



Suzhou Medinoah Co., Ltd
苏州美诺医药科技有限公司

中国江苏苏州工业园区星湖街 218 号 C-9 楼 501 室
Suite 501, C-9 Building, 218 Xinghu Road
Suzhou Industrial Park, Jiangsu, China
Tel: 86-512-6956-1981, Fax: 86-512-6956-1982

Certificate of Analysis

Product name	Alpha Lipoic Acid		
Batch No.	2206007	Source	Production Plant
Quantity	266.08 kg	Specification	USP43
Manufacturing date	2022-06-29	Sampling date	2022-06-30
Test date	2022-06-30	Retest date	2024-06-28

Test items		Specification	Results	Conclusion
Appearance		Yellow crystalline powder	Yellow crystalline powder	Conforms
Identification	HPLC	Conforms to reference spectrum	Conforms	Conforms
	IR	Conforms to reference spectrum	Conforms	Conforms
Loss on drying (%)		≤ 0.2	0.2	Conforms
Optical rotation (°)		- 1.0~+1.0	0.1	Conforms
Melting point (°C)		60.0~62.0	60.8~61.7	Conforms
Residue on ignition (%)		<0.1	<0.1	Conforms
Heavy metals		≤ 0.001%	Conforms	Conforms
Hg (ppm)		≤ 0.1	< 0.01	Conforms
Cd (ppm)		≤ 1	< 0.002	Conforms
Pb (ppm)		≤ 3	< 0.02	Conforms
Polymer content		Conforms to reference	Conforms	Conforms
Residual solvents (%)		Ethanol ≤ 0.5	ND	Conforms
		Acetone ≤ 0.5	ND	
		Ethyl acetate ≤ 0.5	0.04	
		Cyclohexane ≤ 0.388	0.193	
		Toluene ≤ 0.089	ND	
Related substance (%)		Single impurity ≤ 0.1	ND	Conforms
		Total impurities ≤ 2.0	ND	





Suzhou Medinoah Co., Ltd
苏州美诺医药科技有限公司

中国江苏苏州工业园区星湖街 218 号 C-9 楼 501 室
Suite 501, C-9 Building, 218 Xinghu Road
Suzhou Industrial Park, Jiangsu, China
Tel: 86-512-6956-1981, Fax: 86-512-6956-1982

Assay (%)	Calculated on the dried basis within 99.0%~101.0%.	99.6%	Conforms
Particle size	100% through 40 mesh	Conforms	Conforms
Loose bulk density	Report result	0.39g/ml	Conforms
Total plate counts	$\leq 10^3$ cfu/g	< 10cfu/g	Conforms
Moulds and Yeasts	$\leq 10^2$ cfu/g	< 10cfu/g	Conforms
Escherichia coli	Absence/g	ND	Conforms
Conclusion: According to the specification, it meets the requirements.			

Reporter/date: *Caixia Wang*
July 7, 2022

Reviewer/date: *Mingye Zhou*
July, 7, 2022

Approver/date: *Mao*
July 7, 2022



WWW.CHEMBALL.COM





Suzhou Medinoah Co., Ltd
苏州美诺医药科技有限公司

中国江苏苏州工业园区星湖街 218 号 C-9 楼 501 室
Suite 501, C-9 Building, 218 Xinghu Road
Suzhou Industrial Park, Jiangsu, China
Tel: 86-512-6956-1981, Fax: 86-512-6956-1982

Certificate of Analysis

Product name	Alpha Lipoic Acid		
Batch No.	2206008	Source	Production Plant
Quantity	255.36 kg	Specification	USP43
Manufacturing date	2022-06-30	Sampling date	2022-07-01
Test date	2022-07-01	Retest date	2024-06-29

Test items		Specification	Results	Conclusion
Appearance		Yellow crystalline powder	Yellow crystalline powder	Conforms
Identification	HPLC	Conforms to reference spectrum	Conforms	Conforms
	IR	Conforms to reference spectrum	Conforms	Conforms
Loss on drying (%)		≤ 0.2	0.2	Conforms
Optical rotation ($^{\circ}$)		- 1.0~+1.0	0.6	Conforms
Melting point ($^{\circ}\text{C}$)		60.0~62.0	60.5~61.6	Conforms
Residue on ignition (%)		<0.1	<0.1	Conforms
Heavy metals		$\leq 0.001\%$	Conforms	Conforms
Hg (ppm)		≤ 0.1	< 0.01	Conforms
Cd (ppm)		≤ 1	< 0.002	Conforms
Pb (ppm)		≤ 3	< 0.02	Conforms
Polymer content		Conforms to reference	Conforms	Conforms
Residual solvents (%)	Ethanol ≤ 0.5		ND	Conforms
	Acetone ≤ 0.5		ND	
	Ethyl acetate ≤ 0.5		0.03	
	Cyclohexane ≤ 0.388		0.173	
	Toluene ≤ 0.089		ND	
Related substance (%)	Single impurity ≤ 0.1		0.05	Conforms
	Total impurities ≤ 2.0		0.12	





Suzhou Medinoah Co., Ltd
苏州美诺医药科技有限公司

中国江苏苏州工业园区星湖街 218 号 C-9 楼 501 室
Suite 501, C-9 Building, 218 Xinghu Road
Suzhou Industrial Park, Jiangsu, China
Tel: 86-512-6956-1981, Fax: 86-512-6956-1982

Assay (%)	Calculated on the dried basis within 99.0%~101.0%.	99.7%	Conforms
Particle size	100% through 40 mesh	Conforms	Conforms
Loose bulk density	Report result	0.42g/ml	Conforms
Total plate counts	$\leq 10^3$ cfu/g	< 10cfu/g	Conforms
Moulds and Yeasts	$\leq 10^2$ cfu/g	< 10cfu/g	Conforms
Escherichia coli	Absence/g	ND	Conforms
Conclusion: According to the specification, it meets the requirements.			

Reporter/date: *Caixia Wang*
July 7, 2022

Reviewer/date: *Mingyue Zhou*
July, 7, 2022

Approver/date: *Lima Mao*
July 7, 2022



WWW.CHEMBALL.COM





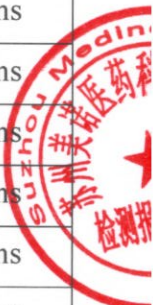
Suzhou Medinoah Co., Ltd
苏州美诺医药科技有限公司

中国江苏苏州工业园区星湖街 218 号 C-9 楼 501 室
Suite 501, C-9 Building, 218 Xinghu Road
Suzhou Industrial Park, Jiangsu, China
Tel: 86-512-6956-1981, Fax: 86-512-6956-1982

Certificate of Analysis

Product name	Alpha Lipoic Acid		
Batch No.	2207001	Source	Production Plant
Quantity	250.0 kg	Specification	USP43
Manufacturing date	2022-07-01	Sampling date	2022-07-02
Test date	2022-07-02	Retest date	2024-06-30

Test items		Specification	Results	Conclusion
Appearance		Yellow crystalline powder	Yellow crystalline powder	Conforms
Identification	HPLC	Conforms to reference spectrum	Conforms	Conforms
	IR	Conforms to reference spectrum	Conforms	Conforms
Loss on drying (%)		≤ 0.2	0.1	Conforms
Optical rotation ($^{\circ}$)		- 1.0~+1.0	-0.3	Conforms
Melting point ($^{\circ}\text{C}$)		60.0~62.0	60.2~61.7	Conforms
Residue on ignition (%)		<0.1	<0.1	Conforms
Heavy metals		$\leq 0.001\%$	Conforms	Conforms
Hg (ppm)		≤ 0.1	< 0.01	Conforms
Cd (ppm)		≤ 1	< 0.002	Conforms
Pb (ppm)		≤ 3	< 0.02	Conforms
Polymer content		Conforms to reference	Conforms	Conforms
Residual solvents (%)	Ethanol ≤ 0.5		ND	Conforms
	Acetone ≤ 0.5		ND	
	Ethyl acetate ≤ 0.5		0.01	
	Cyclohexane ≤ 0.388		0.083	
	Toluene ≤ 0.089		ND	
Related substance (%)	Single impurity ≤ 0.1		0.06	Conforms
	Total impurities ≤ 2.0		0.12	





Suzhou Medinoah Co., Ltd
苏州美诺医药科技有限公司

中国江苏苏州工业园区星湖街 218 号 C-9 楼 501 室
Suite 501, C-9 Building, 218 Xinghu Road
Suzhou Industrial Park, Jiangsu, China
Tel: 86-512-6956-1981, Fax: 86-512-6956-1982

Assay (%)	Calculated on the dried basis within 99.0%~101.0%.	100.1	Conforms
Particle size	100% through 40 mesh	Conforms	Conforms
Loose bulk density	Report result	0.41g/ml	Conforms
Total plate counts	$\leq 10^3$ cfu/g	< 10cfu/g	Conforms
Moulds and Yeasts	$\leq 10^2$ cfu/g	< 10cfu/g	Conforms
Escherichia coli	Absence/g	ND	Conforms
Conclusion: According to the specification, it meets the requirements.			

Reporter/date: *Cai Xia Wang*
July 7, 2022

Reviewer/date: *Mengyue Zhou*
July, 7, 2022

Approver/date: *Lina Mao*
July 7, 2022



WWW.CHEMBALL.COM

