

EXPERIENCE YOU CAN TRUST

Achieving your goals more
easily, safely and rapidly.



APIs

For generic
market

With you every step of the way, bringing innovation

What we offer

We develop **proprietary chemical processes and alternative solutions** to support the generic API industry.

You can rely on a true turnkey service where **commercially competitive products** are promptly conceived and manufactured in full compliance with third-party intellectual property rights.

Along with **quality, confidentiality, safety** and the ability to meet deadlines, **we ensure a well-established and reliable supply chain for your peace of mind.**

Our talent

Our collaboration extends beyond technical skills with **more than 70 years of experience** in the field. We realise how valuable it is for you **to rely on a trusted partner** to propose the right solution and support your formulation team for a **successful launch that respects the timeline.**

This talent is, for us, a matter of pride. **We are with you every step of the way**, from the first gram in the Lab until the commercial launch.



Why you can trust us

As part of the global pharmaceutical industry, we serve human health and, therefore, operate under **the highest standards of safety and quality.** This is confirmed by an extensive list of **successful inspections run by EU and US Health Authorities** certifying the cGMP level of our production sites. We have the right dimensions and several scale capabilities **to manage processes efficiently:** sizable and experienced enough to be solid, but flexible and agile enough **to promptly solve any challenge** in the life of the project.

Taking the API supply further



More than 40 commercially APIs



A history of **more than 70 years** of constant reliability



All four sites governed by the strictest **cGMP Quality System**



Extensive positive track record of **inspections** by the main **Regulatory Agencies**



Experience in **filing DMF** worldwide



More than 250 patents filed to protect our innovation rights



Specializing in the **handling of hazardous process**



Customizing particle size to match your formulation requirements



Providing pre-formulation and solubility data to enhance the API proposal



Core Technologies

- ✓ High-pressure hydrogenation*
- ✓ Nitration*
- ✓ Nitroesterification*
- ✓ Azide chemistry
- ✓ Borane reductions
- ✓ Cross-coupling reactions
- ✓ Curtius reaction
- ✓ Dissolving metal reduction
- ✓ Enzymatic chemistry
- ✓ Epichlorohydrin chemistry
- ✓ Hoffman reaction
- ✓ Hydrogen peroxide oxidations
- ✓ Carbohydrate chemistry
- ✓ Enantioselective reactions
- ✓ Use of nitroalkanes (Henry reaction)
- ✓ Wolff-Kishner reduction

*Strategic cooperation with Biazzi, engineering sister company specializing in hazardous chemistry

Our products

Commercial products

- ◇ AMINOCAPROIC ACID*
- ◇ AMITRIPTYLINE HCl
- ◇ BUPROPION HCl
- ◇ CHENODEOXYCHOLIC ACID*
- ◇ CILOSTAZOL
- ◇ CYCLOBENZAPRINE HCl
- ◇ CYPROHEPTADINE HCl
- ◇ DAPSONE
- ◇ DICLOFENAC POTASSIUM
- ◇ DICLOFENAC SODIUM
- ◇ DOTHIEPIN HCl (DOSULEPIN HCl)
- ◇ DOXEPIN HCl
- ◇ ENTACAPONE
- ◇ FEXOFENADINE HCl
- ◇ GLIBENCLAMIDE (GLYBURIDE)
- ◇ IBUPROFEN LYSINE SALT
- ◇ ISOSORBIDE DINITRATE
- ◇ ISOSORBIDE-5-MONONITRATE
- ◇ MINODRONIC ACID
- ◇ MODAFINIL
- ◇ NIFEDIPINE
- ◇ NITROGLYCERINE
- ◇ NORTRIPTYLINE HCl
- ◇ PIRFENIDONE
- ◇ PIROXICAM
- ◇ SELEGILINE BASE*
- ◇ SELEGILINE HCl
- ◇ TAUROURSODEOXYCHOLIC ACID
- ◇ TOLBUTAMIDE
- ◇ TRAMADOL HCl
- ◇ TRIAMTERENE
- ◇ URSODEOXYCHOLIC ACID
- ◇ ZONISAMIDE

New products

Already validated/under validation

- ◇ BENSERAZIDE HCl
- ◇ BIPERIDEN HCl
- ◇ CRISABOROLE
- ◇ DEXLANSOPRAZOLE ANHYDROUS CRYSTALLINE
- ◇ EFINACONAZOLE
- ◇ FESOTERODINE FUMARATE
- ◇ RUFINAMIDE
- ◇ VARENICLINE TARTRATE
- ◇ VORTIOXETINE HBr



* only for specific markets

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Our team in action

How to develop an innovative, successful and cost-competitive API for Generic



PROCESS RESEARCH

Selecting a non-infringing and cost-effective process by **combining technological innovation with our experience.**



PROCESS DEVELOPMENT

Defining and investigating key process parameters including a **complete safety** and **calorimetric assessment.** Securing the **protection of IP rights.**



SUPPLY CHAIN EVALUATION

Suppliers for the main raw materials are identified and selected based on **reliability, quality, geographical risk mitigation and cost competitiveness.**



ANALYTICAL RESEARCH

In order to guarantee the highest quality, **dedicated analytical methods are developed in-house** to characterize products and intermediates.



PROCESS INDUSTRIALIZATION

R&D coordinates process scaling-up to commercial scale batch validation, **ensuring a complete and smooth transfer** to the production teams.



REGULATORY SUPPORT

Full regulatory support is available, including CEP or DMF filing in almost all countries worldwide.



A STEP FORWARD

Pre-formulation trial with excipient, solubility studies in different solvents and particle size adjustment, move our API a step forward.



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For generic
market



Where we are

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