

Current Batch Certificate of Analysis

RESEARCH USE ONLY      Public batch: PEP260714-CD5

Certificate of Analysis

|                                |                                                                                                                                                                                         |                   |                                 |             |               |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|---------------------------------|-------------|---------------|
| 品 名                            | Product                                                                                                                                                                                 | CJC-1295 with DAC | 批 号                             | Batch       | PEP260714-CD5 |
| CAS                            | No.                                                                                                                                                                                     | 446262-90-4       | 数 量                             | Quantity    | 5mg           |
| 生产日期                           | Mfg Date                                                                                                                                                                                | 2026-07-15        | 复检期                             | Retest Date | 2028-07-14    |
| 检验日期                           | Test Date                                                                                                                                                                               | 2026-07-19        | 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 powder                                                                                                                                                                            |                   | White powder                    |             |               |
| 性状                             | 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       | 3647.28±1.0 Da                                                                                                                                                                          |                   | 3647.79 Da                      |             |               |
| 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<br>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<br>符合规定    |             |               |
| 色谱鉴别                           |                                                                                                                                                                                         |                   |                                 |             |               |
| PH                             | 5.0-6.6                                                                                                                                                                                 |                   | 5.8                             |             |               |
| Clarity and Color of Solution  | Clarity: Clear transparent solution, free from turbidity, precipitate and insoluble particles.<br>应澄清无色                                                                                 |                   | Colour:Colorless, clear<br>符合要求 |             |               |
| 溶液的澄清度与颜色                      |                                                                                                                                                                                         |                   |                                 |             |               |
| Chromatographic Purity         | NLT98.0%<br>不小于 98.0%                                                                                                                                                                   |                   | 99.71%                          |             |               |
| 色谱纯度                           |                                                                                                                                                                                         |                   |                                 |             |               |
| Related Substances             | Maximum unknown single impurity NMT 1.0%<br>最大未知单杂不得过 1.0%                                                                                                                              |                   | 0.12%                           |             |               |
| 有关物质                           |                                                                                                                                                                                         |                   |                                 |             |               |
| High Molecular Weight Proteins | NMT0.8%                                                                                                                                                                                 |                   | 0.36%                           |             |               |
| 高分子蛋白质                         |                                                                                                                                                                                         |                   |                                 |             |               |
| Water Content                  | NMT 5%                                                                                                                                                                                  |                   | 0.25%                           |             |               |
| 水分                             |                                                                                                                                                                                         |                   |                                 |             |               |

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| TestItem                         | AcceptanceCriteria                                                             |                   |     | TestResult                    |               |
| 检测项目                             | 可接受标准                                                                          |                   |     | 检验结果                          |               |
| Heavy Metals 重金属                 | NMT 10ppm                                                                      |                   |     | 3ppm                          |               |
|                                  | Methanol NMT 3000ppm<br>甲醇不得过 3000ppm                                          |                   |     | 77ppm                         |               |
|                                  | Acetonitrile NMT 410ppm<br>乙腈不得过 410ppm                                        |                   |     | 42ppm                         |               |
|                                  | Dichloromethane NMT 600ppm<br>二氯甲烷不得过 600ppm                                   |                   |     | 35ppm                         |               |
| Residual Solvents<br>残留溶剂        | N,N-Dimethylformamide NMT 880ppm<br>N,N-二甲基甲酰胺不得过 880ppm                       |                   |     | 47ppm                         |               |
|                                  | Total Aerobic Microbial Count NMT100 cfu/g<br>需氧菌总数应不得过 100cfu/g               |                   |     | Meet the requirement<br>符合要求  |               |
| Microbial Limit<br>微生物限度         | Total Aerobic Microbial Count NMT100 cfu/g<br>需氧菌总数应不得过 100cfu/g               |                   |     | Meet the requirement<br>符合要求  |               |
| Bacterial<br>Endotoxins<br>细菌内毒素 | <0. 25EU/mg                                                                    |                   |     | Meet the requirements<br>符合要求 |               |
| Peptide Content<br>肽含量           | 95. 0%~105. 0% (On Anhydrous and Sodium<br>Free)<br>95. 0%~105. 0% (以无水、无钠离子计) |                   |     | 103. 3%                       |               |
| Assay<br>含量                      | 4. 75~5. 25mg                                                                  |                   |     | 5. 17mg                       |               |
| Conclusion<br>结论                 | Meets specification                                                            |                   |     |                               |               |