Recombinant Insulin

For biomanufacturing of therapeutic proteins and regenerative medicine

Key component in serum-free cell culture media for mammalian cells.

- Improve **process performance** with increased productivity
- Reduce risk of viral contamination using **animal-free** recombinant insulin
- Avoid process variability with **consistent quality** from batch-to-batch
- Ensure **robust supply chain** without risk of shortages

One ingredient. Many applications.

High-performance biomanufacturing processes are needed to accelerate the time-to-market of safe and efficient drugs, reaching millions of patients worldwide. Recombinant Insulin (also known as Insulin Human AF) is widely used in a broad range of biomanufacturing processes, improving the production of monoclonal antibodies (mAbs), antibody-drug conjugate drugs (ADCs), fusion proteins, viral particles, viral vectors, as well as stem cells and immune cells for cell therapy.

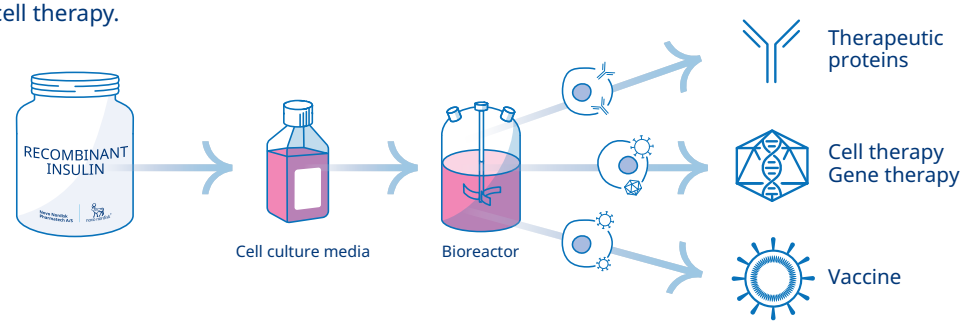

Figure 1: Overview of the biomanufacturing process for the production of therapeutic proteins, viral vectors, stem cells, and cell-based vaccines using insulin in the formulation of cell culture media.

Improved yields across different biopharma processes

To keep up with the increased demand of the biotherapeutics market, mammalian cell production expectations are rising every year. Incorporating efficient and safe components such as Recombinant Insulin into serum-free cell culture media enhances biomanufacturing processes and drives higher yields. Enhanced process performance enables reduced production volumes, ultimately decreasing time-to-market and associated costs.

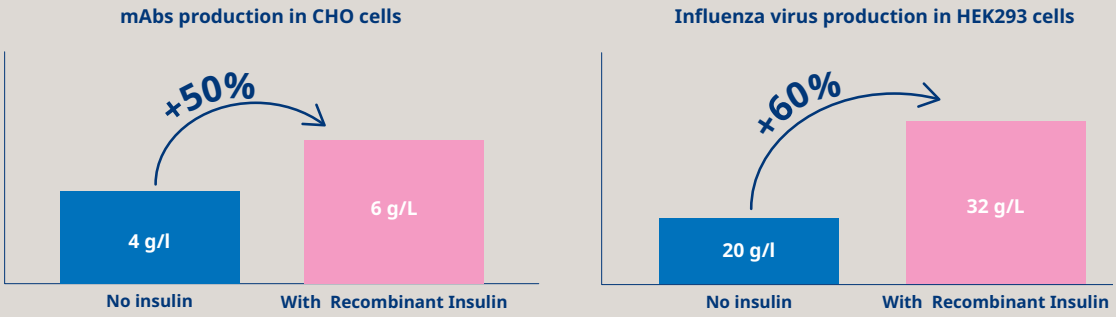

Figure 2: Supplementation of chemically-defined cell culture media with Recombinant Insulin enhances therapeutic protein production (e.g., monoclonal antibodies in CHO cell lines) and viral production for vaccine manufacturing (e.g., influenza virus in HEK293 cells).

Insulin Human AF is for further manufacturing use only, and not for therapeutic use.

Simplified regulatory approval with high-quality raw materials

Raw materials used in cell and gene therapy development must meet stringent quality standards. Rigorous regulatory processes can delay approval of new therapeutic options, extending the time before patients can access treatments. Integrating high-quality, safe raw materials such as Recombinant Insulin from the early development stages can accelerate the overall process.

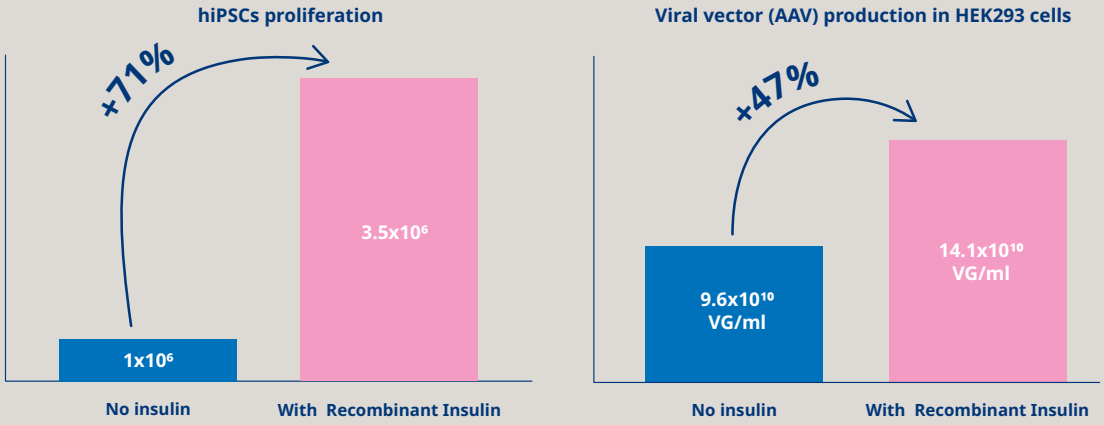

Figure 3: The addition of Recombinant Insulin to serum-free cell culture media boosts human induced pluripotent stem cells (hiPSC) proliferation and the titer of viral vectors (i.e. AAV) produced in HEK293 cells.

Recombinant Insulin: Premium quality standards

- Produced by recombinant expression in yeast and does not contain materials of animal origin
- Manufactured by Novo Nordisk under cGMP and EU GMP part II/ICH Q7 standards
- Packaged in compliance with the quality systems of Novo Nordisk and Novo Nordisk Pharmatech, as per ISO 9001
- Compliant with US and European Pharmacopoeia monographs for Insulin Human
- Fully traceable manufacturing with comprehensive documentation and service support

Recombinant Insulin products

Recombinant Insulin is available in five packaging sizes to fulfill the different needs from small to large-scale production.

Products are shipped on dry ice according to validated transport.

Product name	Size	Item number
Insulin Human AF	1 g	3068855
Insulin Human AF	10 g	3068856
Insulin Human AF	50 g	3068857
Insulin Human AF	100 g	3068858
Insulin Human AF	1 Kg	3068859

Novo Nordisk Pharmatech A/S
Københavnsvej 216
4600 Køge, Denmark

+45 5667 1000
nnprinfo@novonordisk.com
novonordiskpharmatech.com