



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



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

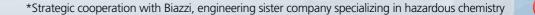


# **Core Technologies**

- High-pressure hydrogenation\*
- ✓ Nitration\*
- ✓ Nitroesterification\*
- Azide chemistry
- Borane reductions
- Curtius reaction
- Oissolving metal reduction
- Enzymatic chemistry
- Epichlorohydrin chemistry
- ∀ Hoffman reaction
- Hydrogen peroxide oxidations
- Carbohydrate chemistry

Enantioselective reactions

- Use of nitroalkanes (Henry reaction)
- ✓ Wolff-Kishner reduction





### **Our products**

# **Commercial products**

#### AMINOCAPROIC ACID\*

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

## **New products**

Already validated/under validation

- **BENSERAZIDE HCI**
- BIPERIDEN HCI
- CRISABOROLE
- DEXLANSOPRAZOLE ANHYDROUS CRYSTALLINE
- EFINACONAZOLE
- **PESOTERODINE 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.







### Where we are

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