



World Class APIs

Building on almost 100 years of experience

About Aspen Oss



Aspen Oss has a proud history in the production of complex and highly potent APIs (HPAPIs), spanning over almost 100 years. We work from a deeply rooted and pro-active quality culture. We offer our customers a true partnership by consistently delivering high product quality on schedule.

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 insulin production.

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, chorionic gonadotrophin and several peptides.

Aspen Oss, whose activities are supported by approximately 800 employees, specializes in the production of complex, highly potent APIs (HPAPIs), in amongst others the therapeutic areas of gynaecology / women's health, male 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, established from humble beginnings in Durban, South Africa. With a 160 years heritage Aspen has grown into a leading specialty and branded multinational pharmaceutical company.

An extensive basket of products treat a broad spectrum of acute and chronic conditions experienced through all stages of life. The core categories that receive the highest focus include Regional Brands, Anaesthetics, Thrombosis, High Potency and Cytotoxics.

Core Competencies

How we can add significant value to your product or business goals.



Quality Culture

We work from a deeply rooted and pro-active quality culture.

Our robust quality system ensures high product quality, which are manufactured in compliance with GMP, ICH and SHE regulations. Our key success factor is teamwork, supported by a highly motivated, knowledgeable and educated staff.

Our facilities are successfully inspected and approved by governmental authorities such as the US FDA, EMA, PMDA and others. Also, we are inspected almost weekly by our customers and therefore can proudly say that we are permanent inspection ready. We are complimented by authorities and customers for our degree of implementing data integrity in the organization.

Our Quality Control laboratories form an integral part of our cGMP manufacturing network. With the stringent controls for chemical starting materials, in-process controls and the extensive characterization of final products, we can ensure the right quality API, manufactured in compliance with the relevant regulations and its regulatory dossier (US-DMF, ASMF, CEP, J-DMF, etc.).



SHE

We value the protection of our employees, the environment and our products.

Aspen Oss is committed to ensuring a proactive safety culture and considers SHE awareness and compliance as an imperative to our success. We manage SHE as an integral part of our business and we are an ISO 14001 and OHSAS 18001 certified company.

We have a dedicated team of over 25 in-house SHE specialists with expert knowledge to ensure continuous improvement in SHE management and performance.



Complex and HPAPIs

Almost 100 years strong in handling HPAPIs and complex chemical reactions.

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 OEB 4 and 5 classifications and 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.



Regulatory Excellence

We understand your regulatory requirements.

Our team with a broad range of experience is available to support you at all stages from development through registration and commercialization. We facilitate your ongoing product support and new product launches globally and have broad regulatory experience, also in countries such as Japan, Brazil, Russia, India and China. We know, are involved, and act pro-actively on changes in monographs and on governmental regulations and expectations.

Aspen Oss is an active member of APIC and as such directly involved in discussions within EMA, FDA, EDQM and ICH. Furthermore, Aspen Oss is represented in expert groups of both USP and EP.

Customers appreciate our continuous high quality regulatory dossiers and high level of customer support.



Products and Expertise

All our APIs are produced routinely and on commercial scale according to cGMP. Our facilities are successfully 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

- Extensive expertise and over 90 years experience in the large scale extraction and purification of biochemical products from natural sources.
- Own collection programs for starting materials using dedicated facilities and equipment for extraction and purification
- Through our long-lasting experience in the sourcing of raw materials, from several continents we have ensured full quality oversight, control and traceability
- In order to comply with the highest standards for API quality and viral safety, our biochemical manufacturing processes include validated and approved viral and prion reduction steps
- 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

Peptide APIs

- Building on more than 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 high purity profiles
- Extensive know-how of and experience in both solution (SPPS) and solid-phase synthesis (LPPS).
- In addition, we have a patented green method for the large-scale manufacturing in solution, called Green Continuous Liquid Phase Peptide Synthesis (GC-LPPS). It combines the advantages of the LPPS with SPPS and is characterized by the fact that intermediates are not isolated.
- For the synthesis manufacturing we have stainless steel and glass-lined reactors ranging from 100 to 1500 liters
- 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

Chemical APIs

- We have more than 100 stainless steel and glass-lined reactor vessels with capacities ranging from 250 to 10,000 liters
- Through our best-in-class cleaning procedures, we are able to make use of a broad range of multipurpose reaction vessels
- Our highly potent APIs (HPAPIs) 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

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

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.



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 small scale chemical manufacturing. Furthermore, our Process and Analytical Development, Quality Control and Quality Assurance departments are located at Moleneind, as well as our stability chambers.

- > Inspection approvals: ANVISA, Dutch HA, KFDA, PMDA, Russian HA, Turkish HA, US FDA

Location Boxtel the Netherlands

Since 1971 Aspen Oss runs a biochemical operation in Boxtel (The Netherlands). Urine from pregnant women is collected in the Netherlands and further processed in this dedicated facility into the final API Chorionic Gonadotrophin (HCG). The facility has undergone a major renovation in 2018 including the building of a modern purification suite and the introduction of a virus filtration step, thereby meeting worldwide regulatory requirements.

- > Inspection approvals: Dutch HA, PMDA, Russian HA, Turkish HA, US FDA

Oss > Location Diosite the Netherlands

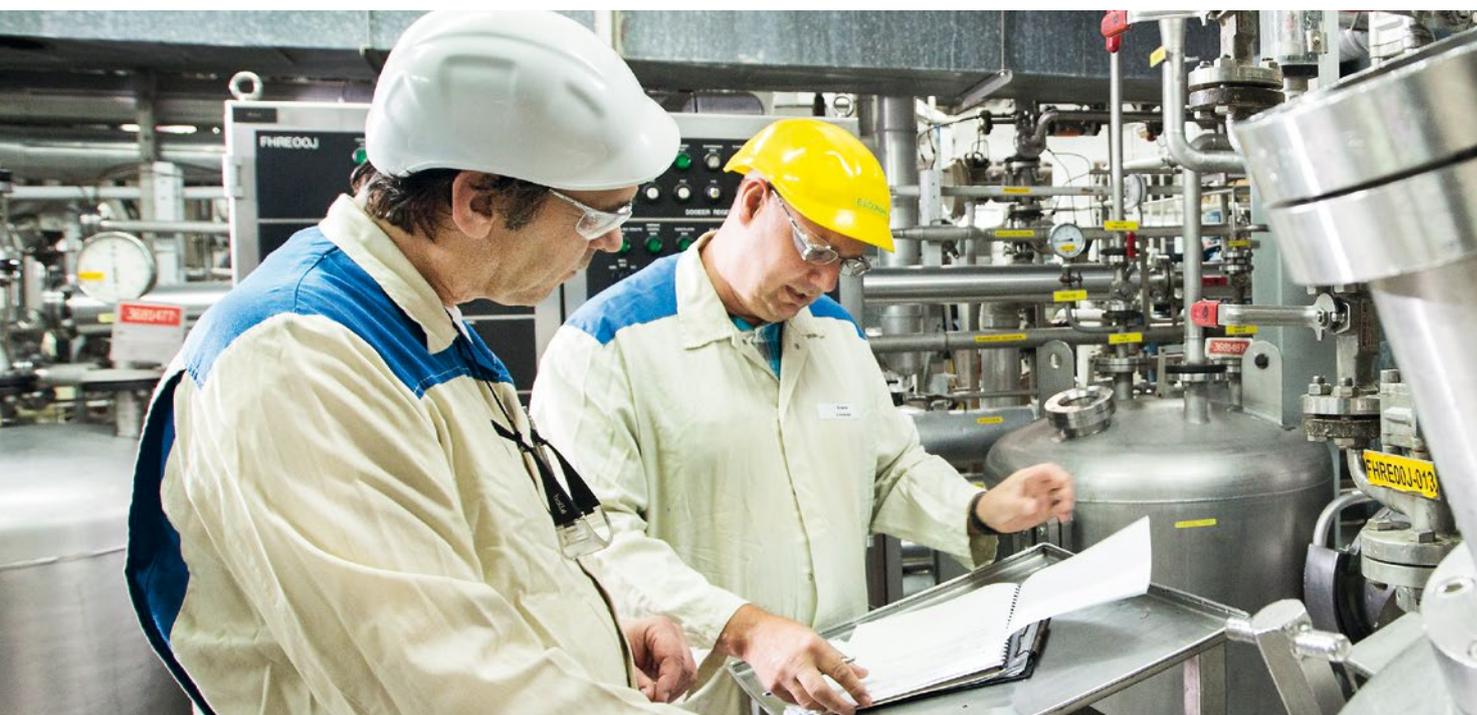
The Diosite facility was constructed in the 1990's and is a production facility dedicated to chemical manufacturing. This site contains a modern, computer-directed, multi-purpose factory used for larger production campaigns with reaction vessels up to a volume of 10,000 liters. Furthermore, the sieving,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

- > Inspection approvals: ANVISA, Dutch HA, KFDA, PMDA, Russian HA, Turkish HA, US FDA

Location Sioux City, Iowa USA

In our facility in Sioux City (Iowa, USA), in use since 1985, we collect porcine mucosa and produce a crude heparin, that is then transported to our facilities in Oss for final purification and product release. Having this Sioux City based facility in an important livestock area in the USA, provides close access to many large slaughterhouses, and thus to large mucosa quantities. Large-scale mucosa collection is indispensable to be able to continuously serve the world market needs for heparin sodium.

- > Inspection approvals: US FDA



Product List



API	CEP/ ASMF	US-DMF	J-DMF	Brazil DMF	China DMF	Other ¹
Biochemical APIs						
Heparin Sodium	✓	✓	✓			✓
Human Chorionic Gonadotrophin (HCG)	✓	✓	✓ ²			✓
Peptide APIs						
Desmopressin	✓	✓				✓
Gonadorelin acetate (LH-RH)	✓	✓				✓
Gonadorelin diacetate tetrahydrate		✓				
Leuprolide acetate (Leuprorelin)	✓	✓	✓		✓	✓
Oxytocin	✓	✓			✓	✓
Chemical APIs - Estrogens						
Conjugated Estrogens		✓ ²				
Esterified Estrogens		✓				
Estradiol	✓	✓	✓	✓	✓ ²	✓
Estradiol valerate	✓	✓		✓	✓ ²	✓
Estriol	✓	✓	✓	✓	✓ ²	✓
Ethinyl estradiol	✓	✓	✓	✓	✓	✓
Chemical APIs - Norsteroids and others						
Desogestrel	✓	✓		✓	✓	✓
Ethinodiol diacetate		✓				✓
Hydroxyprogesterone caproate ³	✓	✓				✓
Lynestrenol	✓					
Nandrolone decanoate	✓	✓		✓		✓
Norethindrone	✓	✓	✓	✓		✓
Norethindrone acetate	✓	✓	✓	✓		✓
Progesterone	✓	✓	✓		✓ ²	✓
Tibolone	✓			✓	✓ ²	✓
Chemical APIs - Testosterones						
Testosterone	✓	✓		✓		✓
Testosterone cypionate (cyclopentylpropionate)		✓				✓
Testosterone decanoate	✓			✓ ²		✓
Testosterone isocaproate	✓			✓ ²		✓
Testosterone phenylpropionate	✓			✓ ²		✓
Testosterone propionate	✓			✓ ²		✓
Testosterone undecanoate (undecylate)	✓	✓				✓
Chemical APIs - Other APIs						
Mirtazapine	✓	✓	✓	✓	✓ ²	✓
Rocuronium Bromide	✓	✓	✓	✓	✓	✓

Chemical APIs: development upon request		Peptide APIs: development upon request	
Dydrogesterone	Segesterone acetate	Etelcalcetide	
Nomegestrol acetate	Testosterone enanthate	Goserelin	

Specific Disclaimer. Some of these active ingredients could be protected by a patent in force and would be therefore developed on request exclusively for the purposes stated in Article 10.6 of the Directive 2001/83/EC as amended by the Directive 2004/27/EC (Bolar provision). No activity will be performed with the active ingredients protected by a patent in force beyond the scope of the Bolar provision in any concerned jurisdiction. Nothing herein should be construed as an offer or promotion or advertisement for the sale or use of any product, if such sale or use infringes valid patents and is not authorized under applicable laws and regulations. This information is provided to you solely for your evaluation, to determine your interest in a potential relationship with Aspen Oss B.V.

1) other can include Canada, Russia, India, etc. 2) in progress 3) only available for selected countries.

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