

PEPTIDE PRODUCT DEVELOPMENT

Overcoming challenges when harnessing synthetic peptides in drug development



Across the pharmaceutical industry, there is growing interest in medicines that harness peptides as the active pharmaceutical ingredient (API). Like proteins, peptides are chains of amino acids, but peptides are significantly shorter, ranging from just a single digit number of amino acids up to about 50 amino acids.

Peptides regulate functions such as burning fat, building muscle, and serve as hormones and neurotransmitters. Because of this, they can be used as drugs that against a number of serious diseases including cancer, infections and diabetes. Peptide-based drugs accumulate only in low levels in body tissue, which reduce toxicity levels. Moreover, they are highly selective which makes them effective at lower doses with less serious side effects.

At Recipharm, we have experience supporting drug companies in overcoming the unique development challenges posed by peptides so they can utilise the benefits of these ingredients for end-patients.



The challenges of peptide development

Two challenges are common when developing drug products based on peptides:

- ▶ Bioavailability
- ▶ Stability

Most peptides have no or a very low oral bioavailability and for this reason parenteral administration is usually needed. In addition, the stability of many peptides is poor in-solution, and it is common to formulate peptides as a lyophilised powder to be dissolved prior to injection.

How Recipharm can help

Recipharm has years of experience developing drug products based on synthetic peptides. Our services include:

- ▶ Formulation
- ▶ Chemical analytical development
- ▶ Stability studies
- ▶ Manufacture of clinical trial material
- ▶ Labelling
- ▶ QP release

We also take care of scale-up and tech-transfer to one of our commercial manufacturing sites on your behalf. We minimise time and cost at the early stage by using streamlined approaches, and work to help you develop a final product that is well adapted to all the requirements of a commercial product.

We have access to a small-scale GMP-facility for aseptic manufacture of material to smaller clinical trials as several full-scale manufacturing units for parenteral products, enabling us to supply products for all clinical phases.

If your peptide and indication require an alternative administration route to parenteral, we can develop dosage forms including tablets, capsules, liquids, semi-solids, and inhalation products to meet your peptide product's unique needs.

At Recipharm we offer:

- ▶ Development of drug products for all clinical phases
- ▶ Development of control methods
- ▶ Stability studies
- ▶ GMP-manufacture of clinical trial material in small and large scale
- ▶ Development and manufacture of placebo
- ▶ Packaging and labelling according to GMP requirements
- ▶ CMC support
- ▶ Quality control
- ▶ QP release
- ▶ Scale-up and tech-transfer to commercial manufacture



About Recipharm: Recipharm is a leading contract development and manufacturing organisation (CDMO) headquartered in Stockholm, Sweden. We operate development and manufacturing facilities in France, Germany, India, Israel, Italy, Portugal, Spain, Sweden, the UK and the US and are continuing to grow and expand our offering for our customers.

Employing around 9,000 people, we are focused on supporting pharmaceutical companies with our full service offering, taking products from early development through to commercial production. For over 25 years we have been there for our clients throughout the entire product lifecycle, providing pharmaceutical expertise and managing complexity, time and time again. Despite our growing global footprint, we conduct our business as we always have and continue to deliver value for money with each customer's needs firmly at the heart of all that we do. That's the Recipharm way.