

Current Batch Certificate of Analysis

RESEARCH USE ONLY Public batch: PEP260705-SS50

Certificate of Analysis

品 名	Product	SS-31	批 号	Batch	PEP260705-SS50
CAS	NO.	341001-38-7	数 量	Quantity	50mg
生产日期	Mfg Date	2026-07-05	复检期	Retest Date	2028-07-04
检验日期	Test Date	2026-07-20	标 准	Standard	In house
包装形式	双层聚乙烯袋，双层铝塑袋				
Package	Double layer polyethylene bag,Double layer aluminum-plastic film bag				
TestItem	AcceptanceCriteria		TestResult		
检测项目	可接受标准		检验结果		
Appearance	Freely dissolves in sterile dilute acetic acid solution		freely dissolves in 0.1% ice acetic acid solution		
性状	易溶于无菌稀乙酸水溶液		易溶于 0.1% 冰醋酸溶液		
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	639. 80±1.0 Da		640.81Da		
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	6.0-9.0		7.22		
Clarity and Color of Solution	Clarity: Clear transparent solution, free from turbidity, precipitate and insoluble particles.		Colour: Characteristic bright sky blue solution.		
溶液的澄清度与颜色	应澄清无色		符合要求		
Chromatographic Purity	NLT98.0%		98.72%		
色谱纯度	不小于 98.0%				
Related Substances	Maximum unknown single impurity NMT 1.0%		0.26%		
有关物质	最大未知单杂不得过 1.0%				
High Molecular Weight Proteins	NMT0.8%		0.13%		
高分子蛋白质					
Water Content	NMT 5.0%		2.06%		
水分					

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Heavy Metals 重金属	NMT 10ppm			均未检出 ND	
Residual Solvents 残留溶剂	Methanol NMT 3000ppm 甲醇不得过 3000ppm			79ppm	
	Acetonitrile NMT 410ppm 乙腈不得过 410ppm			66ppm	
	Dichloromethane NMT 600ppm			26pm	
	二氯甲烷不得超过 600pp				
	N, N-Dimethylformamide NMT 880ppm N, N-二甲基甲酰胺不得过 880ppm			34pm	
Microbial Limit 微生物限度	Total Aerobic Microbial Count NMT100 cfu/g 需氧菌总数应不得过 100cfu/g			Meet the requirement 符合要求	
Bacterial Endotoxin 细菌内毒素	≤10 EU/mg			0. 08 EU/mg	
Peptide Content 肽含量	NLT 88. 0%			92. 56%	
Assay 含量	95. 0%~105. 0% (On Anhydrous and Sodium Free) 95. 0%~105. 0% (以无水、无钠离子计)			101. 52%	
Conclusion 结论	Meets specification				