

Current Batch Certificate of Analysis

RESEARCH USE ONLY Public batch: PEP260716-TA10

Certificate of Analysis

品 名	Product	Thymosin Alpha- 1	批 号	Batch	PEP260716-TA10
CAS	NO.	2381089-83-2	数 量	Quantity	10mg
生产日期	Mfg Date	2026-07-16	复检期	Retest Date	2028-07-15
检验日期	Test Date	2026-07-28	标 准	Standard	In house
包装形式	3ML 西林瓶冻干粉包装				
Packaging	3ML vial lyophilized powder				
TestItem	AcceptanceCriteria		TestResult		
检测 项目	可接受标准		检验结果		
Appearance	White or off-white powder		white powder		
性状	白色或类白色粉末		白色粉末		
Solubility	Soluble or freely soluble in water		freely soluble in water		
溶解度	在水中溶解或易溶		易溶于水		
Average Molecular Weight	3108. 27±1.0 Da		3109. 13Da		
平均分子量					
Chromatographic Identification	The retention time of the main peak of Sample Solution should be consistent with that of the Standard solution, as obtained in the Assay		Meet the requirement		
色谱鉴别	在含量测定项下记录的色谱图中，供试品溶液主峰的保 留时间应与对照品溶液主峰的保留时间一致		符合规定		
PH	4. 0-6. 0		5. 7		
Clarity and Color of Solution	Clarity: Clear transparent solution, free from turbidity, precipitate and insoluble particles.		Colour:		
溶液的澄清度与颜色	应澄清无色		Characteristic bright sky blue solution.		
			符合要求		
Chromatographic Purity	NLT98. 0%		99. 37%		
色谱纯度	不小于 98. 0%				
Related Substances	Maximum unknown single impurity NMT 0. 5%		0. 21%		
有关物质	最大未知单杂不得过 0. 5%				
High Molecular Weight Proteins	NMT0. 8%		0. 21%		
高分子蛋白质					
Water Content	NMT 3. 0%		0. 50%		
水分					

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Heavy Metals 重金属	NMT 10ppm			均未检出 ND	
Residual Solvents	Methanol NMT 3000ppm			129ppm	
	甲醇不得过 3000ppm				
	Acetonitrile NMT 410ppm				
	乙腈不得过 410ppm			60ppm	
	Dichloromethane NMT 600ppm			73ppm	
	二氯甲烷不得过 600ppm				
Microbial Limit	Total Aerobic Microbial Count NMT100 cfu/g			Meet the requirement	
	微生物限度			需氧菌总数应不得过 100cfu/g	
Bacterial Endotoxin	≤0.25 EU/mg			0.21 EU/mg	
细菌内毒素					
Peptide Content	95.0%~105.0%(On Anhydrous and Sodium Free)			103.5%	
肽含量	95.0%~105.0%(以无水、无钠离子计)				
Assay	9.5~10.5mg			10.35mg	
含量					
Conclusion	Meets specification				
结论					