

# CERTIFICATE OF ANALYSIS

**Product Name** SOMATROPIN POWDER FOR INJECTION  
**Batch No.** Y20250312  
**Specification** 10 IU / 3.7 mg / 1.0 ml / vial  
**MFG Date** 2025.03.14  
**Storage** Sealed, 2-8°C  
**Expire Date** 2027.03.13  
**Test Standard** EP 11.2

| TEST                            | SPECIFICATION   | RESULT  |
|---------------------------------|---|---|
| Appearance                      | White or off-white lyophilized powder   | White lyophilized powder  |
| Identification                  | Retention time of sample = standard   | Conformed   |
| Content retention time          | Retention time of sample = standard   | Conformed   |
| Related protein                 | Total related protein $\leq$ 10.0%  | 2.7%  |
| High molecular protein          | High molecular protein $\leq$ 6.0%  | 0.3%  |
| Impurities with charge          | Deaminated impurities $\leq$ 6.5% <br> Max individual impurities $\leq$ 2.0% <br> Total impurities $\leq$ 11.5% | Deaminated impurities 2.5% <br> Max individual impurities 1.7% <br> Total impurities 5.2% |
| Sterility                       | Conforms  | Conformed   |
| Bacterial endotoxin             | $\leq$ 5.0 EU/mg  | Conformed   |
| Biological activity             | $\geq$ 3.0 IU/mg  | 3.4 IU/mg   |
| Water                           | $\leq$ 3.0%   | 1.1%  |
| Visible particles               | Conforms  | Conformed   |
| Undue toxicity                  | Conforms  | Conformed   |
| Content uniformity              | Conforms  | Conformed   |
| Insoluble particle              | Conforms  | Conformed   |
| Clarity and colour of solutions | Solution should be clear & colourless, $\leq$ Turbidity Standard No.2   | Clear and Colourless  |
| Assay                           | SOMATROPIN content 89.0%~105.0% of labelled amount  | 100.4%  |

Note: This product is for research or production use only. Not for direct human use.