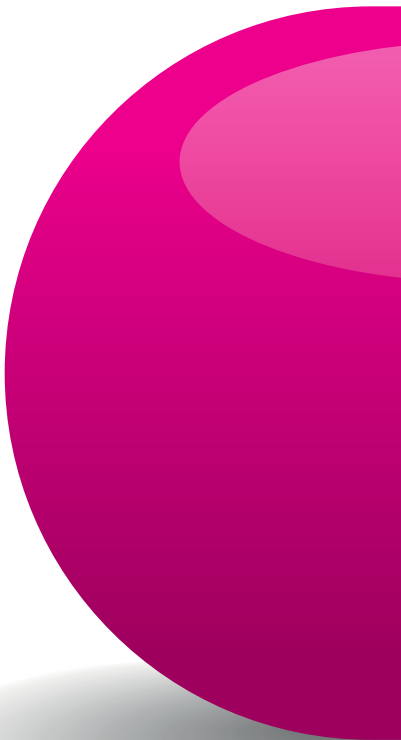


Science. People.
Affordable Medicines.



Synthon

Synthon is a company
committed to delivering
quality medicines at
sustainable pricing through
innovative science



Science-driven innovation

Good health is something we all desire and deserve. We believe that everyone on the planet is entitled to have access to quality medicines at sustainable pricing. We will put our cutting-edge science, ability to innovate and talented people into action to provide solutions to the healthcare challenges of today and tomorrow.

Innovation and continuous improvement are the heartbeat of our company. We work to develop medicines that address the needs of people worldwide and help improve their health and well-being. Through the provision of high-quality generic and hybrid medicines we make treatments more affordable and increase access to important remedies. To make this happen, we hold ourselves to the highest standards of scientific and operational excellence in everything we do – from R&D through production and to delivery of our products to our customers – across every technological platform.

A growing, global operation

Our products are currently approved by regulatory agencies in around 100 countries. We have globally oriented API or drug product manufacturing facilities in the Czech Republic, Argentina, Chile and Spain. Our subsidiary in Chile is also active in the direct commercialization of a diverse portfolio of products to the local market, as is our affiliate in Mexico. Furthermore, Synthon has dedicated business development and registration offices in Russia, South Korea and the United States. Our worldwide infrastructure is fully rigged up, positioning us to deliver on our ambitions.

We continue to invest and expand globally and are continually looking to find partners for our products in all major markets. Synthon's strategy from its inception included the development of a vertically integrated organization. Today, we control every facet of the development chain beginning with research, development and production of active pharmaceutical ingredients through to manufacture of our drug products and sale via our marketing partners. This is, and has always been, one of our great strengths in enabling us to deliver high-quality medicines to the people most in need of them.





Synthon's vertically integrated business model has proven to deliver





Distinctive in generics

Complex small-molecule generics and hybrids form the backbone of our product portfolio. Our product range covers many therapeutic areas with medicines to treat a large number of diverse indications. One common factor drives our business and that is the pursuit of innovative excellence with a clear preference for complex synthesis and sophisticated dosage forms. This results in first-rate medicines that meet market needs, supported by strong patents that guarantee a long product lifespan. As an example, Synthon is the only company to have obtained regulatory clearance in Europe for both dosage strengths of glatiramer acetate, a therapeutically equivalent version of the originator medicine Copaxone®, thereby providing an affordable, efficacious and safe alternative for patients with relapsing remitting multiple sclerosis.

Our products are marketed at the earliest possible opportunity and sold at competitive prices. Furthermore, our pipeline is rich with research projects and pending regulatory applications.





Strength through collaborative partnerships



We believe in a collaborative model based upon robust business-to-business partnerships with our marketing partners. This enables us to share knowledge with and draw upon the specialist skills of partner companies. This helps to manage costs, deliver short product development cycle times and bring much-needed products to market. Such has been the success of our efforts that we now have over 200 partner companies.

Our focus is on creating added value for our partners through quality, service and reliability. We aim to be first-to-market for new products and emphasize continuous improvement for our commercialized products. This can only be achieved by collaborating closely with internal and external stakeholders in all stages, from development to delivery and follow-up. We always strive to be best-in-class in the increasingly competitive market.



Intellectual property rights will remain a crucial factor in the pharmaceutical industry. Our strong Intellectual Property group plays a critical role early in the product development process to identify and analyze the validity and scope of protection of relevant competitor patents and to generate our own strong patents to ensure freedom to operate. We actively promote and defend our interests worldwide, particularly with regard to patent and regulatory issues. To this end, we have access to high-quality legal representation and employ in-house patent attorneys, information specialists and support staff. By having the right legal expertise at hand, we can proactively ensure that our interests are fully protected and a seamless and effective business operation is maintained.

Intellectual property expertise





We provide our customers with a complete product, including all components necessary for trouble-free registration, anywhere in the world. In practical terms, this means that our experts are familiar – down to the smallest detail – with increasingly stringent and ever-changing regulatory regimes in around 100 countries. We compile and submit robust registration files, compliant with the chemical, pharmaceutical and clinical requirements of regulatory authorities, such as the EMA, U.S. FDA and TGA. After final approval, we also ensure maintenance of the dossiers.



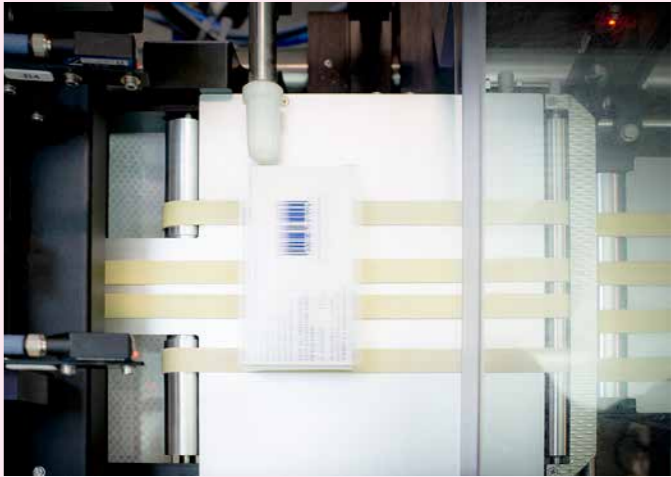
Regulatory affairs competence





Leadership by example

Synthon was founded in 1991. Within two years, our creative vision and passion for making healthcare more affordable led to the development of a generic version of dobutamine, a sympathomimetic drug used in the treatment of heart failure and cardiogenic shock. The success of this first product marked the start of our rapid international growth. Synthon quickly grew from a small Nijmegen-based company employing fewer than a hundred people into the fully-fledged company it is today with a headcount of over 1,600 highly educated people, and laboratories, production plants and offices in nine countries around the world. This would not have been possible without the right combination of technical expertise, business discipline and entrepreneurial capability at every level of management.



A core of talented people

Our continued success depends on the quality of our people. We openly seek to attract and reward talented men and women who share the same values and who are both entrepreneurial in attitude and able to work selflessly as part of a team for the good of our company and our ambitious goals. One of our core beliefs is that the people who work for Synthon do so with pride and real satisfaction in their work. We believe that success is not just what you achieve, but also how you achieve it. We want our colleagues to be able to see the bigger picture and think outside their own field of expertise. In short, we require people who are willing to share knowledge with other disciplines, who are prepared to work hard to produce commercially viable products, who are team players, but above all share our commitment to bringing important medicines to our ultimate focal point: the patient.



An overview of Synthon's worldwide facilities



Active pharmaceutical ingredients

Synthon s.r.o.

Blansko

Czech Republic

Surface area
86,000 m²

Employees
240

Including:

- 1,100 m² offices
- 2,000 m² laboratories*
- 1,650 m² manufacturing area*
- 400 m² warehouse

Capabilities

Production unit I
OEB level A-D / 650 m²

- two separate production zones, one with 1,600-liter capacity, the other with 250-liter capacity in total, completed by separators, dryers, mill and a separate micronizer suite
- compliant with the strictest cGMP and safety guidelines, and fit for handling of highly potent APIs

Production unit II
OEB level A-C / 1,000 m²

- production lines of 250-1,600 liters
- 250-liter autoclave

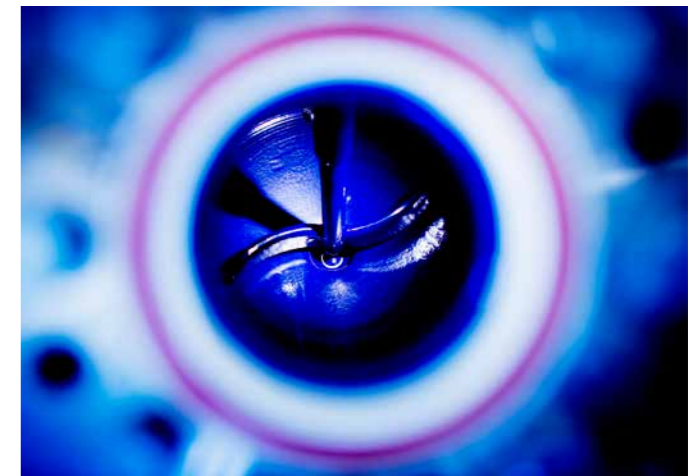
Pilot plants I and II
OEB level A-E

- submission batches and small-scale commercial production (up to 50 liters)
- fit for handling of highly potent APIs

* Laboratories: R&D center, analytical operations, analytical development, pilot plants I and II
Manufacturing area: production units I and II

Synthon s.r.o. is a fully integrated site for active pharmaceutical ingredients, housing API research, development and manufacturing facilities. The core activities at the site consist of chemical and analytical R&D, technology and manufacturing facilities with the highest Occupational Exposure Banding (OEB) level. This enables working with highly potent active pharmaceutical ingredients. Synthon s.r.o. holds the latest ISO and OHSAS certifications.

With nearly 240 employees, the site handles over 30 different APIs. Regulatory highlights include full GMP approvals from the Czech health authorities (EMA) and the U.S. FDA and an accreditation from the Japanese health authorities.



Synthon Argentina S.A.

San Lorenzo

Argentina

Surface area
26,500 m²

Employees
150

Including:

- 800 m² offices
- 400 m² laboratories
- 2,800 m² manufacturing area*
- 800 m² pilot plant and R&D laboratory
- 760 m² warehouse

Capabilities

Production unit I
OEB level A-C / 1,000 m²

- one production line, with a capacity of 250 - 2,500 liters, completed by centrifuges, dryers, mills, an ultrafiltration and lyophilization area

Production unit II
OEB level A-C / 1,800 m²

- three production lines dedicated to MS product portfolio. Reactor capacity from 250 - 2,500 liters, completed by dryers, mill, filters press, an ultrafiltration and a lyophilization area

Pilot plant
OEB level A-D

- capable of handling of highly potent API
- optimization laboratory (0.2 - 2 kg)
- submission batches and small-scale commercial production (1 - 7 kg)

* Manufacturing area: unit I and II
Warehouse: with separate storage for flammables

Our site in San Lorenzo consists of two production units, analytical laboratories, two separate warehouses and an R&D pilot plant, which plays an important role in the development and small-scale manufacturing of strategic products. Production unit I has a capacity of 2,500 liters, production unit II is dedicated to support our MS product line. Synthon Argentina holds the latest ISO and OHSAS certifications.

With over 150 employees, the site manufactures products for the U.S. and non-U.S. markets. Regulatory approvals from the U.S. FDA, TGA Australia, FBI 'SIDGP' Russian Federation, COFEPRIS Mexico and the Argentinean Medicine Agency INAME confirm the site's GMP capabilities.



Drug product

Synthon Hispania S.L.

Barcelona

Spain

Surface area
13,700 m²

Employees
465

Including:

- 1,500 m² offices
- 2,100 m² laboratories*
- 3,700 m² manufacturing area*
- 3,700 m² warehouse

Capabilities

Total manufacturing capacity
2,685 million solids

- 1,375 million tablets
- 1,310 million capsules/pellets

Packaging capacity
5 blister lines
1 sachet line
1 bottle line

- blister lines: total capacity of 85 million units/year, including labelling, carton folding and case packing
- sachet line: capacity of 8 million units/year
- bottle line: capacity of 2 million units/year

* Laboratories: pharmaceutical development, pilot plant, quality control, analytical development, stability studies
Manufacturing area: production of solids and packaging activities

Our Barcelona facility accommodates full drug product research & development - including prototyping, developing and scaling up of production processes, the development and validation of analytical methods and stability studies of the prototypes - as well as production and packaging of registration batches. Production activities involve the manufacture of tablets and capsules, as well as packaging in blisters and sachets and further release to the market.

With its 465 employees, the site handles over 50 different products (molecules/strengths). Regulatory approvals include those of the Spanish Drug Agency (EMA), U.S. FDA, Korean FDA, ANVISA Brazil and the governmental health department of Catalonia. Synthon Hispania holds the latest ISO and OHSAS certifications.



Synthon Chile Ltda.

Santiago

Chile

Surface area
22,000 m²

Employees
350

Including:

- 11,000 m² R&D unit, pilot plant, and manufacturing area*
- 1,030 m² packaging unit
- 1,000 pallets warehouse capacity
- 90 office workplaces
- 240 m² solar panels fully catering to hot water requirements

Capabilities

Conventional drug products

High-containment plant
OEB level A-D

- 1,100 million tablets
- 162 million capsules
- 486 million film-coated tablets
- 89 million blisters
- 2.7 million prefilled syringes (sterile)
- 3.6 million tubes

- 300 million tablets
- 100 million capsules
- 102 million film-coated tablets

* Including R&D unit, solids unit, contained pilot plant, prefilled-syringe unit and a semi-solids/liquids unit

** Double façade partly hanging over 1,600 m² pond allowing evaporated water to precipitate and be used for cooling purposes of the office façade. Resistant to earthquakes up to 9 on the Richter scale. LED technology for lighting 4,000 light tubes.

Our ultramodern multi-purpose drug product site in Chile contains highly advanced facilities varying from development to large-scale production of tablets, capsules and prefilled syringes. The plant has been GMP approved by both the Chilean and European health authorities and complements our Barcelona drug product facility in serving global markets, in terms of production as well as R&D.

The site is highly sustainable** and the first drug product manufacturing site in Chile to obtain approval by an EU health authority to manufacture products for the EU market. Synthon Chile holds the latest ISO and OHSAS certifications.

With its 350 employees, the site handles over 50 different products (molecules/strengths) from both the local and Synthon's global portfolio.





Global headquarters and commercial organization

Synthon B.V.

Nijmegen

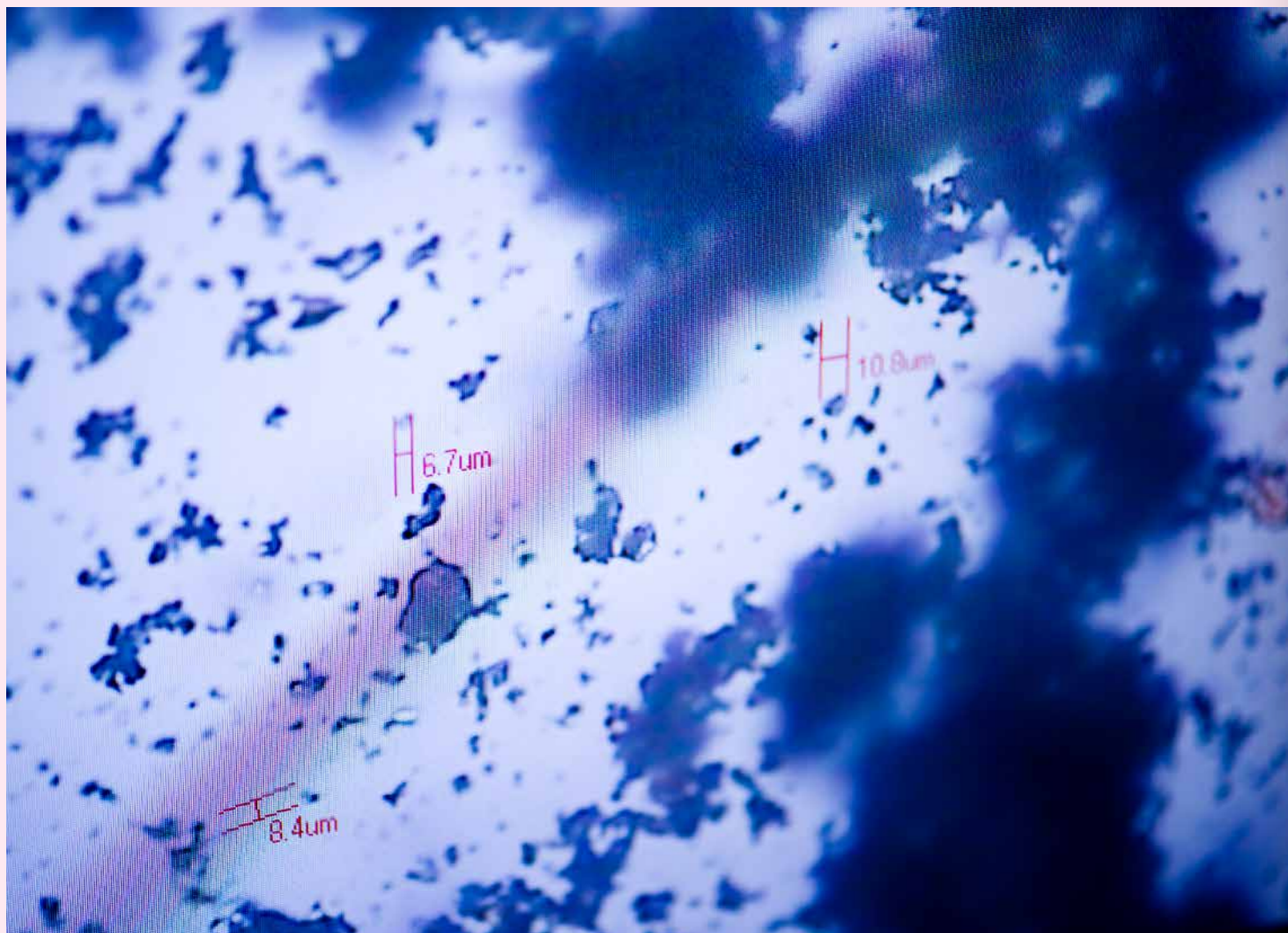
The Netherlands

Our business is centrally managed from our global headquarters in the Netherlands, covering all responsibilities related to the core process.

To safeguard coherence between the different sites and efficiency in the core process, strategic management, global portfolio management and global project management for R&D activities are based at HQ. This is also the case for the majority of staff in our Regulatory Affairs, Intellectual Property and Quality Assurance groups. Our own Clinical Drug Development group encompasses all functions required to conduct bio-equivalence studies, whether these are pivotal clinical trials or pilot studies.

Encompassing business development and account management, our commercial division consists of a group of dedicated professionals, catering to the needs of our customer base of over 200 marketing partners worldwide.

All these activities are naturally supported by a high-quality service organization, including Information Services, Finance & Accounting, Human Resources and Legal Affairs.



Contact

Would you like to learn more about Synthon?
Please visit www.synthon.com

If you are interested in our product portfolio,
please feel free to contact us.

Business Development

Businessdevelopment@synthon.com
(+31) 24 37 27 700
P.O. Box 7071
6503 GN Nijmegen, the Netherlands

If you would like to know more about job
opportunities, please visit www.synthon.com
and click on Careers.

Disclaimer

Copyright © 2019 Synthon International Holding B.V.
All rights reserved. Reproduction of the content in
other publications is permitted. However, credit to
Synthon would be appreciated.

This brochure contains information on pharmaceutical
products and has been composed for healthcare
professionals. It has been composed with the
greatest possible care. It may however contain
inconsistencies and for that reason it cannot be
relied upon. Synthon is not liable for any
consequences as a result of the reliance on any
information contained in this brochure.

Editorial coordination

Synthon Corporate Communications
Nijmegen, the Netherlands

Design

Zuiderlicht
Maastricht, the Netherlands

Printing

Drukkerij Walters
Maastricht, the Netherlands

October 2019

© Synthon International Holding B.V.

www.synthon.com

