

Current Batch Certificate of Analysis

RESEARCH USE ONLY      Public batch: PEP260716-RT30

Certificate of Analysis

|                                |                                                                                                                                          |                  |                          |             |                |
|--------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|------------------|--------------------------|-------------|----------------|
| 品 名                            | Product                                                                                                                                  | 瑞他鲁肽 Retatrutide | 批 号                      | Batch       | PEP260716-RT30 |
| CAS                            | NO.                                                                                                                                      | 2381089-83-2     | 数 量                      | Quantity    | 30mg           |
| 生产日期                           | Mfg Date                                                                                                                                 | 2026-07-16       | 复检期                      | Retest Date | 2028-07-15     |
| 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 water  |             |                |
| 溶解度                            | 在水中溶解或易溶                                                                                                                                 |                  | 易溶于水                     |             |                |
| Average Molecular Weight       | 4731.33±1.0 Da                                                                                                                           |                  | 4732.16Da                |             |                |
| 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                             | 4.8-6.2                                                                                                                                  |                  | 6.0                      |             |                |
| Clarity and Color of Solution  | Clarity: Clear transparent solution, free from turbidity, precipitate and insoluble particles.                                           |                  | Colour: Colorless, clear |             |                |
| 溶液的澄清度与颜色                      | 应澄清无色                                                                                                                                    |                  | 符合要求                     |             |                |
| Chromatographic Purity         | NLT98.0%                                                                                                                                 |                  | 99.12%                   |             |                |
| 色谱纯度                           | 不小于 98.0%                                                                                                                                |                  |                          |             |                |
| Related Substances             | Maximum unknown single impurity NMT 0.5%                                                                                                 |                  | 0.12%                    |             |                |
| 有关物质                           | 最大未知单杂不得过 0.5%                                                                                                                           |                  |                          |             |                |
| High Molecular Weight Proteins | NMT0.8%                                                                                                                                  |                  | 0.05%                    |             |                |
| 高分子蛋白质                         |                                                                                                                                          |                  |                          |             |                |
| Water Content                  | NMT 3.0%                                                                                                                                 |                  | 0.35%                    |             |                |
| 水分                             |                                                                                                                                          |                  |                          |             |                |

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| 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                                 |                  |     | 21ppm                        |                |
|                              | Acetonitrile NMT 410ppm<br>乙腈不得过 410ppm                               |                  |     | 55ppm                        |                |
|                              | Dichloromethane NMT 600ppm                                            |                  |     | 86ppm                        |                |
|                              | 二氯甲烷不得过 600ppm                                                        |                  |     |                              |                |
|                              | N, N-Dimethylformamide NMT 880ppm                                     |                  |     | 102ppm                       |                |
|                              | 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 |                |
| Bacterial Endotoxin<br>细菌内毒素 | ≤0.25 EU/mg                                                           |                  |     | 0.06 EU/mg                   |                |
| 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                  | 28.5~31.5mg                                                           |                  |     | 29.58mg                      |                |
| Conclusion<br>结论             | Meets specification                                                   |                  |     |                              |                |