

Current Batch Certificate of Analysis

RESEARCH USE ONLY Public batch: PEP260802-DS2

Certificate of Analysis

品 名	Product	δ-促睡眠肽 DSIP	批 号	Batch	PEP260802-DS2
CAS	NO.	62568-57-4	数 量	Quantity	2mg
生产日期	Mfg Date	2026-08-02	复检期	Retest Date	2028-08-01
检验日期	Test Date	2026-08-07	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	848.82±10.0 Da		848.82Da		
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 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		Meet the requirement 符合规定		
色谱鉴别					
PH	4.0-6.0		4.5		
Clarity and Color of Solution	Clarity: Clear transparent solution, free from turbidity, precipitate and insoluble particles. 应澄清无色		Colour: Characteristic bright sky blue solution. 符合要求		
溶液的澄清度与颜色					
Chromatographic Purity	NLT98.0% 不小于 98.0%		99.8%		
色谱纯度					
Related Substances	Maximum unknown single impurity NMT 0.5% 最大未知单杂不得过 0.5%		0.18%		
有关物质					
High Molecular Weight Proteins	NMT0.8%		0.11%		
高分子蛋白质					
Water Content	NMT 3.0%		0.98%		
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			15ppm	
	Acetonitrile NMT 410ppm 乙腈不得过 410ppm			80ppm	
	Dichloromethane NMT 600ppm			65ppm	
	N, N-Dimethylformamide NMT 880ppm N, N-二甲基甲酰胺不得过 880ppm			15ppm	
	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	
	<1CFU/mg			Meet the requirements 符合要求	
Peptide Content 肽含量	95.0%~105.0%(On Anhydrous and Sodium Free) 95.0%~105.0%(以无水、无钠离子计)			99.7%	
Assay 含量	1.9mg~2.1mg			1.99mg	
Conclusion 结论	Meets specification				