



Certificate of Analysis

Product Name	Acetyl-L-Carnitine Hydrochloride	Check Foundation	In house Standard
Batch Quantity	1000kgs	Batch No	ALC17071001
Package	25kg/drum	Manufacturing Date	JUL. 10, 2017
Checking Date	JUL. 10, 2016	Retesting Date	JUL. 09, 2019

Check Item	Specification	Methods	Check Results
Identification	IR	USP<197K>	Positive
Specific rotation	-29.0°~ -27.0°	USP<781S>	-28.6°
PH	2.0~3.0	USP<791>	2.5
Loss on drying	≤0.5%	USP<921>method A	0.16%
Residual solvent	≤0.5%	USP<921>method A	0.15%
Residue on ignition	≤0.5%	USP<281>	0.14%
Residual solvents (Ethanol)	≤0.5%	USP<467>method	0.16%
Particle size	Through 20 mesh	20 Mesh Screen	100% passed
Bulk density	0.3-0.7 g/ml	Physical	0.44 g/ml
Tapped density	0.5- 0.9 g/ml	Physical	0.67 g/ml
Assay	≥98.0%	Titration	99.34%
Heavy metal	≤10ppm	USP<231> method A	<10ppm
Lead (Pb)	≤3ppm	AAS	<3ppm
Cadmium (Cd)	≤1ppm	AAS	<1ppm
Mercury (Hg)	≤0.1ppm	AAS	<0.1ppm
Arsenic (As)	≤1ppm	Ch.P Appendix VIII J.	<1ppm
TPC	≤1000Cfu/g	EP(2.6.12)	50Cfu/g
Yeast & Mold	≤100Cfu/g	EP(2.6.12)	25Cfu/g
E.Coli	Negative	Ch.P Appendix XI J.	Negative
Salmonella	Negative	Ch.P Appendix XI J.	Negative

Conclusion: Comply with In house Standard

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