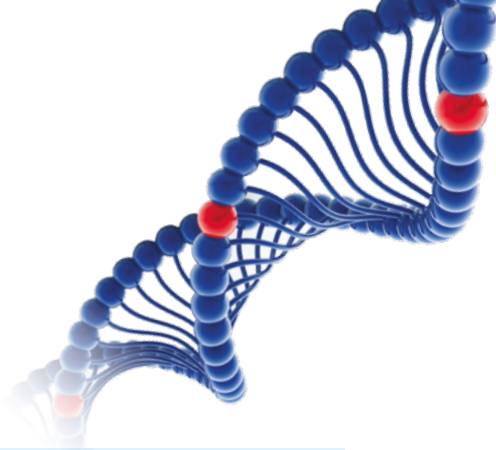


Our HPAPI development and manufacturing capabilities



About Aspen Oss

Aspen Oss has a proud history of almost 100 years in the production of complex, highly potent APIs (HPAPIs). We work from a deeply rooted and pro-active quality culture. Our facilities are successfully inspected and approved by governmental authorities such as the US FDA, EMA, PMDA, and others. We offer our customers a true partnership by consistently delivering high product quality on schedule. Aspen provides you extensive support at all stages of the project: from proof of concept forward through registration and commercialization.

How our HPAPI competencies will add value to your product or goals

We are strong in the development, manufacturing and handling of complex reactions and highly potent compounds at various production scales with a specialization in steroid hormones. Our HPAPIs are produced in units with OEB 4 and 5 classifications. We have a long history in working with OEL levels going as low as 0.01 µg/m³.

Our heritage of working in the manufacturing of complex HPAPIs has enabled Aspen Oss to establish world class systems and procedures for the safe handling of these compounds. Our ISO14001 and OHSAS18001 certification show that we are committed to the protection of the health and safety of our employees, our community and the environment.

Besides our specialization in **steroid hormones**, Aspen Oss has been developing and currently manufactures several other HPAPIs:

- Leuprolide acetate
- Oxytocin
- Mirtazapine
- Gonadorelin acetate
- Desmopressin
- Rocuronium Bromide

When bringing your HPAPI project to Aspen Oss, you will be sure to find a reliable quality partner, through our transparent and professional way of communication.

We welcome you to contact us and to find out more about how our competencies will add significant value to your product or business goals.



HPAPI manufacturing capabilities

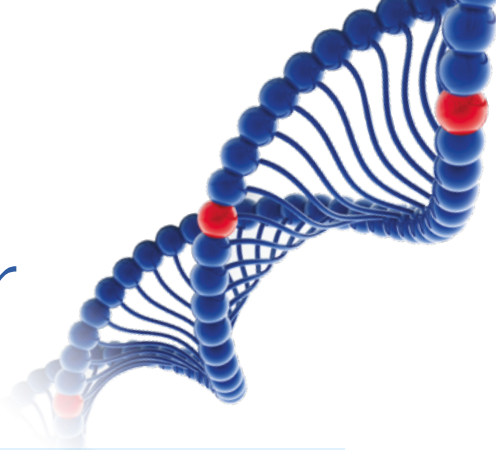
- Manufacturing under full cGMP
- Batches ranging from 1 kg to 500 kg API
- Commercial manufacturing ranging from 100 to 10.000 liters
- Best-in-class cleaning procedures
- Isolator technology for micronization and milling of OEB 4 and 5 compounds
- Grade D clean room manufacturing for weighing and dispensing



Integration in our processes

- Over 25 in-house SHE specialists with expert knowledge
- Well trained staff and best-in-class safety protocols
- Safety assessments using calorimetry on processes, intermediates and APIs
- All intermediates and APIs on site assigned to OEB category
- ISO14001 and OHSAS 18001 certified

Your development and manufacturing partner for World Class APIs



Serving for many years a stable customer portfolio including global multinationals, generic manufacturers and innovative new tech start-ups, we understand what you need in an API partner. Our expertise and capability to develop, scale-up and commercially manufacture your API, will ensure that you will be working with a reliable high quality partner. At the same time we establish a strong technical foundation for your project success.

API development

Our team of highly skilled scientists has a long standing expertise in synthesis and process development and is focused on taking your project to the next stage. Our cGMP production facility is able to produce product from gram to kilo quantities to support pre-clinical, clinical and commercial demands.

Besides a direct contact with our SME's, we ensure you of the following services:

- Professional project management
- Route selection
- Process development and optimization
- Analytical development and validation
- ICH stability studies
- Extensive sourcing network for raw materials
- Global regulatory expertise and support

API chemical and peptide manufacturing capabilities

We are specialized in complex chemical reactions and are able to combine this with developing the most efficient processes. Supported by a robust quality system, we ensure a high product quality, manufactured in compliance with cGMP, ICH and SHE regulations. Being part of a global Aspen API network, we ensure flexibility and delivery reliability.

Our chemical capabilities

- More than 100 stainless steel and glass-lined reactor vessels
- Conversion of steroidal starting material through microbiological fermentation

- Large scale purification through crystallisation, filtration and chromatography
- State-of-the-art Powder Processing and Dispensing unit for sieving, milling and micronization

Examples of our complex chemical reactions

- Ethynylation
- Oxidation (Jones, Oppenauer)
- Grignard
- Lithium aluminum hydride & sodium borohydride reduction
- Liquid ammonia reduction
- Bromination

Our peptide capabilities

- Liquid (solution) Phase Peptide Synthesis (LPPS)
- Solid Phase Peptide Synthesis (SPPS)
- Green Continuous Liquid Phase Peptide Synthesis (GC-LPPS; combining the best of LPPS and SPPS)
- Preparative HPLC columns up to 45 cm
- 100 liter tray lyophilization



We welcome you to contact us and to find out more about how our competencies will add significant value to your product or business goals.

