



# Reduce your risk with a reliable pharma supplier

*Get peace of mind for your full product life cycle with a pharma organisation like Novo Nordisk Pharmatech. We ensure you get the quality Quats and Insulin Human AF you need – with zero compromise.*

For many pharmaceutical and biopharmaceutical companies, the coronavirus pandemic has put supply chains to the test, while regulatory requirements are increasingly tightening. Novo Nordisk Pharmatech helps customers reduce their risk, with a high level of consistency in both the quality and supply of our Quats and Human Insulin AF. You can be sure you get the same high quality product, time after time, reliably delivered through local distribution networks. Our comprehensive documentation package and tailored support, which continues through the whole product life cycle, gives you total peace of mind.

## High quality Quats and Insulin Human AF

Reduce the risk for your raw materials with pharma-grade Quats. We are a specialist and dedicated manufacturer of Quats, for use as both APIs and excipients, in an unequalled, full cGMP grade. Our stringent Quality Management System ensures the right quality products, with a high degree of consistency. We receive excellent ratings in audits from our customers and authorities, including the FDA and EMA, and continue to improve from every audit. Our multi-compendial range of Quats complies to the highest regulatory guidelines, including ICH Q7, the European Pharmacopoeia (Ph. Eur.) and the United States Pharmacopoeia (USP). Some Quats products also follow the Japanese Pharmacopoeia (JP) or the British Pharmacopoeia (BP).

Our high quality Insulin Human AF is manufactured by our parent company, Novo Nordisk, a leading supplier of insulin for over 100 years. With Insulin Human AF, you avoid the risk of impurities such as mycoplasmas, which can pass line to line from the upstream bioreactor and contaminate your whole line. Novo Nordisk manufactures its Insulin Human AF in cGMP facilities, following an ISO 9001 quality system. With very few manufacturing batches a year, the large scale of our manufacturing and our highly standardised processes ensure product consistency. The insulin is analysed according to the current European Pharmacopoeia (Ph. Eur.) and the United States Pharmacopoeia (USP).



### Tailored support through the whole product life cycle

Whether you are using insulin as a processing aid or using Benzalkonium Chloride for a highly critical API, we can support you with the level of service and documentation you need. For example, knowing that many of our customers use our Quats as APIs and excipients, we provide a very high level of support for quality control testing. We provide extensive and detailed information about our quality testing methodologies, which are often better than the monograph methodology. This means our customers can replicate our methodologies in their labs and reconfirm that their raw materials are compliant with the certificate of analysis. We can also help our customers decide what testing they need to do for each process, by supporting their risk assessment documentation. For example, ICH Q3D regulations require a defined control strategy for elemental impurities. Our extensive documentation can save our customers the expense of running additional tests.

You have our support for the whole product life cycle and beyond. We keep all records required by authorities to ensure full traceability from manufacturing to delivery. This means that you will continue to have our support towards the end of your product's shelf life – or even after. We also understand that when you are audited by local authorities, you need a fast response to any questions or requests. We enter into agreements with our customers directly, even if you buy through a distributor, so you can quickly solve any problems. To support this, we have agreements with our distributors and suppliers to ensure traceability across the whole supply chain.

### A reliable supplier and a robust supply chain

Your business continuity is our priority. We understand you need a reliable supplier – financially, environmentally and socially – even in times of crisis. As part of Novo Nordisk, we are one of the world's most financially stable pharma companies. And as all our activities happen within the one company, you also mitigate your risk with fewer players in your supply chain. Our manufacturing and business operations are located in Denmark, which provides very stable political and civil conditions. We assisted the Danish government during the coronavirus crisis, and Novo Nordisk provided rebates to ensure that people around the world still got their insulin. This is an example of our Triple Bottom Line principle: we believe this social investment is also an investment in the long-term profitability of our business.

We are also increasingly reducing our impact on the environment, while mitigating the risk of environmental events on our supply. For example, after the volcanic eruption in Iceland, we developed a robust local distribution network for both our Quats and insulin products around the world. With all our operations closely connected within one site, we pride ourselves on our ability to adapt quickly. All this ensured that we did not experience significant disruptions at the outbreak of the coronavirus pandemic. We were able to continue manufacturing – and even upped production to meet increased demand for some Quats products – and our customers received their orders as planned.

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