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

ALPHA LIPOIC ACID

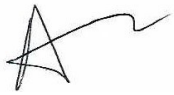
MOLECULAR FORMULA: C8H14O2S2

CAS #: 1077-28-7 **ORIGIN: CHINA**

Tests	Specification	Test Method
Characteristics	Yellowish Crystalline powder	Visual
Odor	Slight, typical odor	Olfactory perception
HPLC IR Spectrum	Meet the requirements. Meet the requirements. In USP<197K>	USP Monograph USP Monograph
Melting Point	60-62 degree C	USP<741>
Solubility (1N NaOH)	Clear and pale yellow.	Inhouse Method
Residue on Ignition	<0.10%	USP<281>
Heavy Metals	5ppm max	USP Method II <231>
Benzoic Acid	<1ppm	Inhouse Method
Arsenic	<1ppm	Atomic Absorption
Cadmium	<1.5ppm	Atomic Absorption
Lead	<0.5ppm	Atomic Absorption
Mercury	<0.1ppm	Atomic Absorption
Chloride	<0.1 %	Inhouse Method
Sulfate	<0.2 %	USP<221>
Loss on Drying	0.20 % max	USP<731>
Assay by HPLC	99.0-101.0%	USP Monograph
Specific Rotation	-1-+1	USP<781S>
Particle Size	100% through 80 mesh	USP29-811
Related Substances : Single Impurity 6,8-Epitrithioctic Acid Total Impurities	 0.10 % max 0.20 % max 0.50% max	 Inhouse Method USP Monograph USP Monograph
Residual Solvents: Toluene Cyclohexane	 30ppm max 0.20 %	 USP<467> USP<467>
Microbiological: Total Aerobic Counts	 1000 cfu /g	 USP<61>
Total yeast & mold	100 cfu/g	USP<61>
Total coliform	10 cfu/g	USP<61>
Salmonella	Negative	USP<62>
E. Coli	Negative	USP<61>
Bulk Density	0.35 g/ml – 0.5g/ml	USP<616>

Conclusion: Conforms to USP Standard. **Storage:** Preserve in a sealed container at temperature between 20-25 C

Note: The above information is based on the specifiction sheet 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)