



Custom Synthesis

Reliable, Flexible and Competitive

About ISOICHEM

ISOICHEM manufactures products and offers services that meet the most recent and stringent regulatory standards of the Pharmaceutical industry. ISOICHEM implements complex reactions and technologies, while mastering the risk to produce the highest quality products in full compliance with EHS and International Standards of Quality.



A FINE CHEMICAL COMPANY

ISOICHEM serves a broad range of customers in many application fields, from leading global companies to virtual and emerging organizations. ISOICHEM implements almost all the chemical reactions classically used in multi-step synthesis and offers you renowned differentiating know-how:

- Safe implementation of hazardous reaction such as phosgenation, nitration, cryogenic reaction and high pressure hydrogenation.
- Attractive building blocks such as activated aminoacids (N-CarboxyAnhydride) in peptide chemistry.

ISOICHEM products play an important role in the production of novel healthcare, functional and specialty products.



ISOICHEM



ISOICHEM OPERATES 5 PRODUCTION SITES, ALL CERTIFIED ISO 9001.

This offers a total reaction capacity of 450 m³ including 3 cGMP production sites with 270 m³ of reaction capacity.

ISOICHEM runs a large range of glass lined and stainless steel vessels, from 100L to 25,000L, coupled with equipments for liquid and solid purification and separation. This offers the most attractive multipurpose industrial capacity for your products.

Manufacturing facilities

- Gennevilliers
- Pithiviers
- Vert-Le-Petit
- Pont-de-Claix
- Kazincbarcika



QUALITY

Appropriate Quality:

ISOICHEM's quality system based on a long experience working with the guidelines of various markets is designed to meet the exact quality standard required by your market.

Global Quality System:

ISOICHEM established a global Quality System which complies with internal policies as well as with national and international standards (e.g. ISO) and regulations (e.g. cGMP).

cGMP standards

With a long tradition of manufacturing active pharmaceutical ingredients and regulatory intermediates, ISOICHEM is able to manage your project according to the best practices.

In addition, ISOICHEM brings all necessary regulatory support such as registration of new substances through IND or DMF filing in CTD format. More than 40 DMF were filed by ISOICHEM in different countries.

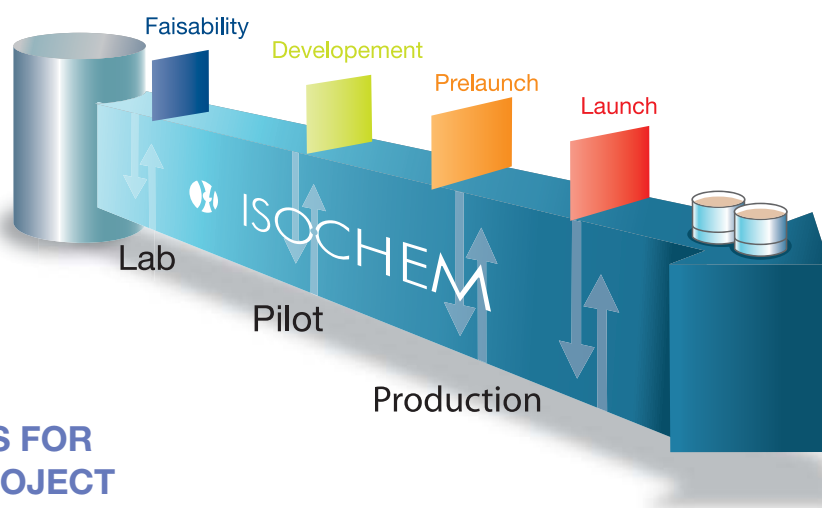
Our certifications:

	GENNEVILLIERS	PITHIVIERS	VERT-LE-PETIT	PONT DE CLAIX	KAZINCBARCIKA
ISO 9001: 2008	✓	✓	✓	✓	✓
cGMP (Q7)	✓	✓	✓		
Inspected by the FDA	✓	✓			
FDA listed	✓	✓	✓		



Custom Synthesis

ISOCHEM offers GMP and non GMP industrial exclusive custom synthesis and provides tailor made services that range from development to production, including route selection, process and analytical development as well as process optimization.



BENEFITS FOR YOUR PROJECT

Flexible Solutions: ISOICHEM's highly skilled teams interact closely with the pilot units and multipurpose facilities. The proven project management system combined with a broad technology platform allow to design custom tailored programs adapted to your timeline.

Appropriate Quality: ISOICHEM's quality policy based on a long experience working with the guidelines of various markets ensures the exact quality level required by your product.

Reduced Time to Market: ISOICHEM's knowledge and management tools ensure the optimized timing for your project.

Continuous Cost Savings: ISOICHEM delivers substantial improvements in manufacturing and creates additional value by reducing capital and operating costs.

Security of Supply Chain: ISOICHEM optimizes and secures sourcing of raw materials, based on total transparency with customers.



Project management

PROJECT EVALUATION

- identification:
 - of critical points
 - of key technologies and required skills
- regulation diagnostic
- economic evaluation

COMPREHENSIVE SERVICE OFFER

- prerequisites - hypotheses
- technical program
- regulation support (DMF, REACH)
- project management
- transparency - communication
- detailed planning

KICK OFF MEETING

- validation of input data and objective

RELIABILITY AND TRANSPARENCY

- project team leader
- regular reporting
- project reviews
- creative process
- analytic support
- tailor-made documentation
- timely supplies (product and reports)
- confidentiality
- controlled lead times and costs

RELIABLE PRODUCTION

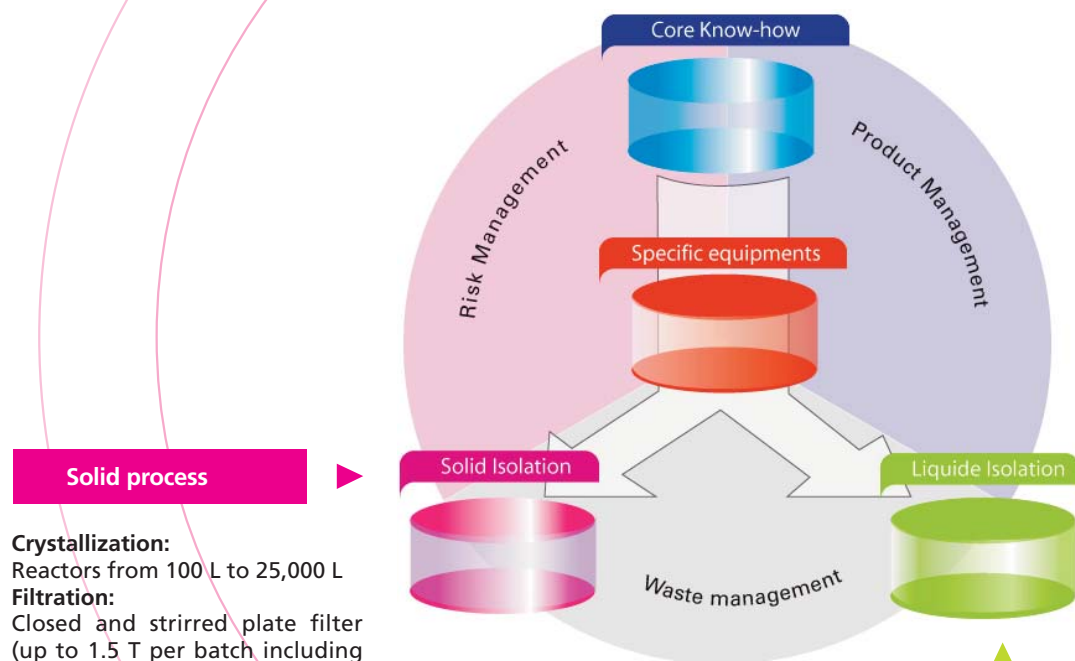
- FDA and customer audit satisfaction
- best EHS standards

Our technologies

- Hydrazines and downstream heterocyclic chemistry
- Phosgene chemistry
- Organometallic chemistry including organo-lithium reagents (BuLi, LDA, LiHMDS,...)
- Chlorination (POCl₃, PCl₃, SOCl₂, SO₂Cl₂, ...)
- Reductions with boron and aluminium hydrides and in situ generated B₂H₆
- Catalytic hydrogenation up to 40 bar
- Carbon disulfide chemistry
- Lewis catalyst (BCl₃, TiCl₄, BF₃, AlCl₃ ...)
- Amino acid N-Carboxyanhydride synthesis and polymerization (NCA, UNCA)
- Liquid phase peptide synthesis
- Chiral chemistry

Reaction process

Reaction volume: of 450 m³
Reactor size: from 100 L to 25,000 L (glass lined and stainless steel)
Reaction temperature: from -70°C to 250°C
Pressure reaction: up to 40 bar



Solid process

Crystallization:

Reactors from 100 L to 25,000 L

Filtration:

Closed and stirred plate filter (up to 1.5 T per batch including for corrosive chemicals), automatic Larox press filter, centrifuge filtration

Drying:

Stirred dryer (up to 1.5 T perbatch), tray dryers, vacuum dryers, sieving and packaging

Liquid process

Distillation:

Batch and film units, including for corrosive product, vacuum down to 1 mbar and temperature up to 200°C



Innovation

Considering innovation as an opportunity, ISOICHEM's teams are day to day seeking for new valuable solution from any field of our activity.

Innovation is powered by skilled teams who combine, open-mind, creativity, enthusiasm, and pragmatism. Customer Satisfaction is ISOICHEM's favorite metric of its innovation performance.



ISOICHEM
is member of Britest*.

Track record in some figures

- 38 years of experience in fine chemistry
- 16 FDA audits (2 audits in 2011 with no 483 forms)
- 76 customers audits last 5 years
- More than 40 DMF submitted
- 5200 chemical entities synthesized
- 1100 chemical processes developed
- Hundreds of methods of analysis developed

(*) Britest is a global leader offering a platform of methodologies and tools for the development of innovative process.

SUSTAINABLE DEVELOPMENT

Sustainable development is a corner stone of ISOICHEM's policy. ISOICHEM long term success relies on respect of core values like the protection of social environment and the safety and health of employees and neighbours in a strict compliance with local and international regulations.

ISOICHEM is a member of the Responsible Care program. ISOICHEM management defines objectives for continuous improvement and progress.

ISOICHEM's best practices for Safety, Health and Environment are stated in a Policy Act on Safety Health and Environment.





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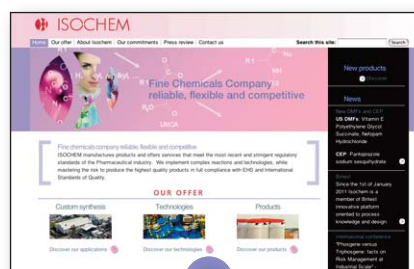
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