

# Recombinant insulin for innovative biologics



Novo Nordisk  
Pharmatech A/S



**By delivering excellence  
at every step, we help  
you do the same**



**Excellence. Multiplied**

### From manufacturing to delivery

As the leading supplier of recombinant insulin for innovative biologics, Novo Nordisk Pharmatech can help you keep development on track, production flowing and product supplied to hospitals and patients. We remain the best supplier of insulin for cell culture processes by providing excellence at every step of the supply chain – beginning with the quality of our insulin, which is sourced directly from Novo Nordisk, the world's largest producer. We are a reliable partner in helping

you find the right quality ingredients for your projects and supplying you with the appropriate documentation – even tailoring ingredients to match specific application needs.

Manufacturing and quality control, precision delivery and a risk mitigation strategy that assures continuous availability are a few of the reasons why you should grow your cells with our insulin. Many of the world's leading pharmaceutical companies already do.



### For cell growth media

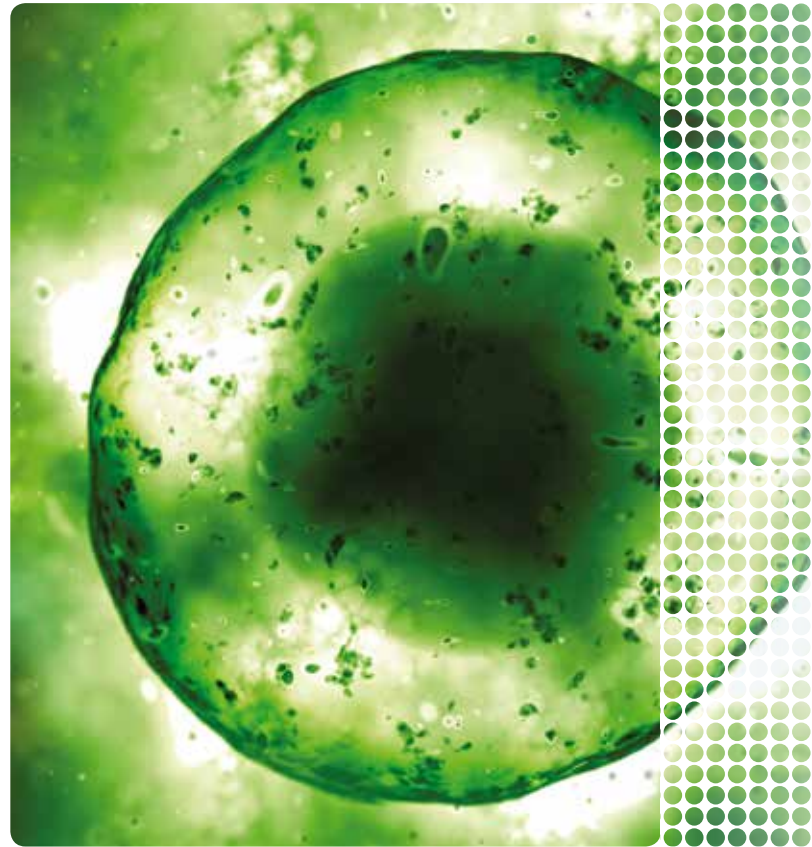
Our Insulin Human AF is a key component in serum free growth media for mammalian cells. It is used for the manufacturing of monoclonal antibodies, virus vaccines, gene therapy products and other biological drug products approved by regulatory bodies worldwide, including FDA and EMA. Recombinant insulin stimulates the proliferation of cells and enhances the yield.

### We guarantee

- Pure and animal-free recombinant insulin
- Manufactured at cGMP facility
- Consistent high quality
- Full traceability
- Secure global supply chain
- Extensive regulatory documentation
- Continuous availability
- High levels of service and support
- Cost-effective customised solutions
- Narrower specification than pharmacopoeia requirements



# Every successful product needs a secure supply chain



**Reliability. Proven**

### Assured availability

- Manufacturing facilities inspected by FDA
- Safety stock at multiple secured locations
- Large-scale bulk batches solely for the cell growth market
- Five-year shelf life
- Robust risk mitigation strategy
- Certified *Known Consignor* supplier

### Precision delivery

Novo Nordisk Pharmatech can assure you of dependable availability and a continuous supply of products for your cell culture media applications. We have sufficient packed off-the-shelf recombinant insulin in stock for at least five months of consumption, enabling us to respond immediately to your specific requirements. Our two locally placed distribution centers – near Copenhagen, Denmark, and in Indiana, USA – ensure short lead-times and precision delivery worldwide.

### Tamper-proof packaging

We pack in our own classified room facilities. The product is dispensed into a range of HDPE plastic containers, which are placed in individual tamper-proof plastic bags. The tamper-proofed containers are placed in approved thermo containers, inside a cardboard box and packed with sufficient dry ice to ensure that the product is kept below the recommend maximum temperature during shipment.

### Risk mitigation

Our manufacturing facilities are carefully placed to ensure the most secure geographic, weather, political and civil conditions. They have strong, long-standing relations with suppliers and meet the highest standards of fire and explosion risk prevention. Due to our risk mitigation strategy, we are able to rapidly and efficiently manage and counteract threats to your product supply.



**Produced to the highest standards, handled and stored accordingly**



**Purity. Proven**







### Packing sizes for Insulin Human AF

1 g	Item No: 3068855
10 g	Item No: 3068856
50 g	Item No: 3068857
100 g	Item No: 3068858
1 kg	Item No: 3068859

### Product properties

Recombinant Insulin Human AF consists of human insulin crystals, a biosynthetic white to almost white powder produced by a recombinant microbial expression in yeast with a synthetic gene insert. Insulin is a small and hydrophobic molecule and is easily dissolved in a buffer at relatively low pH. At neutral pH, insulin will take longer to dissolve:

- Solubility: Soluble at 10 mg/mL in pH 2-3
- Activity:  $\geq 27.5$  IU/mg (dry basis)

It is recommended to add dissolved insulin to the media while stirring. The recommended concentration of recombinant insulin in cell culture media is 1-10 mg/L, depending on cell type and specific application. Information sheet available on request.

### Handling and storage

Insulin Human AF has a shelf life of 60 months. It must be stored at  $-20^{\circ}\text{C} \pm 5^{\circ}\text{C}$  to avoid potential degradation and to ensure compliance with the product specification for the entire shelf life period.

Insulin Human AF can be stored at refrigerator temperature ( $+2$  to  $+8^{\circ}\text{C}$ ) for up to 14 days in total, accumulated over its shelf life period. Within the shelf life period, the product should not be thawed/re-frozen more than five times. In connection with dispensing the product, keeping and handling the product at up to  $25^{\circ}\text{C}$  is allowed for up to 24 hours.

To place an order or receive more detailed information please call +45 5667 1000 or visit our website, [www.novonordiskpharmatech.com](http://www.novonordiskpharmatech.com)

# Our insulin gives your growth media a sure start



## Quality. Proven





### Highest standards

Novo Nordisk Pharmatech lives up to the highest quality standards, providing pure, efficacious and safe products. Our entire supply chain, manufacturing and quality control takes place in Denmark.

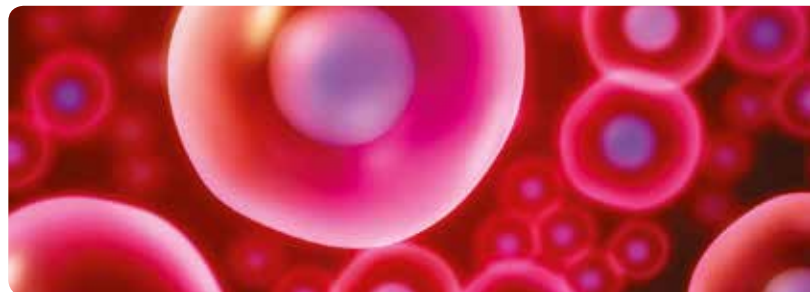
Our recombinant Insulin Human AF is manufactured in accordance with Novo Nordisk and Novo Nordisk Pharmatech quality systems, based on ISO 9001 and fulfils all relevant European and USA regulatory guidelines. It is produced under cGMP compliance and analysed according to the current European Pharmacopoeia (Ph. Eur.) and United States Pharmacopoeia (USP). Both Novo Nordisk and Novo Nordisk Pharmatech are regularly audited by major and minor pharmaceutical companies, as well as health authorities.

### Fully animal free

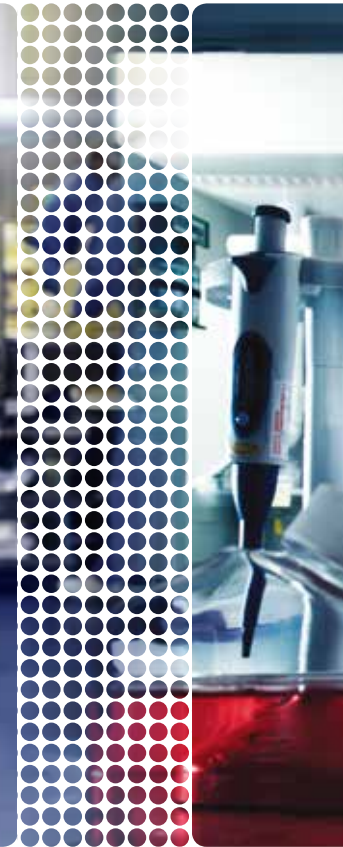
Our recombinant insulin supports major growth media suppliers' definition for an animal free product. No animal origin component is used in the cell bank and manufacturing process. The yeast organism used for production does not contain genes nor express antigens of livestock or disease agents. The trypsin is replaced by a proprietary process aid of non-animal origin. Additionally, our insulin is antibiotic free, both in terms of production facilities and on a cell bank level.

### Comprehensive documentation and services

- ISO 9001 Certificate
- Certificate of Analysis (current version of pharmacopoeias)
- Customer audits
- Declarations, statements (stability, residual solvents, TSE/BSE, GMO, allergens, environment, etc.)
- Change Notification
- Answering of questionnaires
- Process flowchart
- Packaging details
- MSDS



# Our resources help you keep development on track



## Consistency. Proven



### **More than 65 years of experience**

Novo Nordisk Pharmatech specialises in supplying ingredients for the biopharmaceutical and pharmaceutical industries. We were established in 1949, acquired by Novo Nordisk in 1986 and have been part of the pharmaceutical group since then. With more than 90 years of experience within the biopharmaceutical industry, Novo Nordisk gives us access to a large number of in-house specialists who can assist with advice, even from early product development stages.

Our own highly qualified personal work continuously on product development and improving documentation to suit your needs. We also collaborate with internationally recognized experts. This expertise – together with product and documentation availability and global compliance – has made Novo Nordisk Pharmatech a preferred supplier with the major leading biopharmaceutical and pharmaceutical companies.

### **Sustainability and triple bottom line**

Novo Nordisk is a member of the UN Global Compact and World Business Council for Sustainable Development (WBSCD). As a fully owned subsidiary, we follow the general policies of Novo Nordisk for sustainability, business ethics and code of conduct.

We believe that a healthy economy, environment and society are fundamental to long-term business success. This is why we manage our business in accordance with the Triple Bottom Line (TBL) business principle, conducting activities in a financially, environmentally and socially responsible way.





The Apis bull logo is a registered trademark of Novo Nordisk A/S.

Novo Nordisk Pharmatech A/S  
Københavnsvej 216  
DK-4600 Køge  
Denmark  
Phone: +45 5667 1000  
Fax: +45 5667 1001  
[www.novonordiskpharmatech.com](http://www.novonordiskpharmatech.com)

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