

EXPERIENCE YOU CAN TRUST

Quality and Excellence in
Small Molecule API Manufacturing

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 integrate **comprehensive QA systems** and ensure **CGMP compliance**, confirmed by **successful inspections worldwide**. We also guarantee a **well-established and reliable supply chain**, thanks to multi-level supplier qualification and continuous risk mitigation **for your peace of mind**.

Our talent

Our know-how goes beyond technical skills, backed by **more than 75 years of experience in the field**. We understand the importance of having a **trusted partner** who can provide the right solutions and support your formulation team **to ensure a timely and successful launch**. We are proud to bring this know-how to our partners. **From the first gram in the lab to commercial scale-up and smooth technology transfer, we embed quality assurance and statistical process controls to secure batch-to-batch consistency**. Dedicated analytical methods, pre-formulation studies and particle size tuning further enhance our **ability to tailor each API to your formulation needs**. **We are with you every step of the way**.



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 commitment is confirmed by an extensive track record of **successful inspections by EU and US Health Authorities**, certifying the CGMP level of our production sites. We combine the right dimensions and scale capabilities to manage processes efficiently: **sizable and experienced enough to be solid, yet flexible and agile enough to adapt and promptly solve any challenge**. **With integrated quality assurance systems, robust risk management and proven reliability**, we provide the confidence our partners need across the entire API lifecycle.

Our products

Commercial products

- ◇ AMINOCAPROIC ACID
- ◇ AMITRIPTYLINE HCl
- ◇ BENSERAZIDE HCl
- ◇ BIPERIDEN HCl
- ◇ BUPROPION HCl
- ◇ CANDESARTAN CILEXETIL
- ◇ CYCLOBENZAPRINE HCl
- ◇ DAPSONE
- ◇ DEXLANSOPRAZOLE ANHYDROUS CRYSTALLINE
- ◇ DICLOFENAC POTASSIUM
- ◇ DICLOFENAC SODIUM
- ◇ DOTHIEPIN HCl (DOSULEPIN HCl)
- ◇ DOXEPIH HCl
- ◇ FESOTERODINE FUMARATE
- ◇ FEXOFENADINE HCl
- ◇ GLIBENCLAMIDE (GLYBURIDE)
- ◇ IBUPROFEN LYSINE SALT
- ◇ METARAMINOL*
- ◇ MINODRONIC ACID
- ◇ MODAFINIL
- ◇ NIFEDIPINE
- ◇ NORTRIPTYLINE HCl
- ◇ PIRFENIDONE
- ◇ PIROXICAM
- ◇ RUFINAMIDE
- ◇ SELEGILINE BASE*
- ◇ SELEGILINE HCl
- ◇ SODIUM PHENYLBUTYRATE
- ◇ TOLBUTAMIDE
- ◇ TRIAMTERENE
- ◇ ZONISAMIDE

Specialty Organic Nitrates

- ◇ ISOSORBIDE DINITRATE
blends with lactose; solutions in acetone or saline.
- ◇ ISOSORBIDE-5-MONONITRATE
pure, blends with lactose, cellulose, talc, sucrose.
- ◇ NITROGLYCERINE
blends with lactose, mannitol, dextran; solutions in ethanol or propylene glycol.

Customized formulations can also be developed in close collaboration with our partners.

Bile Acid Derivatives

- ◇ CHENODEOXYCHOLIC ACID*
- ◇ CHOLIC ACID*
- ◇ GLYCOCHOLIC ACID
- ◇ TAUROURSODEOXYCHOLIC ACID
- ◇ URSODEOXYCHOLIC ACID

* only for specific markets

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New products

Under evaluation/validation

- ◇ CRISABOROLE
- ◇ DICLOFENAC EPOLAMINE
- ◇ EFINACONAZOLE
- ◇ ELINZANETANT
- ◇ ETRIPAMIL
- ◇ LETERMOVIR
- ◇ TRADIPITANT
- ◇ VORTIOXETINE HBr



Taking the API supply further



A history of more than **75 years** of proven **reliability**



All four sites harmonized with the highest international **CGMP Quality System** standards



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



Full regulatory support, including **CEP** and **DMF filing** **worldwide**



Supply chain managed for **reliability, quality, risk mitigation and cost**



More than 250 patents filed to protect our innovation rights



Specializing in the **handling of hazardous processes**



Customizing particle size to match your formulation requirements



Providing pre-formulation and solubility data to strengthen FDF development



Core Technologies

✓ **High-pressure hydrogenation***

✓ **Nitration***

✓ **Nitroesterification***

✓ **Azide chemistry**

✓ **Bile acid derivatives**

✓ **Borane reductions**

✓ **Carbohydrate chemistry**

✓ **Cross-coupling reactions**

✓ **Curtius reaction**

✓ **Dissolving metal reduction**

✓ **Enantioselective reactions**

✓ **Enzymatic chemistry**

✓ **Epichlorohydrin chemistry**

✓ **Hofmann reaction**

✓ **Hydrogen peroxide oxidations**

✓ **Use of nitroalkanes (Henry reaction)**

✓ **Wolff-Kishner reduction**

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

BIAZZI

Product Lifecycle Management

Dipharma Since 1949

We oversee the entire Product Lifecycle with a continuous and structured approach: integrating innovation, compliance, supply chain and quality. Every step is supported by project management to guarantee consistency and reliability.

SUPPLY CHAIN

Sustained search for alternative suppliers

R&D INNOVATION MANAGEMENT

Innovation and IP management to ensure long-term product value

REGULATORY COMPLIANCE

Continuous updates to the latest authorities' guidelines

SCALE-UP & TT

Scale-Up & Tech Transfer activities to sustain our business

PROCESS REVISION

Constant revision of our commercial products to be up-to-date

QUALITY & CUSTOMER SUPPORT

End-to-end quality and support across the API lifecycle



Where we are

SALES DEPARTMENT

Headquarters

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APIs
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Market

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