



# CERTIFICATE OF ANALYSIS

CoA No.: 2023126

| Sample Information                                  |  |   |                      |
|---|--|---|----------------------|
| Product Name/Code                                   | Ertugliflozin L-Pyroglutamic acid  |   |                      |
| CAS #   | 1210344-83-4   | Molecular Structure   |                      |
| Project No.   | YPP23001WM-1   |   |                      |
| Molecular Formula                                   | C <sub>22</sub> H <sub>25</sub> ClO <sub>7</sub> · C <sub>5</sub> H <sub>7</sub> NO <sub>3</sub> |   |                      |
| Molecular Weight                                    | 566.01   |   |                      |
| Batch No.   | PF-20230401  | Sampling Date   | 2023-04-25           |
| Batch Size  | 21.45kg  | Retest Date   | 2024-04-24           |
| Manufacturing Date                                  | 2023-04-23   | Specification No.   | QS-API-001 -20211124 |
| Supplied by   | YaoPu (Shanghai) Pharma Tech Co., Ltd.   |   |                      |
| Test Results & Conclusion                           |  |   |                      |
| Test Items  | Acceptance Criteria  | Test Results  |                      |
| Appearance  | White to off-white solid   | Off-white solid   |                      |
| Solubility  | Slightly soluble in ethyl acetate and acetonitrile and practically insoluble in water            | Slightly soluble in ethyl acetate and acetonitrile and practically insoluble in water |                      |
| Optical Rotation                                    | +6°~+10°   | +8.5°   |                      |
| Identification, IR                                  | Consistent with reference spectrum   | Consistent with reference spectrum  |                      |
| Identification, HPLC                                | Retention time corresponds to that of the reference standard                                     | Retention time corresponds to that of the reference standard                          |                      |
| Crystal form, XRPD                                  | Consistent with reference standard   | Consistent with reference standard  |                      |
| Water Content, KF                                   | ≤ 1.0%   | 0.19%   |                      |
| Residue on Ignition                                 | ≤ 1.0%   | 0.00%   |                      |
| Heavy Metals  | ≤ 20ppm  | < 20ppm   |                      |
| L-Pyroglutamic Acid Assay (Calculated as anhydrous) | 22.1%~25.0%  | 23.5%   |                      |
| Related Substances                                  | PFSM01   | ≤ 0.1%  | N.D.                 |
|   | PF04   | ≤ 0.1%  | N.D.                 |



| Test Items  |                              | Acceptance Criteria                          | Test Results |
|---|------------------------------|--|--------------|
|   | PF04                         | ≤ 0.1%                                       | N.D.         |
|   | PF-Impurity01                | ≤ 0.1%                                       | N.D.         |
|   | Unknown Max. Single Impurity | ≤ 0.1%                                       | 0.09%        |
|   | Total Impurities             | ≤ 1.0%                                       | 0.12%        |
| Residual Solvents   | Ethanol                      | ≤ 5000 ppm                                   | N.D.         |
|   | Dichloromethane              | ≤ 600 ppm                                    | N.D.         |
|   | Pyridine                     | ≤ 200 ppm                                    | N.D.         |
|   | Triethylamine                | ≤ 5000 ppm                                   | N.D.         |
|   | Isopropyl Acetate            | ≤ 5000 ppm                                   | N.D.         |
|   | Methanol                     | ≤ 3000 ppm                                   | N.D.         |
|   | Isopropanol                  | ≤ 5000 ppm                                   | 170 ppm      |
|   | Dimethyl Sulfoxide           | ≤ 5000 ppm                                   | N.D.         |
|   | Methyl Tert-butyl Ether      | ≤ 5000 ppm                                   | 39 ppm       |
|   | Ethyl Acetate                | ≤ 5000 ppm                                   | N.D.         |
| PSD   | Report value                 | D10: 58.75μm<br>D50: 142.9μm<br>D90: 242.1μm |              |
| Assay (Calculated as anhydrous)   | 98.0%~102.0%                 | 100.6%                                       |              |
| Conclusion: The test results meet specification.                            |                              |  |              |
| Recommended Storage Conditions: Shading seal and store at room temperature. |                              |  |              |

Reported by/Date: *Zhengbing Wu/2023-05-10* Checked by/Date: *weibing juy/2023-05-10* Approved by/Date: *Lixia Chen/2023-05-10*