

Current Batch Certificate of Analysis

RESEARCH USE ONLY      Public batch: PEP260723-XA10

Certificate of Analysis

|                      |                                            |            |                       |             |                |
|----------------------|--------------------------------------------|------------|-----------------------|-------------|----------------|
| 品 名                  | Product                                    | 脑力肽 Semax  | 批 号                   | Batch       | PEP260723-XA10 |
| CAS                  | NO.                                        | 80714-61-0 | 数 量                   | Quantity    | 10mg           |
| 生产日期                 | Mfg Date                                   | 2026-07-23 | 复检期                   | Retest Date | 2028-07-22     |
| 检验日期                 | Test Date                                  | 2026-07-29 | 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     |             |                |
| 溶解度                  | 在水中溶解或易溶                                   |            | water                 |             |                |
|                      |                                            |            | 易溶于水                  |             |                |
| Average Molecular    |                                            |            |                       |             |                |
| Weight               | 813.93±1.0 Da                              |            | 813.92Da              |             |                |
| 平均分子量                |                                            |            |                       |             |                |
| Chromatographic      | The retention time of the main peak of     |            |                       |             |                |
| Identification       | Sample Solution should be consistent with  |            |                       |             |                |
| 色谱鉴别                 | that of the Standard solution, as obtained |            | Meet the requirement  |             |                |
|                      | in the Assay                               |            | 符合规定                  |             |                |
|                      | 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                                     |            |                       |             |                |
| PH                   | 4.5-6.5                                    |            | 5.3                   |             |                |
| Clarity and Color of | Clarity: Clear transparent solution,       |            | Colour:               |             |                |
| Solution             | free from turbidity, precipitate and       |            | Characteristic bright |             |                |
| 溶液的澄清度与颜色            | insoluble particles.                       |            | sky blue solution.    |             |                |
|                      | 应澄清无色                                      |            | 符合要求                  |             |                |
| Chromatographic      | NLT98.0%                                   |            |                       |             |                |
| Purity               | 不小于 98.0%                                  |            | 98.7%                 |             |                |
| 色谱纯度                 |                                            |            |                       |             |                |
| Related Substances   | Maximum unknown single impurity NMT 0.5%   |            | 0.16%                 |             |                |
| 有关物质                 | 最大未知单杂不得过 0.5%                             |            |                       |             |                |
| High Molecular       |                                            |            |                       |             |                |
| Weight Proteins      | NMT0.8%                                    |            | 0.13%                 |             |                |
| 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 | Methanol NMT 3000ppm                       |            |     | 25ppm                 |                |
|                   | 甲醇不得过 3000ppm                              |            |     |                       |                |
|                   | Acetonitrile NMT 410ppm                    |            |     |                       |                |
|                   | 乙腈不得过 410ppm                               |            |     | 64ppm                 |                |
|                   | Dichloromethane NMT 600ppm                 |            |     | 54ppm                 |                |
|                   | 二氯甲烷不得过 600ppm                             |            |     |                       |                |
| Microbial Limit   | N,N-Dimethylformamide NMT 880ppm           |            |     | 21ppm                 |                |
|                   | N,N-二甲基甲酰胺不得过 880ppm                       |            |     |                       |                |
|                   | 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                         |            |     | 符合要求                  |                |
| Total bacteria    | <1CFU/mg                                   |            |     | Meet the requirements |                |
| 细菌总数              |                                            |            |     | 符合要求                  |                |
| Peptide Content   | 95.0%~105.0%(On Anhydrous and Sodium Free) |            |     | 99.9%                 |                |
| 肽含量               | 95.0%~105.0%(以无水、无钠离子计)                    |            |     |                       |                |
| Assay             | 9.5mg~10.5mg                               |            |     | 9.9mg                 |                |
| 含量                |                                            |            |     |                       |                |
| Conclusion        | Meets specification                        |            |     |                       |                |
| 结论                |                                            |            |     |                       |                |