

Current Batch Certificate of Analysis

RESEARCH USE ONLY      Public batch: PEP260706-TR10

Certificate of Analysis

|                                |                                                                                                                                                                                         |                  |                                 |             |                |
|--------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|---------------------------------|-------------|----------------|
| 品 名                            | Product                                                                                                                                                                                 | 替尔泊肽 Tirzepatide | 批 号                             | Batch       | PEP260706-TR10 |
| CAS                            | NO.                                                                                                                                                                                     | 2023788-19-2     | 数 量                             | Quantity    | 10mg           |
| 生产日期                           | Mfg Date                                                                                                                                                                                | 2026-07-06       | 复检期                             | Retest Date | 2028-07-05     |
| 检验日期                           | Test Date                                                                                                                                                                               | 2026-07-15       | 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       | 4813. 45±10. 0 Da                                                                                                                                                                       |                  | 4813. 32Da                      |             |                |
| 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                             | 7. 0-9. 0                                                                                                                                                                               |                  | 7. 4                            |             |                |
| 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. 6%                          |             |                |
| 色谱纯度                           |                                                                                                                                                                                         |                  |                                 |             |                |
| Related Substances             | Maximum unknown single impurity NMT 0. 5%<br>最大未知单杂不得过 0. 5%                                                                                                                            |                  | 0. 29%                          |             |                |
| 有关物质                           |                                                                                                                                                                                         |                  |                                 |             |                |
| High Molecular Weight Proteins | NMT0. 8%                                                                                                                                                                                |                  | 0. 22%                          |             |                |
| 高分子蛋白质                         |                                                                                                                                                                                         |                  |                                 |             |                |
| Water Content                  | NMT 3. 0%                                                                                                                                                                               |                  | 0. 51%                          |             |                |
| 水分                             |                                                                                                                                                                                         |                  |                                 |             |                |

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| Packaging                 | 3ML vial lyophilized powder                                           |                  |     |                               |                |
| Test Item                 | Acceptance Criteria                                                   |                  |     | Test Result                   |                |
| 检测项目                      | 可接受标准                                                                 |                  |     | 检验结果                          |                |
| Heavy Metals 重金属          | NMT 10ppm                                                             |                  |     | 均未检出 ND                       |                |
| Residual Solvents<br>残留溶剂 | Methanol NMT 3000ppm<br>甲醇不得过 3000ppm                                 |                  |     | 91ppm                         |                |
|                           | Acetonitrile NMT 410ppm<br>乙腈不得过 410ppm                               |                  |     | 16ppm                         |                |
|                           | Dichloromethane NMT 600ppm                                            |                  |     | 6ppm                          |                |
|                           | 二氯甲烷不得过 600ppm                                                        |                  |     |                               |                |
|                           | N, N-Dimethylformamide NMT 880ppm                                     |                  |     | 47ppm                         |                |
|                           | N, N-二甲基甲酰胺不得过 880ppm                                                 |                  |     |                               |                |
| 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  |                |
| Total bacteria<br>细菌总数    | <1CFU/mg                                                              |                  |     | Meet the requirements<br>符合要求 |                |
| Peptide Content<br>肽含量    | 95.0%~105.0%(On Anhydrous and Sodium Free)<br>95.0%~105.0%(以无水、无钠离子计) |                  |     | 98.6%                         |                |
| Assay<br>含量               | 9.5~10.5mg                                                            |                  |     | 9.86mg                        |                |
| Conclusion<br>结论          | Meets specification                                                   |                  |     |                               |                |