

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: <u>L-肉碱酒石酸盐</u>	Product Name: <u>L CARNITINE L TARTRATE</u>
检验依据: <u>Q/CDJ3.09(04)-2011</u>	Quality Specification: <u>Q/CDJ3.09(04)-2011</u>
包装容器: <u>纸板桶</u>	Packing: <u>Fiber Drum</u>
数量: <u>1300KG</u>	Quantity: <u>1300KG</u>
批号: <u>D030-1206074</u>	Batch No.: <u>D030-1206074</u>
生产日期: <u>20120602</u>	MFG. Date: <u>20120602</u>
检验日期: <u>20120602</u>	Test Date: <u>20120602</u>
有效期: <u>20140601</u>	EXP. Date: <u>20140601</u>

检验项目 Items	检验指标 Specification	检验结果 Results
外观 Description	白色或类白色结晶性粉末 White or Off-white Crystalline Powder	White Crystalline Powder
鉴别 Identification	与对照品红外图谱一致 In accordance with the IR absorption spectrum of the reference	Conform
含量(以干品计) Assay(by anhydrous)	≥98.0%	99.6%
比旋度 Specific Rotation [α] _D ²⁰	-9.5° ~ -11.0°	-10.3°
水分 Water Content	≤0.50%	0.23%
灼烧残渣 Residue On Ignition	≤0.5%	0.03%
重金属(以 Pb 计) Heavy Metals	≤0.001%	<0.001%
砷(以 As 计) Arsenic	≤0.0001%	<0.0001%
PH	3.0~4.5	3.68
溶解度 Solubility	澄清 Clear	Conform
氯化物 Chloride	≤0.4%	<0.4%
L-肉碱含量 L-Carnitine Content	68.2% ± 1.0%	68.0%
L-酒石酸含量 L-Tartaric Acid Content	31.8% ± 1.0%	31.2%

结论: 符合企业标准
Conclusion: Comply with In-house standard

合格

检验: 张同平
Analyzed by:

审核:
Approved by:

张同平