



检验报告单

CERTIFICATE OF ANALYSIS

[品名] Product Name: Alpha Lipoic Acid(α -硫辛酸)

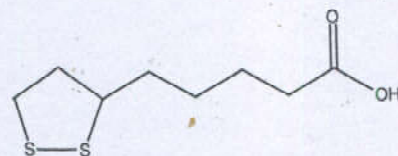
[分子式] Molecular Formula: $C_8H_{14}O_2S_2$

[分子量] Molecular Weight: 206.33

[结构式] Structural Formular:

[批号] Batch No.: 2107012

[数量] Quantity: 2000kgs



FDA NO.: 1391855528

[生产日期] MAN.Date: JUL.01,2021

[有效日期] EXP.Date: JUN.30,2023

ITEMS	SPECIFICATIONS	RESULTS	Method
[性状] Appearance	Slightly yellow crystal powder	Conforms	Organoleptic
[鉴别] Identification	Meets the requirements	Conforms	HPLC
[溶解性] Solubility	Practically insolubility in water and solubility in organicsolvent	Conforms	USP
[熔点] Melting Point	60.0~62.0°C	61.7°C	USP
[重金属] Heavy Metals	10ppm max	<10ppm	USP
[铅] Lead	3ppm max	<3ppm	USP
[砷] Arsenic	1ppm max	<1ppm	USP
[镉] Cadmium	1ppm max	<1ppm	USP
[汞] Mercury	0.1ppm max	<0.1ppm	USP
[干燥失重] Loss on drying	0.20% max	0.08%	USP
[灼烧残渣] Residue on Ignition	0.10% max	0.02%	USP
[旋光度] Specific rotation	-1.0° to +1.0°	0°	USP
[聚合物的限度] Limit of polymer content	2.0% max	<2.0%	TLC
Related Substance (相关物质) By HPLC			
[6,8-表三硫辛酸] 6,8-Epitrithiooctanoic acid(EPI)	0.10% max	0.01%	HPLC
[单一杂质] Single Impurity	0.10% max	0.04%	HPLC
[总杂质] Total Impuritieschromatographic	0.50% max	0.06%	HPLC
[色谱纯度] Chromatographic purity	99.50% min	99.9%	HPLC
Residual Solvent (残留溶剂) By GC			
[环己烷] Cyclohexane	3880ppm-max	1190ppm	GC
[乙酸乙酯] Ethyl Acetate	500ppm max	80ppm	GC
[甲苯] Toluene	20ppm max	Not Detectable	GC
[需氧菌总数] Total plate counts	1000 CFU/gmax	<10 CFU/g	USP
[霉菌和酵母菌] Moulds and Yeasts	100 CFU/gmax	<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
[肠细菌] Enterobacteriae	Absence/g	Not Detectable	USP
[铜绿假单胞菌] Presudomonas aeruginosa	Absence/g	Not Detectable	USP
[假丝酵母菌] Candida albicans	Absence/g	Not Detectable	USP
[梭菌] Clostridium	Absence/g	Not Detectable	USP
[目数] Particle Size	100% through 40 mesh	Conforms	USP
[松堆密度] Loose Bulk Density		0.36g/ml	USP
[含量] Assay	99.0%~101.0%	99.2%	HPLC

[结论] Conclusion: Conformed USP43 该批货物本厂生产, 厂检合格。

[质量控制部门]

[复核人] 邢健

[检验者] 庞赛健

Quality Control Department

Corrector

Inspector

