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.

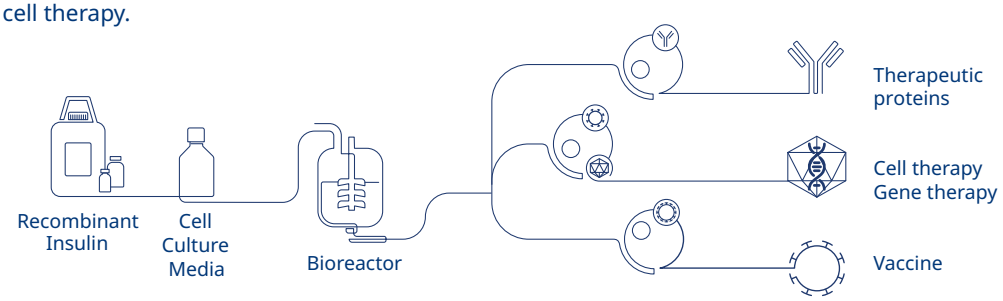

Figure 1: Overview of the biomanufacturing process for the production of therapeutic proteins, viral vectors, stem cells, and cell-based vaccines using insulin in the formulation of cell culture media.

Biomanufacturing – 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. The addition of efficient and safe components to serum-free cell culture media, like recombinant insulin, improves dramatically the biomanufacturing process, resulting in increased yields. Improved process performance allows lower production volumes, reducing time and cost to market.

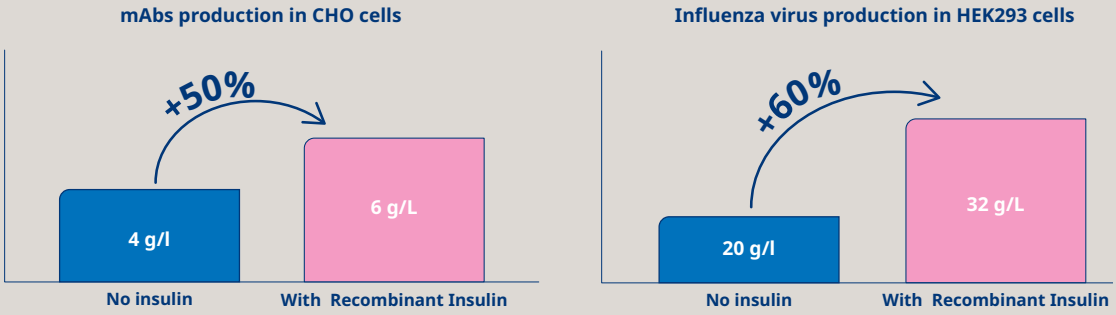

Figure 2: The addition of Recombinant Insulin to chemically-defined cell culture media boosts the production of therapeutic proteins (i.e. monoclonal antibody in CHO cell lines, +50%) and virus for vaccine production (i.e. influenza virus in HEK293, +60%).

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

Regenerative medicine – Simplified regulatory approval with high-quality raw materials

Stringent quality requirements apply to raw materials used in the development of cell and gene therapies. Rigorous regulatory processes hinder the approval of new therapeutic options, causing longer lead time to the patient. Incorporating top-tier, safe raw materials, like recombinant insulin, already in the early stages of development can expedite the process.

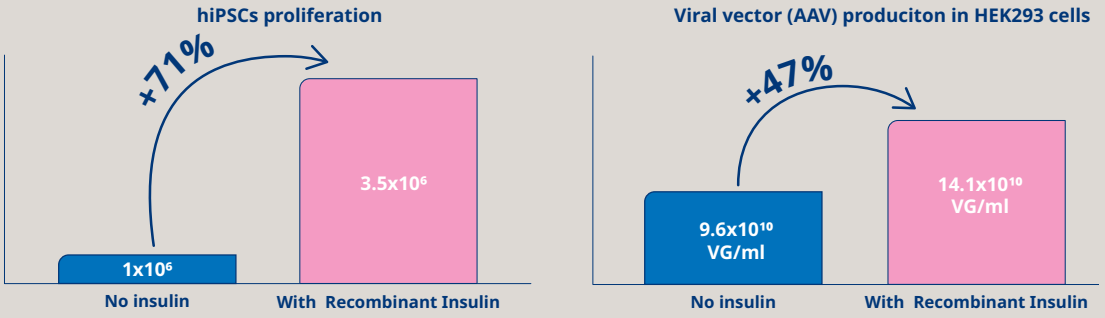

Figure 3: The addition of Recombinant Insulin to serum-free cell culture media significantly boost pluripotent stem cells (hiPSC) proliferation and HEK293 cell productivity of viral vectors (i.e. AAV).

Recombinant Insulin is:

- Produced by recombinant expression in yeast and does not contain materials of animal origin
- Produced by Novo Nordisk in accordance with current Good Manufacturing Practice (cGMP) and EU GMP part II and ICH Q7
- Packaged in compliance with the quality systems of Novo Nordisk and Novo Nordisk Pharmatech, as per ISO 9001
- Compliant with the US and European Pharmacopoeia monographs for Insulin Human
- Manufactured with fully traceable process and supported by extensive documentation package and service

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.

Catalog no.	Product Name	Size
3068855	Insulin Human AF	1 g
3068856	Insulin Human AF	10 g
3068857	Insulin Human AF	50 g
3068858	Insulin Human AF	100 g
3068859	Insulin Human AF	1 Kg

Being sustainable

Novo Nordisk Pharmatech operates with the highest standard in a financially, environmentally and socially responsible way which has resulted in a top 1% company rating for the EcoVadis Sustainability Assessment Report.

PLATINUM Top 1%
ecovadis
Sustainability Rating
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