

METAPHARMACEUTICAL

N DE LOTE:

0260921

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22/09/2021.



Certificate of Analysis

AMINATURE

Ver_3.0_Issued in Apr, 2019

Product N-Acetyl-L-Cysteine
Production Date 2021.03.28
Expiration Date 2024.03.27
Lot Number IADF210328
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	99.08%
Residue on Ignition (Sulfated Ash)	NMT 0.2%	USP 41	0.05%
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 20 ppm	In house	< 20 ppm
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-Cysteine (impurity)	NMT 0.5%	Ep 8	< 0.5%
N,S'-diacetyl-L-Cysteine (impurity)	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	+25.04°
pH	2.0 ~ 2.8	USP 41	2.29
Loss on Drying	NMT 1.0%	USP 41	0.19%

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 place; Keep away from heat and oxidizing agents.
Shelf life: Recommend usage within 3 years from date of production

PO No.:5500235193

Container No.:EGHU9616772



QA: *Stephan Zhou*