



### Certificate of Analysis

|                |               |                  |             |
|----------------|---------------|------------------|-------------|
| Product Name   | Abaloparatide | Manufacture Date | Jul.10.2023 |
| Batch Number   | SW2307010     | Analysis Date    | Jul.11.2023 |
| Batch Quantity | 200kg         | Expiry Date      | Jul.10.2025 |

| ANALYSIS           | SPECIFICATION                                                                                                                                                                                     | RESULT   |
|--------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| Assay              | 99.0%~101.0% (anhydrous substance).                                                                                                                                                               | 99.8%    |
| Identification     | A.H-NMR:Comply with the structure                                                                                                                                                                 | Complies |
|                    | B.LC-MS:Comply with the structure                                                                                                                                                                 | Complies |
|                    | C.The IR spectrum of sample should be identical with that of reference standard;                                                                                                                  | Complies |
|                    | D.HPLC-ESI-MS<br>The retention time of the major peak in the chromatogram of the Assay preparation corresponds to that in the chromatogram of the Standard preparation, as obtained in the Assay. | Complies |
| Loss on drying     | ≤2.0%                                                                                                                                                                                             | 0.19%    |
| Heavy metals       | ≤10 ppm                                                                                                                                                                                           | <10ppm   |
| Water              | ≤1.0%                                                                                                                                                                                             | 0.1%     |
| Sulphated ash      | ≤0.5%, determined on 1.0 g.                                                                                                                                                                       | 0.009%   |
| Related substances | Unspecified impurities: for each impurity                                                                                                                                                         | <0.10%   |
| Total plate count  | ≤1000cfu/g                                                                                                                                                                                        | Complies |
| Yeast and Moulds   | ≤100cfu/g                                                                                                                                                                                         | Complies |
| E. Coli.           | Absent                                                                                                                                                                                            | Negative |
| Salmonella         | Absent                                                                                                                                                                                            | Negative |
| S.aureus           | Absent                                                                                                                                                                                            | Negative |
| Conclusion         | This product conforms to international standards                                                                                                                                                  |          |

|                     |                                                                     |
|---------------------|---------------------------------------------------------------------|
| Packing description | Sealed export grade drum & double of sealed plastic bag             |
| Storage             | Store in a cool and dry place, stay away from strong light and heat |
| Shelf life          | 2 years when properly stored                                        |

Quality Assurance Officer:李强

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