

Shortening the Path to Pharmaceutical Development

No pharmaceutical company can market new drugs without going through the long and expensive process of getting them approved. Optimizing this process can save time and money, and Icelandic pharmaceutical manufacturer Alvotech has achieved this goal by collaborating with a university and using X-ray technology.

Alvotech is a specialty biopharmaceutical company that develops and manufactures high-quality bio-similar medicines. A great deal of production time is spent on pre-clinical testing, that is, testing conducted before human beings are enrolled in clinical trials. With the aim of increasing its global competitiveness, Alvotech sought to improve its quality control by examining which products, specimens and other materials are physically similar at the molecular level. X-ray technology provided a way to do this.

Exploring Molecular Structure with X-rays

In a process facilitated by the LINX Association, Alvotech contacted the University of Copenhagen (KU), home to experts in small-angle X-ray scattering (SAXS), a technique that functions like an incredibly powerful microscope.

The company approached the project with two high-priority issues to settle. First of all, could SAXS make it possible to view the molecular structure of each of four selected antibodies?

Such insight could reveal whether the products met Alvotech's high quality standards. Second, how stable would those four antibodies be at higher temperatures? Would their properties be diminished?

The project was a success. One antibody proved to be unique, and further research will focus on just how that particular one differs from the other three. The X-ray technique SAXS showed itself to be an effective tool for Alvotech at a critical stage of product development and quality testing.

The technique can also be applied to liquids and a variety of pharmaceutical and food products, revealing details of molecular or chemical reactions as they are happening. The result is useful knowledge about product development, stability, mixing ability and a number of other characteristics—information vital to optimizing sales.



Innovative methods can speed up the approval process for new medicines.



X-ray techniques promise to help shorten the typically lengthy process of producing medicines.

Chemical reactions are hard to spot and identify. In the case of, for example, a dairy product that lacks the desired consistency or taste, researchers can use X-ray techniques to determine the product's exact molecular structure. That can provide important clues as to how to remedy the problem, avoiding both more expensive tests and dissatisfied customers!