

Insulin Human AF



10 reasons why

using Insulin Human AF will
improve the production of
your innovative biologics

**Novo Nordisk
Pharmatech A/S**



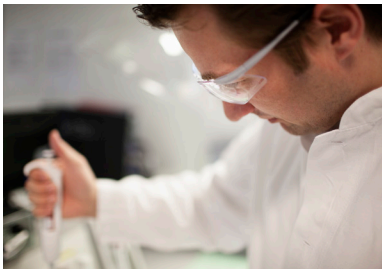
Reason 1

Highest standards

We live up to the highest quality standards, with a quality management system complying with DS/EN ISO 9001 for all activities.

Insulin Human AF is sourced directly from our mother company Novo Nordisk, the world's largest producer of Insulin. Insulin is manufactured under ISO 9001 Quality Systems and cGMP compliance and fulfils all relevant European and US guidelines and pharmacopoeia.

Our manufacturing facilities are inspected by the US FDA, and both Novo Nordisk and Novo Nordisk Pharmatech are regularly audited by pharmaceutical companies and inspected by the Danish Medicine Agency.



Reason 2

High purity

Insulin Human AF is produced in yeast. This organism is neither stored nor grown in animal-containing media and does not contain genes or express antigens of livestock or poultry disease agents.

Our recombinant insulin meets major cell culture media suppliers' requirement for animal-free products. No animal origin component is used in the cell bank and manufacturing process. The trypsin used during insulin manufacture is replaced by a proprietary process aid of non-animal origin. Additionally, our insulin is antibiotic free. Insulin Human AF complies with ICH Q3C Note for Guidance on residual solvents.



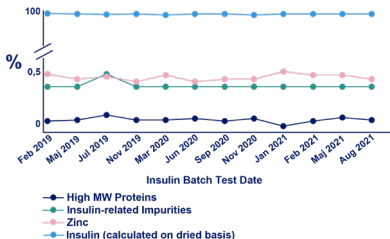
Reason 3

High consistency

Controlling product variability is a central challenge for all biopharmaceutical manufacturers to ensure batch-to-batch consistency.

Insulin Human AF is manufactured in large-scale bulk batches and complies with ICHQ1 guidelines for stability testing for new drug products.

Testing of different batches of Insulin Human AF shows consistent batch-to-batch quality.



Reason 4

Reliability

With 100 years of experience with Insulin, Novo Nordisk ensures the most stable and well-established manufacturing processes and specialist know-how on the market.

We are specialized in supplying ingredients to the biopharmaceutical and pharmaceutical industries and we deliver as promised, on-spec and on time.

Our recombinant Insulin is used by global large biopharmaceutical companies for the manufacture of their blockbuster drugs.



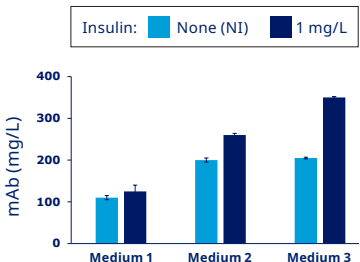
Reason 5

Improved cell growth and protein yield

Used in serum-free growth media for mammalian cells, insulin stimulates cell proliferation. Insulin Human AF is supplemented to culture media for many cell lines (i.e. CHO, HEK 293 or Sf9), for the manufacturing of monoclonal antibodies (mAb), virus vaccines, or gene therapy products, and other biological drugs approved by regulatory bodies worldwide, including FDA and EMA.

Insulin Human AF, supplemented to three different culture media for CHO cells, leads to a 66% increase in mAb yield

mAb production



Reason 6

Global regulatory compliance

We offer a comprehensive list of documentation and services:

- ISO 9001 certificate
- Certificate of Analysis (current versions of Ph.Eur. And USP/NF pharmacopoeias)
- Customer audits
- Declarations, statements (stability, residual solvents, TSE/BSE, GMO, allergens, etc.)
- Change Notification
- Pre-filled Supplier Questionnaire
- Process flowchart
- Packaging details
- Quality assurance agreements
- Certification as known consignor supplier



Reason 7

Secure global supply chain

Every successful product needs a secure supply chain. Novo Nordisk Pharmatech A/S can help by ensuring dependable availability and a continuous supply of products.

Our customers can rely on our robust risk mitigation strategy. Our entire manufacturing and quality control take place in Denmark, and our supply chain is limited within Scandinavia.

Our manufacturing facilities are carefully placed to ensure the most secure geographic, weather, political and civil conditions.

We maintain safety stocks at multiple secure locations and we have full traceability of the entire supply chain.



Reason 8

Packaging ensuring unaltered quality

Insulin Human AF has a shelf life of 5 years.

The product is dispensed in HDPE plastic container, 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 recommended maximum temperature during shipment.

Depending on the volume of the primary plastic containers, either a small or large shipment box is used.



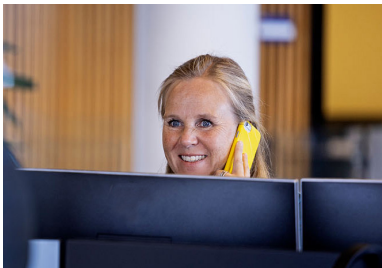
Reason 9

High levels of service and support

Relying over Novo Nordisk's 100 years of experience within the biopharmaceutical industry, our customers can have access to many in-house specialists who can offer technical support, even from early product development stages.

According to their needs, our customers can find a broad range of cost-effective customised solutions.

Our dedicated customer support team is ready to assist with all types of requests, including documentations and shipping requests.



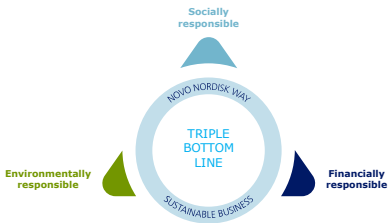
Reason 10

Circular mindset and Triple Bottom Line

The target of our environmental strategy for the next 10 years is to have zero environmental impact by 2030.

We collaborate proactively with suppliers to embed a circular mindset for reduced environmental impact across our value chain and switch towards circular sourcing and procurement.

We aim to eliminate the environmental footprint from our operations and drive a circular transition across the company.





Enabling better medicines

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