



World Class APIs

Building on almost 95 years of experience

About Aspen Oss



Aspen Oss has a proud history in the production of Active Pharmaceutical Ingredients, spanning over almost 95 years. Aspen Oss specializes in the manufacture of high complexity APIs. We are dedicated to the production of high quality APIs and delivering extensive support.

The origins of Aspen Oss date back to 1923, when the owner of a slaughterhouse initiated the extraction of animal pancreases for the use in the production of pharmaceutical grade insulin.

From these humble beginnings the operations have gradually been expanded, culminating in Aspen Oss's position today as a global supplier and one of the world's best known producers of steroid hormones APIs, many of which are registered and used in originator Drug Products. Aspen Oss is also well known for its production of heparin sodium, several peptides and alkaloid products.

Aspen Oss, whose activities are supported by approximately 1000 employees, specializes in the manufacture of high complexity products, in amongst others the therapeutic areas of gynaecology / women's health, muscle relaxation and the central nervous system.

Aspen Oss production is performed in production sites located in the Netherlands and the USA, which operate in accordance with cGMP regulatory guidelines worldwide. We are dedicated to the production of high quality products and delivering extensive support. Our experienced sales professionals, through personal interaction and with tailor-made solutions, serve customers ranging from large multinationals, to generic manufacturers and innovative start-ups.

Aspen Oss is part of South-African based Aspen Group, whose heritage dates back more than 160 years. Aspen is a global supplier of branded and generic pharmaceutical products as well as infant nutritional and consumer healthcare products in selected territories. Aspen has an extensive global presence employing more than 10,000 people.

Aspen's vision is to deliver value to all our stakeholders as a responsible corporate citizen that provides quality, affordable medicines globally.

Our Values

1

Commitment

We go the extra mile seeking to exceed expectations.

2

Excellence

We strive to be the best we can be and to deliver to the highest standards.

3

Innovation

We constantly search for better ways of doing things and are solution orientated.

4

Integrity

Our integrity is not negotiable.

5

Teamwork

We optimise our performance by pulling together. Our combined capabilities exceed the sum of each individual.

Our values define the foundation on which Aspen has been built. These are values we share as we work together towards achieving the vision of the Group.



Core Competences

All our APIs are produced routinely and on commercial scale according to cGMP. Our facilities are regularly inspected and approved by international health authorities such as the FDA, Dutch Health Authorities and PMDA. Through our extensive product know-how we are able to offer a consistently high quality.



Biochemical APIs

- Within our biochemical production environment we have dedicated facilities and equipment for extraction and purification
- Through our long-lasting experience in the sourcing of raw materials from qualified slaughterhouses in the US and Europe, we have ensured full quality oversight, control and traceability
- To secure viral and TSE safety, our biochemical manufacturing processes include validated viral and prion reduction steps, which are approved by governmental bodies
- Through our in-house developed and validated real time PCR analysis technique, we certify the absence of bovine, ovine and caprine material
- We continuously monitor and are involved in changing governmental regulations throughout the complete value chain. Our customers benefit from this experience by receiving a high level of pro-active quality and regulatory support
- Sourcing of the raw materials for the production of Heparin Sodium is exclusively performed in North America and Europe

Peptide APIs

- With approximately 50 years of peptide experience, we have built a strong reputation by producing cGMP peptides with batch to batch reproducibility combined with high yields and purity profiles
- For the synthesis manufacturing we have stainless steel and glass-lined reactors ranging from 100 to 1500 liters
- Peptide synthesis is designed according to the most efficient process, which can be Solution Phase, - or Solid Phase Synthesis, as well as our DioRaSSP® method (“best of both worlds”)
- For purification we use ion exchange chromatography and reverse-phase preparative HPLC columns up to 45 cm in diameter
- Final isolation is achieved using tray lyophilizers with a capacity up to 100 liters
- Aspen Oss is a member of the USP’s Therapeutic Peptides & Insulins Expert Committee, thereby contributing in the design and review of peptide USP monographs

Chemical APIs

- We have more than 100 stainless steel and glass-lined reactor vessels with capacities ranging from 250 to 10,000 liters
- Through advanced planning techniques and strict application of cleaning procedures, we are able to make use of a broad range of multipurpose reaction vessels in our chemical manufacturing plants



- Our highly active compounds are produced in units with OEB 4 and 5 classifications
- We specialize in complex chemical reactions such as ethynylation, (dissolving metal) reductions, oxidation, bromination and Grignard reactions
- Microbiological fermenters convert steroidal starting material into the desired chemical intermediates
- A broad range of purification methods are applied on large scale, such as crystallisation, filtration and chromatography
- In our state-of-the art Powder Processing and Dispensing Unit we process Active Ingredients by utilizing sieving, milling and micronisation techniques to obtain the required particle size

Our customers benefit from our experience by receiving a high level of pro-active quality and regulatory support.

Extensive Support

Our team with a broad range of experience is available to support you at all stages from development through registration and commercialisation.

- Aspen Oss has a long track record of regulatory compliance underpinned by strong relationships with governmental and regulatory agencies globally
- Our strengths help facilitate customers' ongoing product support and new product launches globally
- Aspen Oss has filed over 120 DMF's worldwide and has a broad regulatory experience in countries such as Japan, Brazil, Russia, India and China
- Aspen Oss is an active member of APIC and as such is directly involved in discussions within EMA, FDA, EDQM and ICH
- Aspen Oss is represented in expert groups of both USP and EP. This makes Aspen Oss one of the main contributing companies when it comes to API related guidelines and monographs
- Aspen Oss is appreciated by its customers for its high quality regulatory dossiers and the high level of customer service received through all stages of the life cycle of customers' Drug Products

API Production Locations

Oss > Location Moleneind the Netherlands

The Moleneind site, located in the heart of Oss, commenced operations back in 1923. Numerous activities are performed on site, including our peptide manufacturing, biochemical manufacturing and chemical manufacturing. Furthermore, our Process and Analytical Development, Quality Control and Quality Assurance departments are located at Moleneind, as well as our stability chambers. At our facilities in Sioux City, USA and Boxtel, the Netherlands, we process starting material for the further manufacturing of a selection of our biochemical APIs.

> Accreditation: Dutch Health Authorities (DHA), US FDA, PMDA, ANVISA and others

Oss > Location Diosite the Netherlands

The Diosite facility was constructed in the 1990's and is a production facility dedicated to chemical manufacturing. This site contains a modern, computer-directed, multi-purpose factory used for larger production campaigns with reaction vessels up to a volume of 10,000 liters. Furthermore, the sieving, milling and micronisation of the APIs are performed at this site, in addition to the central warehousing and distribution operations.

> Accreditation: Dutch Health Authorities (DHA), US FDA, PMDA, ANVISA and others



With our proven track record of regulatory compliance and strong relationships with governmental and regulatory agencies globally, we facilitate customers' new product authorisations.



Product List

API	CEP/ ASMF	US-DMF	J-DMF	BRAZIL-DMF	Other*
 Biochemical APIs					
Heparin Sodium	✓	✓	✓	✓	✓
Human Chorionic Gonadotrophin (hCG)	✓	✓			✓
 Peptide APIs					
Desmopressin	✓	✓			✓
Gonadorelin acetate (LH-RH)	✓	✓			✓
Leuprolide acetate (Leuprorelin)	✓	✓	✓		✓
Oxytocin	✓	✓			✓
 Chemical APIs - Alkaloids					
Naloxone HCl	✓			✓	✓
Naltrexone HCl	✓	✓		✓	
Chemical APIs - Steroid hormones					
Conjugated Estrogens		✓		In progress	In progress
Desogestrel	✓	✓		✓	✓
Estradiol	✓	✓	✓	✓	✓
Estradiol valerate	✓	✓		✓	✓
Estriol	✓	✓	✓	✓	✓
Ethinyl estradiol	✓	✓	✓	✓	✓
Ethinodiol diacetate		✓			✓
Nandrolone Decanoate	✓	✓		✓	✓
Norethindrone	✓	✓	✓	✓	✓
Norethindrone acetate	✓	✓	✓	✓	✓
Progesterone	✓	✓	✓		✓
Testosterone	✓	✓	✓	✓	✓
Testosterone Cypionate (Cyclopentylpropionate)		✓		✓	✓
Testosterone Decanoate	✓			✓	✓
Testosterone Isocaproate	✓			✓	✓
Testosterone Phenylpropionate	✓			✓	✓
Testosterone Propionate	✓			✓	✓
Testosterone Undecanoate (Undecylate)	✓	✓			✓
Tibolone	✓			✓	✓
Chemical APIs - Other					
Mirtazapine	✓	✓	✓	✓	✓
Rocuronium Bromide	✓	✓	✓	✓	✓

*Other can include Canada, Russia, India, China, etc.

Aspen Oss offers the expertise and capability to develop, scale-up and manufacture further APIs. We invite you to contact us to discuss how we can best meet your requirements.

Our APIs are used in among others the following therapeutic areas: **women's health, male health, oncology, central nervous system, drug and alcohol dependency, muscle relaxation, anticoagulant and veterinary applications.**



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