

75
years
Since 1949

 **Dipharma**

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** 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 **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 75 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
- ✓ Carbohydrate chemistry
- ✓ Cross-coupling reactions
- ✓ Curtius reaction reduction
- ✓ Dissolving metal
- ✓ Enantioselective reactions
- ✓ Enzymatic chemistry
- ✓ Epichlorohydrin chemistry
- ✓ Hoffmann reaction
- ✓ Hydrogen peroxide oxidations
- ✓ Use of nitroalkanes (Henry reaction)
- ✓ Wolff-Kishner reduction

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



Our products

Commercial products

- AMINOCAPROIC ACID
- AMITRIPTYLINE HCl
- BUPROPION HCl
- CHENOXYCHOLIC ACID*
- CYCLOBENZAPRINE HCl
- DAPSONE
- DEXLANSOPRAZOLE ANHYDROUS CRYSTALLINE
- DICLOFENAC POTASSIUM
- DICLOFENAC SODIUM
- DOTIPIPIN HCl (DOSULEPIN HCl)
- DOXEPIN HCl
- ENTACAPONE
- FESOTERODINE FUMARATE
- FEXOFENADINE HCl
- GLIBENCLAMIDE (GLYBURIDE)
- GLYCOCHOLIC ACID
- BUPROFEN LYSINE SALT
- SOSORBIDE DINITRATE
- SOSORBIDE-5-MONONITRATE
- METARAMINOL*
- MINODRONIC ACID
- MODAFINIL
- NIFEDIPINE
- NITROGLYCERINE
- NORTRIPTYLINE HCl
- PIRFENIDONE
- PIROXICAM
- RUFINAMIDE
- SELEGILINE BASE*
- SELEGILINE HCl
- TAUROURSODEOXYCHOLIC ACID
- TOLBUTAMIDE
- TRIAMTERENE
- URSODEOXYCHOLIC ACID
- ZONISAMIDE

New products

Already validated/under validation

- BENSERAZIDE HCl
- BIPERIDEN HCl
- CHOLIC ACID
- CRISABUROLE
- DICLOFENAC EPOLAMINE
- EFINACONAZOLE
- SODIUM PHENYLBUTYRATE
- 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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Where we are

Sales Department:

Headquarters

Dipharma Francis S.r.l.
Via Bissone, 5
20021 Baranzate (MI) - Italy

Branch Offices:

USA
Dipharma Inc.
4502 Campus Drive
Kalamazoo, MI 49008

CHINA
Beijing Repr. Office
Dipharma Francis
Room 527 Building 6
No. 9 in FangYuan NanLi
Chaoyang District
100016, Beijing

Manufacturing Sites:

ITALY
Dipharma Francis S.r.l.

- Via Bissone, 5
20021 Baranzate (MI)
- Via Origgio, 23
21042 Caronno
Pertusella (VA)
- Via XXIV Maggio, 40
33036 Mereto di Tomba
(UD)

USA
Dipharma Inc.
4502 Campus Drive
Kalamazoo, MI 49008

R&D Centers:

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Dipharma Francis S.r.l.
Via Bissone, 5
20021 Baranzate (MI)

USA
Dipharma Inc.
4502 Campus Drive
Kalamazoo, MI 49008