

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: DL-肉碱盐酸盐

检验依据: IPC2002 版

包装容器: 纸板桶

数量: 755KG

批号: D071-1206008

生产日期: 20120608

检验日期: 20120608

有效期: 20140607

Product Name: DL-Carnitine HCl

Quality Specification: IPC2002 Edition

Packing: Fiber Drum

Quantity: 755KG

Batch No.: D071-1206008

MFG. Date: 20120608

Test Date: 20120608

EXP. Date: 20140607

检验项目 Items	检验指标 Specification	检验结果 Results
外观 Description	白色结晶性粉末 White Crystalline Powder	CONFORM
鉴定 Identification	符合 Conform	CONFORM
含量 Assay	≥98.5%	100.9%
熔点 Melting Point	196~201°C	197.6~199.8°C
干燥失重 Loss On Drying	≤1.0%	0.05%
灼烧残渣 Residue On Ignition	≤0.20%	0.03%
铵 Ammonium	≤0.01%	<0.01%
重金属(以 Pb 计) Heavy Metals	≤0.002%	<0.001%
砷(以 As 计) Arsenic	≤0.0001%	<0.0001%
PH(2% 水溶液) PH (2% Water Solution)	2.3~2.6	2.39
相关物质 Relate Substance	≤15%	3.89%

结论: 符合日本药典 2002 版

Conclusion: Comply with JPC2002 edition

合格

检验:

Analyzed by: 周国平

审核:

Approved by: Wang