



SPECOM
Biochemical Co., Ltd

张家港市思普生化有限公司
ZHANGJIAGANG SPECOM BIOCHEMICAL CO., LTD

成品检验报告
CERTIFICATE OF ANALYSIS

产品名称 Product Name: L-亮氨酸 L-Leucine	
化学登录号 CAS No.: 61-90-5	质量标准 Quality Standard: USP43
批号 Batch No.: 24060710	数量 Quantity: 1000KGS
生产日期 Manufacture Date: Jun.10,2024	有效期至 Expiry Date: Jun.11,2027

项目 Items	标准 Specifications	结果 Results	检测方法 Test Method
外观 Appearance	白色结晶或结晶性粉末 White crystals or crystalline powder	Conforms	Visual
含量 Assay	98.5~101.5%	99.5%	USP<541>
灼烧残渣 Residue on ignition	≤0.4%	0.16%	USP<281>
氯化物 Chloride(Cl)	≤0.05%	<0.05%	USP<221>
硫酸盐 Sulfate(SO ₄)	≤0.03%	<0.03%	USP<221>
铁盐 Iron(Fe)	≤30ppm	<30ppm	USP<241>
相关物质 Related Compounds	单个杂质不超过 0.5%, 总杂质不超过 2.0% Not more than 0.5% of any individual impurity is found; Not more than 2.0% of total impurities is found	Conforms	USP<621>
比旋度 Specific rotation [α] _D ²⁵	+14.9°~+17.3°	+15.4°	USP<781S>
pH 值	5.5~7.0	6.0	USP<791>
干燥失重 Loss on drying	≤0.2%	0.16%	USP<731>

结论: 本批产品经检验符合美国药典 USP43 标准。

Conclusion: This Batch Is Conforming With The Standard Of USP43.

检验员:

Inspector:

何晓梅

复核人:

Checker:

刘洁

负责人:

Director:

张强

