

# METAPHARMACEUTICAL

N DE LOTE:

0070625

03/06/2025



浙江圣达生物药业股份有限公司

Zhejiang Shengda Bio-Pharm Co., Ltd.

## CERTIFICATE OF ANALYSIS

Product name: Biotin

|                       |               |                |             |
|-----------------------|---------------|----------------|-------------|
| Batch number          | CS1-2503035   | Test No.       | CP2503115   |
| Expiry date           | Mar.17,2029   | Report date    | Mar.27,2025 |
| Manufacturing date    | Mar.18,2025   | Submitted date | Mar.25,2025 |
| Package               | 25kg per drum | Batch size     | 300 Kg      |
| Ref. pharmacopoeia(s) | EP9           | Quantity       | 25 Kg       |

| Test Items                                                    |                                                                          | Specification                                                                                                                                                                 | Results                    |
|---------------------------------------------------------------|--------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Characters                                                    |                                                                          | A white or almost white, crystalline powder or colourless crystals.                                                                                                           | A white crystalline powder |
| Identification                                                | A: IR spectrophotometry                                                  | To match with the reference IR spectrum                                                                                                                                       | Conform                    |
|                                                               | B: Examine the chromatograms obtained in the test for related substances | The principal spot in the chromatogram obtained with test solution is similar in position and size to the principal spot in the chromatogram obtained with reference solution | Conform                    |
|                                                               | C: Color reaction                                                        | The bromine water is decolourised                                                                                                                                             | Conform                    |
| Appearance of solution                                        |                                                                          | Clear and colourless                                                                                                                                                          | Conform                    |
| Specific optical rotation                                     |                                                                          | +89°~ +93°                                                                                                                                                                    | +90.8°                     |
| Related substances                                            |                                                                          | Meets EP9 requirement                                                                                                                                                         | Conform                    |
| Loss on drying                                                |                                                                          | ≤1.0%                                                                                                                                                                         | 0.02%                      |
| Sulphated ash                                                 |                                                                          | ≤0.1%                                                                                                                                                                         | 0.04%                      |
| Assay                                                         |                                                                          | 98.5% ~ 101.0%                                                                                                                                                                | 99.7%                      |
| Arsenic                                                       |                                                                          | ≤1 ppm                                                                                                                                                                        | <0.5 ppm                   |
| Lead                                                          |                                                                          | ≤2 ppm                                                                                                                                                                        | <0.5 ppm                   |
| Cadmium                                                       |                                                                          | ≤1 ppm                                                                                                                                                                        | <0.5 ppm                   |
| Mercury                                                       |                                                                          | ≤0.1 ppm                                                                                                                                                                      | <0.05 ppm                  |
| Conclusion: This batch complies with the specification of EP9 |                                                                          |                                                                                                                                                                               |                            |

QC: 洪小军

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