

Tailor-made excipients, developed the Kolb way



Standard excipients can be sourced from various suppliers, but what if you need to customise an excipient to suit your needs?

FOR MANY YEARS, Kolb has been selected by pharmaceutical companies to develop and supply standard and customised excipients such as polysorbates, macrogols and poloxamers, which are based on our alkoxylation and esterification technologies.

Since the GMP certification by Swissmedic in 2017, we have intensified our commitment to this industry and are now even better set up to serve this market.

We do it the Kolb way

We started operations in 1964 in Hedingen, near Zürich in Switzerland. Through passion and hard work, we have grown steadily and currently have two further production sites in The Netherlands. In 2007 we became a subsidiary of KLK, a reputable Malaysian conglomerate. KLK is committed to the further development of Kolb through ongoing investments in operations.

In 2017, our production site in Hedingen received GMP certification by Swissmedic, an important strategic step to further develop the pharma business. The key to our success is to maintain the mind-set of a medium enterprise; characterised by short communication lines, being flexible and fast in what we do, while keeping the high quality of a Swiss product. This allows us to focus on the needs of our customers.

Product development at Kolb A tailor-made excipient developed the Kolb way. What does it mean?

From the start of the customer journey, we evaluate what their specific requirements are – the so-called product profiling. In a nutshell, we look at the product from different angles with a number of experts to be sure we understand what the customer

needs and evaluate the technical feasibility and commercial viability of the project. Sometimes, this phase might seem intense and overdone, but experience has taught us this isn't the case; time invested here is gained back later.

After the evaluation phase, the next steps are synthesis in our R&D lab followed by scale up in production. Regular exchange with the customer takes place by the appointed Kolb project leader to report on progress and share preliminary results.

Kolb's capabilities for pharma projects

Many nonionic surfactants are described as pharmaceutical excipients in the Pharmacopoeia, and Kolb is an established and reliable manufacturer of pharmaceuticals with products such as macrogols, polysorbates, sorbitan esters and poloxamers. We can produce batches of less than 1kg for testing and optimising, or small batch production before scaling up to large industrial trials of several tonnes.

Our customers sometimes need tight specifications to optimise the effectiveness of the API's, and we can guarantee this. If additional measurements are required, we can carry them out in our own QC laboratory. We also have established partnerships with GLP-certified laboratories. As a GMP certified company by Swissmedic, we can provide the necessary documentation to the product.

Let's do it the Kolb way

Pharmaceutical companies prefer to focus on the development of the API and outsource the development and production of the excipient.

The three reasons they chose Kolb as a partner are:

- We take time to listen to the customer; we want to fully understand their needs and goals
- We assign a focused project team of experts, directly in contact with the customer's specialists
- We expedite a short time to market as a result of fast execution of agreed actions.

Finally, we count on the support of Kolb's QC and RA teams to ensure quality controls are set up properly and necessary regulation covered.

Please contact us at www.kolb.ch/pharma or at pharma@kolb.ch. You will receive a questionnaire, which informs us of your needs as a company and your regulatory requirements. After that, a project meeting will be set up, physically or by videoconference, where both parties confirm their commitment to the project and ensure that the specialists can talk directly to each other. Finally, a project plan will be lined up with clear milestones, approved by both parties.

If there is anything you would like to discuss with us, we look forward to hearing from you about your project and work out the best solution. ■



www.kolb.ch/pharma