decide	This product complies with Enter	prise standards

检验员: 运从 Analyst

Review

审核员: Checker 2024-10-20

本批次产品已经完成检测分析并释放,生产及管控记录由公司质量管理部门完成审核。根据所采用检测标准进行测试,确认该批次产品符 合上述质量标准规格。This lot has been analyzed and released. The production and control records have been completed and audited by the company's quality management department. Testing was performed according to the testing standards used and it was confirmed that the lot meets the above quality standard specifications.

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