



Shandong Longzen Pharmaceutical Co., Ltd

East side of Yuehe Sixth Road, ZouPing City,
ShanDong Province, China.
Tel: 86-543-8106869 Zip: 256200

Specification Sheet

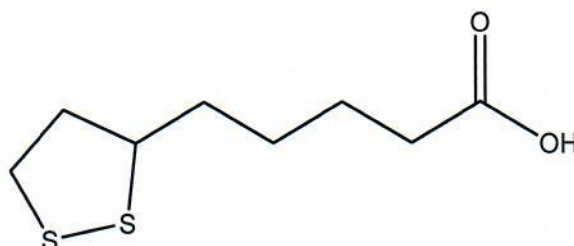
Product Name: Alpha Lipoic Acid solvent low

Molecular Formula: C₈H₁₄O₂S₂

Molecular Weight: 206.33

Structural Formula:

Shelf life: 2 years



| Item | Specification | Test method |
|--------------------------|--------------------------------|--------------|
| Appearance | Slightly yellow crystal powder | Organoleptic |
| Identification by HPLC | Meets the requirements | HPLC |
| Specific rotation | -1.0°~+1.0° | USP |
| Loss on Drying | ≤ 0.5% | USP |
| Melting point | 60.0°~62.0° | USP |
| Residue on ignition | ≤ 0.1% | USP |
| Heavy metals | ≤ 10ppm | USP |
| Lead | ≤ 3ppm | USP |
| Cadmium | ≤ 1ppm | USP |
| Mercury | ≤ 0.1ppm | USP |
| Arsenic | ≤ 1ppm | USP |
| Limit of polymer content | ≤ 2.0% | TLC |
| Residual solvents | Ethyl acetate | ≤ 5ppm GC |
| | Cyclohexane | ≤ 5ppm GC |



| Item | | Specification | Test method |
|------------------------|-----------------------|---|-------------|
| | Toluene | ≤ 5ppm | GC |
| Related substance | Individual impurities | ≤ 0.1% | HPLC |
| | Total impurities | ≤ 2.0% | HPLC |
| Particle Size | | 100% through 40 mesh | USP |
| Loose Bulk Density | | Report Result | USP |
| Assay | | 98.5%~101.0% on the dried basis | HPLC |
| Total aerobic bacteria | | ≤1000cfu/g | USP |
| Mold & yeast | | ≤100cfu/g | USP |
| E.coli | | Absence/g | USP |
| Staphylococcus aureus | | Absence/g | USP |
| Salmonella | | Absence/10g | USP |
| Storage: | | Sealed storage at a temperature below 20°C in a dry and well-ventilated area, avoid exposure to heat and direct sunlight. | |



Valid Date: 2023/01/17

Version: V 1.2