

CERTIFICATE OF ANALYSIS

名] Product Name: Thioctic acid (Alpha Lipoic Acid) (硫辛酸)

式] Molecular Formula: $C_8H_{14}O_2S_2$

分子量] Molecular Weight: 206.33

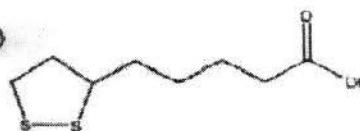
结构式] Structural Formula:

批号] Batch No.: TA.2205211

数量] Quantity: 1500 kgs

[生产日期] MAN.Date: MAY.21,2022

[有效日期] EXP.Date: MAY.20,2024



| ITEMS | SPECIFICATIONS | RESULTS | Method |
|--------------------------------------|--------------------------------|----------------|--------------|
| 性状] Appearance | Slightly yellow crystal powder | Conforms | Organoleptic |
| 鉴别] Identification | Meets the requirements | Conforms | HPLC |
| 熔点] Melting Point | 60.0~62.0°C | 61.7°C | USP |
| 旋光度] Specific rotation | -1.0° to +1.0° | 0° | USP |
| 干燥失重] Loss on drying | 0.20% max | 0.05% | USP |
| 灼烧残渣] Residue on Ignition | 0.10% max | 0.02% | USP |
| 重金属] Heavy Metals | 10ppm max | <10ppm | USP |
| 铅] Lead | 3ppm max | <3ppm | USP |
| 镉] Cadmium | 1ppm max | <1ppm | USP |
| 汞] Mercury | 0.1ppm max | <0.1ppm | USP |
| Chromatographic purity | | | |
| 单一杂质] Single Impurity | 0.10% max | 0.01% | HPLC |
| 总杂质] Total Impurities | 2.0% max | 0.02% | HPLC |
| 聚合物的限度] Limit of polymer content | Conforms | Conforms | TLC |
| Residual Solvent (残留溶剂) By GC | | | |
| 环己烷] Cyclohexane | 3880ppm max | 700ppm | GC |
| 乙酸乙酯] Ethyl Acetate | 5000ppm max | 50ppm | GC |
| 需氧菌总数] Total plate counts | 1000 CFU/g max | <10 CFU/g | USP |
| 霉菌和酵母菌] Moulds and Yeasts | 100 CFU/g max | <10 CFU/g | USP |
| 大肠杆菌/沙门菌] E.coli/Salmonella | Absence/g | Not Detectable | USP |
| 金黄色葡萄球菌] Staphylococcus aureus | Absence/g | Not Detectable | USP |
| 目数] Particle Size | 100% through 40 mesh | Conforms | USP |
| 公堆密度] Loose Bulk Density | | 0.38g/ml | USP |
| 含量] Assay | 99.0%~101.0% | 99.1% | HPLC |
| 结论] Conclusion | Conformed USP43 | | |

Los datos del presente documento son suministrados por el fabricante. Romikin no se responsabiliza por el uso incorrecto del producto.