

诚达药业股份有限公司

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质量检验报告书

CERTIFICATE OF ANALYSIS

品名: L-肉碱
 检验依据: USP 现行版
 包装容器: 纸板桶
 数量: 1070KG
 批号: D010-1206123
 生产日期: 20120621
 检验日期: 20120621
 有效期: 20140620

Product Name: L- Carnitine Base
 Quality Specification: USP current Edition
 Packing: Fiber Drum
 Quantity: 1070KG
 Batch No.: D010-1206123
 MFG. Date: 20120621
 Test Date: 20120621
 EXP. Date: 20140620

检验项目 Items	检验指标 Specification	检验结果 Results
外观 Description	白色结晶吸湿性粉末 White Crystalline hygroscopic powder	Conform
鉴别 Identification	IR 与 CRS 图谱一致 Comparing with the CRS spectrum	Conform
比旋度 Specific Rotation [α] _D ²⁰	-29° ~ -32°	-31.4°
酸碱度 PH	5.5 ~ 9.5	7.22
水分 Water Content	≤4.0%	0.22%
灼烧残渣 Residue On Ignition	≤0.5%	0.03%
氯化物 Chloride	≤0.4%	<0.4%
钾 Limit of potassium	≤0.2%	0.0001%
钠 Limit of sodium	≤0.1%	0.0030%
重金属 Heavy metals	≤0.002%	<0.001%
含量 Assay	97.0 ~ 103.0%	99.7%
残留溶剂(乙醇) Residue solvents (ethanol)	≤0.5%	0.06%
氰化物 Cyanide	不得检出 Not Detectable	N.D

结论: 符合美国药典 35 版
 Conclusion: Comply with USP35 edition

合格

检验: 张同强
 Analyzed by:

审核: 张同强
 Approved by: