



Certificate of Analysis

AMINATURE
WORLDWIDE DISTRIBUTION

Ver_3.0_Issued in Apr, 2019

Product N-Acetyl-L-Cysteine
Production Date 2020.02.13
Expiration Date 2023.02.12
Lot Number IADF200213
Quantity 14000kg
Country of Origin Ningbo, China
Origin Acetylation, using fermentation Cys

1. Chemical / Analytical Information

This product meets quality requirements of USP41, EP8 monographs

Analysis Item	Specification	Method	Result
Characters, Appearance	White or almost white, crystalline powder or colourless crystals	-	White colourless crystals
Characters, Solubility	Freely soluble in water, soluble in ethanol	-	conform
Identification	Infrared absorption	USP 41	conform
Assay	NLT 98.5% and NMT 101.0%	USP 41	100.44%
Residue on Ignition (Sulfated Ash)	NMT 0.2%	USP 41	0.06%
Chloride	NMT 0.04%	In house	<0.04%
Sulfate	NMT 0.03%	In house	<0.03%
Ammonium	NMT 0.02%	In house	<0.02%
Iron	NMT 20ppm	In house	<20ppm
Lead	NMT 1 ppm	USP 41	<1 ppm
Arsenic	NMT 0.5 ppm	USP 41	<0.5 ppm
Cadmium	NMT 0.5 ppm	USP 41	<0.5 ppm
Mercury	NMT 0.1 ppm	USP 41	<0.1 ppm
Zinc	NMT 10ppm	USP 41	<10 ppm
Heavy Metals	NMT 10 ppm	USP 41	<10 ppm
L-Cystine (impurity)	NMT 0.5%	Ep 8	<0.5%
L-Cysteine (impurity)	NMT 0.5%	Ep 8	<0.5%
N,N'-diacetyl-L-Cystine (impurity)	NMT 0.5%	Ep 8	<0.5%
N,S'-diacetyl-L-Cysteine	NMT 0.5%	Ep 8	<0.5%
Any other impurity	NMT 0.5%	Ep 8	<0.5%
Total impurities	NMT 0.5%	Ep 8	<0.5%
Optical Rotation	+21.3° - +27.0° (t = 25°C)	USP 41	+25.24°
pH	2.0 ~ 2.8	USP 41	2.23
Loss on Drying	NMT 1.0%	USP 41	0.18%

2. Microbiological Information

Analysis Item	Specification	Method	Result
Total viable count	NMT 1000 cfu/g	USP 41	<1000 cfu/g
Yeast & mould	NMT 100 cfu/g	USP 41	<100 cfu/g
Enterobacteriaceae	Negative/10g	ISO	Negative
Salmonella sp.	Negative/25g	USP 41	Negative
Coliforms bacteria	Negative/g	USP 41	Negative
Escherichia coli	Negative/g	USP 41	Negative
Staphylococcus aureus	Negative/g	USP 41	Negative
Bacillus sp.	Negative/g	GB	Negative
Clostridium sp.	Negative/g	USP 41	Negative

Keep container dry and tightly closed: Keep in a cool well-ventilated area away from heat and oxidizing agents.
 Shelf life: Recommend usage within 3 years from date of production.



QA: *Stephan Zhou*
 Aihua Zhang

N-ACETYL-L-CYSTEINE

Batch# IADF200213

1 Packs of 25 Kg. Net ()

Kal-Chem International, Inc. PO# 031920S (3/23/2020)