Trafa Pharmaceutical Inc.
140 Padgette Street, Unit D
Chicopee, MA 01022, USA
Tel: 1-866-99-Trafa (87232) FAX: 1-800-627-1880
Sales@TrafaPharma.com www.TrafaPharma.com

SPECIFICATION SHEET

Product Name	L-CYSTEINE
Quantity	2000KGS
Country of Origin	China
Product Information	White crystals or crystalline powder

ITEMS	LIMIT	TEST METHOD
Appearance	White or almost white, crystal or crystalline powder	
Assay	98.5% - 101.5%	USP 39 <541>
Identification	Infrared absorption spectrum	USP 39 <197K>
Specific Test		
Specific Rotation	$+5.7^0$ - $+6.8^0$	USP 39 <781S>
Loss on Drying	8 – 12%	USP 39 <731>
Inorganic impurities		
Residue on ignition	Not more than 0.4%	USP 39 <281>
Sulfate	Not more than 0.03%	USP 39 <221>
Ammonium	Not more than 0.02%	AJI
Heavy Metals	Not more than 15 ppm	USP 39 <231>
Lead	Not more than 1 ppm	USP 39 <233>
Arsenic	Not more than 1 ppm	USP 39 <233>
Cadmium	Not more than 1 ppm	USP 39 <233>
Mercury	Not more than 0.1 ppm	USP 39 <261>
Related compounds	Individual impurities NMT 0.5% total impurities NMT 2.0%	USP 39 <621>
MICROBIOLOGICAL		
Total viable count	Not more than 1000 cfu/g	USP 39 <2021>
Yeast & Mold	Not more than 100 cfu/g	USP 39<2021>
Enterobacteriaceae	Negative/25g	USP 39 <2021>
Coliforms bacteria	Negative/g	USP 39 <2022>
Escherichia coli	Negative/g	USP 39 <2022>
Salmonella sp.	Negative/10g	USP 39 <2022>
Staphylococcus aureus	Negative/g	USP 39 <2022>

STORAGE CONDITION AND SHELF LIFE: L-CYSTEINE is recommended to store in a dry conditions and fresh place in sealed or closed container that is double protected from water, sun light and heat. Avoid direct contact with floor and any other source of combustion.

SHELF LIFE: We recommended the usage within 3 years.

Note: The above information is based on the certificate of analysis received from the manufacturer of this product and not intended as a substitute for strict quality control analysis by the purchaser of this product.

Reviewed by : _____

Abdullah Malik (QA)