

CERTIFICATE OF ANALYSIS

4) 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

[生产日期] MAN.Date: MAY.21.2022

数量) Quantity: 1500 kgs

[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
霉菌总数) 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
松堆密度) Loose Bulk Density		0.38g/ml	USP
含量) Assay	99.0%~101.0%	99.1%	HPLC
结论) Conclusion	Conformed USP43		